

**FISCAL NOTE**  
**Requested by Legislative Council**  
**12/19/2014**

Bill/Resolution No.: SB 2086

- 1 A. **State fiscal effect:** *Identify the state fiscal effect and the fiscal effect on agency appropriations compared to funding levels and appropriations anticipated under current law.*

	2013-2015 Biennium		2015-2017 Biennium		2017-2019 Biennium	
	General Fund	Other Funds	General Fund	Other Funds	General Fund	Other Funds
Revenues				\$(6,000)		\$(6,000)
Expenditures		\$500				
Appropriations						

- 1 B. **County, city, school district and township fiscal effect:** *Identify the fiscal effect on the appropriate political subdivision.*

	2013-2015 Biennium	2015-2017 Biennium	2017-2019 Biennium
Counties			
Cities			
School Districts			
Townships			

- 2 A. **Bill and fiscal impact summary:** *Provide a brief summary of the measure, including description of the provisions having fiscal impact (limited to 300 characters).*

SB2086 would revise the current Wholesaler statutes based on the passage of the Federal Drug Quality and Security Act of 2013. Provisions for a category of Outsourcing Facilities and revisions for Third Party Logistics provider are proposed to be consistent with the Federal standards.

- B. **Fiscal impact sections:** *Identify and provide a brief description of the sections of the measure which have fiscal impact. Include any assumptions and comments relevant to the analysis.*

The current law licenses Outsourcing facilities as Wholesale Distributors. This legislation (Section 4) would create a license category specifically for outsourcing facilities. Currently we have 15 of the Federally registered outsourcing facilities licensed by our agency. The current annual license costs for these business types under Section 3 for Wholesaler/Distributor is set at \$400. Section 3 would propose this to be set at \$200 as an outsourcing facility category. We do not anticipate any significant increase or decrease in the number of outsourcing facilities in which will be licensed.

Third Party logistics providers (section 5) will continue to be licensed under this section and their license cost will be unchanged (section 3).

3. **State fiscal effect detail:** *For information shown under state fiscal effect in 1A, please:*

- A. **Revenues:** *Explain the revenue amounts. Provide detail, when appropriate, for each revenue type and fund affected and any amounts included in the executive budget.*

There are 15 current outsourcing facilities that hold a ND Wholesale license. Their current annual license cost is set at \$400. This legislation in allowing a separate category for outsourcing facilities proposes a \$200 license cost. We anticipate a net loss in revenue by the change of \$3000 per year (15 X \$200) or \$6000 per biennium.

- B. **Expenditures:** *Explain the expenditure amounts. Provide detail, when appropriate, for each agency, line item, and fund affected and the number of FTE positions affected.*

We anticipate a cost of \$500 to implement the database changes to account for the proposed revisions in the legislation.

- C. **Appropriations:** *Explain the appropriation amounts. Provide detail, when appropriate, for each agency and fund affected. Explain the relationship between the amounts shown for expenditures and appropriations. Indicate whether the appropriation or a part of the appropriation is included in the executive budget or relates to a continuing appropriation.*

**Name:** Mark Hardy

**Agency:** ND Board of Pharmacy

**Telephone:** 701-328-9535

**Date Prepared:** 12/22/2014

2015 SENATE INDUSTRY, BUSINESS AND LABOR

SB 2086

# 2015 SENATE STANDING COMMITTEE MINUTES

Industry, Business and Labor Committee  
Roosevelt Park Room, State Capitol

SB 2086  
1/14/2015  
Job Number 21960

- Subcommittee  
 Conference Committee

Committee Clerk Signature

*Eva Leibel*

## Explanation or reason for introduction of bill/resolution:

Relating to the wholesale drug distribution and third-party logistic providers

## Minutes:

Attachment

**Chairman Klein:** Opened the hearing.

**Mark J. Hardy, PharmD, Executive Director of the North Dakota State Board of Pharmacy:** Written Testimony Attached (1). (:40-9:34)

**Senator Miller:** Are the outsourcing facilities like manufacturers? Do you do that because it's not cost effective to keep those substances in your pharmacy?

**Mark J. Hardy:** There is a very extensive process to bring a drug to market and when they have these drugs in which they compound there isn't a strong enough need to go through all the different steps to make it commercially available. That is why a lot of these drugs fall between the cracks. There also might be patients that have trouble with the preservatives or the inactive ingredients and they have ways that they can compound those medications in these locations to make it so the patient is more apt to take it.

**Chairman Klein:** The doctor can write that?

**Mark J. Hardy:** Yes, the doctor can write those. Typically these medications are coming to a hospital facility and coming in bulk and the hospital facility is using them within their patient base.

**Chairman Klein:** In the fifteen facilities that are licensed are there any here or are they all out of state?

**Mark J. Hardy:** They are all out of state.

**Chairman Klein:** We can now offer this?

**Mark J. Hardy:** A location or a pharmacy can register as an outsourcing facility with the FDA and then follow the standards set forth in there.

**Chairman Klein:** The fifteen facilities, know that you're changing the rules here?

**Mark J. Hardy:** That is true. They knew with this new category that the FDA created about sourcing facilities, since the law has passed, that states would have to take an individual stand on how they were going to regulate those facilities moving forward. We want to keep the same standards as what the FDA requires, with the addition that they provide documentation to us if we ever come across a situation where we need it.

**Chairman Klein:** Asked for anyone else in support or opposition. He closed the hearing.

**Senator Miller** moved a do pass.

**Senator Poolman** seconded the motion.

Roll Call Vote: Yes-7 No-0 Absent-0

**Senator Klein will carry the bill.**

**2015 SENATE STANDING COMMITTEE  
 ROLL CALL VOTES  
 BILL/RESOLUTION NO. 2086**

Senate Industry, Business and Labor Committee

Subcommittee

Amendment LC# or Description: \_\_\_\_\_

Recommendation:  Adopt Amendment  
 Do Pass     Do Not Pass     Without Committee Recommendation  
 As Amended     Rerefer to Appropriations  
 Place on Consent Calendar

Other Actions:  Reconsider     \_\_\_\_\_

Motion Made By Senator Miller    Seconded By Senator Poolman

Senators	Yes	No	Senators	Yes	No
Chairman Klein	x		Senator Murphy	x	
Vice Chairman Campbell	x		Senator Sinner	x	
Senator Burckhard	x				
Senator Miller	x				
Senator Poolman	x				

Total (Yes) 7    No 0

Absent 0

Floor Assignment Senator Klein

If the vote is on an amendment, briefly indicate intent:

**REPORT OF STANDING COMMITTEE**

**SB 2086: Industry, Business and Labor Committee (Sen. Klein, Chairman)** recommends **DO PASS** (7 YEAS, 0 NAYS, 0 ABSENT AND NOT VOTING). SB 2086 was placed on the Eleventh order on the calendar.

2015 HOUSE INDUSTRY, BUSINESS AND LABOR

SB 2086

# 2015 HOUSE STANDING COMMITTEE MINUTES

Industry, Business and Labor Committee  
Peace Garden Room, State Capitol

SB 2086  
3/16/2015  
24842

- Subcommittee  
 Conference Committee

*Ellen Letang*

## Explanation or reason for introduction of bill/resolution:

Wholesale drug distribution & third-part logistics providers.

## Minutes:

Attachment 1

**Chairman Keiser:** Opens the hearing on SB 2086.

**Mark Hardy~PharmD-Executive Director of the North Dakota State Board of Pharmacy:** (Attachment 1).

7:00

**Representative Hanson:** The \$200 fee for outsourcing facility, how is that number derived at? Also, currently there is a \$400 fee that does apply to them?

**Hardy:** Our current stance for those companies is they need to be licensed in North Dakota before they make shipments into the state. We classify that under the division of the wholesale distributor in which that fee is set at \$400. It matters not with the cost is to use but the most important thing is that we have them licensed and have jurisdiction for those outsourcing facilities what are shipping into the state. We set the fee at \$200, which is the lowest fee that we have for the wholesale statues.

**Chairman Keiser:** When the FDA came out with their original proposed rules, some of the firms in our state that were doing compounding were concerned. Can we accommodate our firms with this legislation?

**Hardy:** There will be a meeting this week with the Department of Health & Human Services with all 50 states meeting to specifically address compounding to look at MOU's. We like the compounders in which they are conducting business and are located in North Dakota, we feel that they do a very good job. It's the ones located out of state that create some very strong concerns for us. We are working with the compounders in the state which is a very important business.

**Chairman Keiser:** When they are given to a hospital, they still need a prescription to utilize on a specific patient?

**Hardy:** They would need an order before they could utilize it. The compounding is done before that order is received.

**Chairman Keiser:** I think it's important to not over regulate what works well.

**Chairman Keiser:** Anyone else here to testify in support of SB 2086, opposition, neutral?  
Closes the hearing on SB 2086, what are the wishes of the committee?

**Representative M Nelson:** I would like to hold it.

# 2015 HOUSE STANDING COMMITTEE MINUTES

Industry, Business and Labor Committee  
Peace Garden Room, State Capitol

SB 2086  
3/25/2015  
Job Number 25389

- Subcommittee  
 Conference Committee

*Re Mae Kuehn*

## Explanation or reason for introduction of bill/resolution:

Wholesale drug distribution & third-party logistics providers.

## Minutes:

**Chairman Keiser:** Opens the work session on 2086.

**Representative Kasper:** Moved Do Pass

**Representative Sukut:** Seconded the motion.

A Roll Call vote was taken: Yes 14, No 0, Absent 1.

Do Pass carries.

Representative Kasper will carry the bill.

Date: Mar 25, 2015

Roll Call Vote: 1

2015 HOUSE STANDING COMMITTEE  
ROLL CALL VOTES

BILL/RESOLUTION NO. 2086

House Industry, Business & Labor Committee

Subcommittee  Conference Committee

Amendment LC# or Description: \_\_\_\_\_

Recommendation:  Adopt Amendment  
 Do Pass  Do Not Pass  Without Committee Recommendation  
 As Amended  Rerefer to Appropriations  
Other Actions:  Reconsider \_\_\_\_\_

Motion Made By Rep Kasper Seconded By Rep Sukut

Representatives	Yes	No	Representatives	Yes	No
Chairman Keiser	X		Representative Lefor	X	
Vice Chairman Sukut	X		Representative Louser	X	
Representative Beadle	X		Representative Ruby	X	
Representative Becker	X		Representative Amerman	X	
Representative Devlin	X		Representative Boschee	X	
Representative Frantsvog	Ab		Representative Hanson	X	
Representative Kasper	X		Representative M Nelson	X	
Representative Laning	X				

Total (Yes) 14 No 0

Absent 1

Floor Assignment Rep Kasper

If the vote is on an amendment, briefly indicate intent:

**REPORT OF STANDING COMMITTEE**

**SB 2086: Industry, Business and Labor Committee (Rep. Keiser, Chairman)**  
recommends **DO PASS** (14 YEAS, 0 NAYS, 1 ABSENT AND NOT VOTING).  
SB 2086 was placed on the Fourteenth order on the calendar.

2015 TESTIMONY

SB 2086



State of North Dakota  
Jack Dalrymple, Governor

OFFICE OF THE EXECUTIVE DIRECTOR  
1906 E Broadway Ave  
Bismarck ND 58501-4700  
Telephone (701) 328-9535  
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**STATE BOARD OF PHARMACY**

E-mail= [Mhardy@btinet.net](mailto:Mhardy@btinet.net) [www.nodakpharmacy.com](http://www.nodakpharmacy.com)

Mark J. Hardy, PharmD, R.Ph.  
Executive Director

**Senate Bill No 2086 – Wholesale  
Senate Industry, Business & Labor Committee – Roosevelt Room  
11:00 AM - Wednesday – January 14, 2015**

Chairman Klein, members of the Senate Industry, Business & Labor Committee, for the record I am Mark J. Hardy, PharmD, Executive Director of the North Dakota State Board of Pharmacy. I appreciate the opportunity to be here to speak with you today.

Senate Bill No 2086 services three purposes:

- 1) To clarify that a third-party logistics provider needs to be licensed in North Dakota and creates a separate structure for this type of business activity, which is consistent with the Federal Drug Quality and Security Act of 2013.
- 2) It creates a category for the new business type created by the Federal Drug Quality and Security Act of 2013 of Outsourcing Facility and
- 3) Provides a provision that was brought to us by the North Dakota Midwest Association for Medical Equipment Services [MAMES] who works with medical equipment services.

The federal Drug Quality and Security Act of 2013 included a provision which impacts North Dakota Wholesale Drug statutes. This legislation stated that third-party logistic providers could not be licensed as Wholesaler Distributors. Therefore, we are proposing to add a new category which can be found on page 11 under section 5. That requires licensure separate from the Wholesale Drug statutes that still maintains that the third-party logistic providers must meet the standards which are expected of our Wholesale Distributors. The Board feels licensure of third-party logistic providers is an important provision as it ensures proper standards for prescription drugs at each chain of custody. Common third-party logistic providers are UPS and FedEx, at which large warehouses store and secure the drugs. Thus, it is very important that these locations follow proper procedures and protocols to ensure quality and safeguards are in place.

Compounding of pharmaceuticals has been a very hot topic on a national scale in the pharmacy industry. It has long been known that locations were compounding non-patient specific prescriptions and shipping them to various facilities.

These types of activities were not legal and recently came to light with the meningitis outbreak tied to the New England Compounding Center in Massachusetts. The FDA has decided that they should regulate these types of facilities as Outsourcing facilities at which they are able to compound medications that are non-patient specific and ship them accordingly. They hold these facilities to a very high standard level which is similar to a drug manufacturer.

We are asking to add a provision to our Wholesale Statutes in which these facilities be licensed and categorized as such. Currently, since the law has passed, we have maintained that these types of facilities must be licensed under our wholesale provisions before they can do any shipping of non-patients specific compounds into North Dakota.

Currently we have 15 facilities licensed that are licensed which are on the enclosed list of the FDA registered outsourcing facilities.

Also on page 11 in section 4 subsection 2.; you will note that in the unforeseen circumstance in which a contaminated product was identified, upon request the outsourcing facility must provide lists of distribution of products to the state within forty-eight hours.

We set the fee in Section 3 for outsourcing facilities to be \$200 which is less than the current \$400 wholesale license fee in which they are currently licensed. Thus the fiscal note contains a net loss in revenue.

Lastly, on page 8 in Section 2 the North Dakota MAMES brought forward these current standards for Durable Medical Equipment Retailers. Since the passage of this legislation, they noticed one situation in which there was cause for concern for those items that were considered thirteen month capped rental items by the Center of Medicare and Medicaid Services. The current law read that they had to have a new prescription every year, which is interpreted as 12 months. We have clarified that and agree with the Association in which there is no need to have a yearly prescription and those prescriptions can be perpetual moving forward.

Again, I thank you for the opportunity to present this bill and will answer any questions you may have.

# North Dakota Legislative Branch

## Verify Submit

### Fiscal Notes

**Details**

**Bill Number:** SB 2086 **Amendment:** **Engrossment:**  
**Original:** 15.8029.01000 **In Context:**  
**Fiscal Note:** 15.8029.01000  
**Requested:** 12/19/2014 04:37 PM  
**Revision Requested:**  
**Next Hearing:**  
**Engrossment Status:**  
**Agency Contact:**   
**Assigned To/Due:**  
**Agency Comments:**

**Fiscal Note**

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Cities			
School Districts			
Townships			

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We anticipate a cost of \$500 to implement the database changes to account for the proposed revisions in the legislation.

**C. Appropriations:** *Explain the appropriation amounts. Provide detail, when appropriate, for each agency and fund affected. Explain the relationship between the amounts shown for expenditures and appropriations. Indicate whether the appropriation or a part of the appropriation is included in the executive budget or relates to a continuing appropriation.*

Name: Mark Hardy  
 Title: ND Board of Pharmacy  
 Phone: 701-328-9535  
 Date Prepared: 12/22/2014

3

Company	Address	City	State	ZIP Code
Exel Inc	5351 Jurupa Street	Ontario	CALIFORNIA	91761
Exel Inc	8631 Polk Lane Suite B	Olive Branch	MISSISSIPPI	38654
Exel Inc	98 Excellence Way	Vonore	TENNESSEE	37885
Exel Inc	9211 Kaiser Way	Fontana	CALIFORNIA	92335
EXEL INC	300 SALEM CHURCH ROAD	MECHANICSBURG	PENNSYLVANIA	17050
Exel Inc	350 Salem Church Road	Mechanicsburg	PENNSYLVANIA	17050
EXEL INC	1800 CLOISTER DRIVE	LANCASTER	PENNSYLVANIA	17601
Exel Inc	228 Access Drive	Southaven	MISSISSIPPI	38671
Exel Inc.	6345 Brackbill Blvd	Mechanicsburg	PENNSYLVANIA	17050
Exel, Inc	9440 South State Road 39	Mooresville	INDIANA	46158
Exel, Inc	6400 William Keck Bypass	Mt Vernon	INDIANA	47620
Exel, Inc	500 Independence Ave	Mechanicsburg	PENNSYLVANIA	17055
Genco I, Inc	1629 Willow Street	Lebanon	PENNSYLVANIA	17046
Harvard Third Party Logistics	5110 West 74th Street	Indianapolis	INDIANA	46268
Internet Services Corporation dba International Pharma Packagin	1300 Altura Road	Fort Mill	SOUTH CAROLINA	29708
Kuehne + Nagel	6005 Freeport Ave #1034	Memphis	TENNESSEE	38141
Kuehne + Nagel Inc	3735 Workman Mill Road Bldg D	Whitter	CALIFORNIA	90601
Kuehne + Nagel Inc	324 Half Acre Road	Cranbury	NEW JERSEY	8512
Kuehne + Nagel Inc	1800 Walters Ridge Drive Suite 100	Lewisville	TEXAS	75057
Kuehne + Nagel, Inc	2525 Whilden Drive	Durham	NORTH CAROLINA	27713
Owens & Minor Healthcare Logistics	1651 California Street Suite C	Redlands	CALIFORNIA	92374
Ozburn-Hessey Logistics, LLC	1101 Whitaker Road	Plainfield	INDIANA	46168
RxC Acquistion Company dba RxCrossroads Third party Logistics	1001 Cheri Way Suite 100	Louisville	KENTUCKY	40118
UPS Supply Chain Solutions Inc	13501 Independence Parkway	Ft. Worth	TEXAS	76177
UPS Supply Chain Solutions Inc	11811 Landon Drive Suite 200	Mira Loma	CALIFORNIA	91752
UPS Supply Chain Solutions Inc	1645 Satellite Blvd	Duluth	GEORGIA	30097
UPS Supply Chain Solutions Inc	4990 Aircenter Circle	Reno	NEVADA	89502
UPS Supply Chain Solutions Inc	1840 Outer Loop Road	Louisville	KENTUCKY	40219
UPS Supply Chain Solutions Inc	1910 Danielson Place	Memphis	TENNESSEE	38114
UPS Supply Chain Solutions, Inc	222 Lake Drive	Newark	DELAWARE	19702
UPS Supply Chain Solutions, Inc	1860 Outerloop Road	Louisville	KENTUCKY	40219

UPS Supply Chain Solutions, Inc  
UPS Supply Chain Solutions, Inc.  
UPS Supply Chain Solutions, Inc.

2515 S Tricenter Blvd  
401 Quality Circle  
1920 Outer Loop Road  
12055 Sage Point Court,Suite#101  
20 Crestridge Drive  
2260 Outer Loop Road

Durham  
Harrisburg  
Louisville  
Stead  
Suwanee  
Louisville

NORTH CAROLINA 27713  
PENNSYLVANIA 17112  
KENTUCKY 40219  
NEVADA 89506  
GEORGIA 30024  
KENTUCKY 40219

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# Drug Supply Chain Security Act (DSCSA)

## Title II of the Drug Quality and Security Act of 2013

The Drug Quality and Security Act (DQSA), was signed into law by President Obama on November 27, 2013. **Title II of DQSA, the Drug Supply Chain Security Act** ([/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm376829.htm](http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm376829.htm)) outlines critical steps to build an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the United States.

Ten 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.

Drug manufacturers, wholesale drug distributors, repackagers, and many dispensers (primarily pharmacies) will be called on to work in cooperation with FDA to develop the new system over the next 10 years.

Among key provisions implemented over the next 10 years are requirements for:

- **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, wholesaler 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:** Manufacturers, wholesaler 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, wholesaler 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, wholesaler 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.

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The Effect of Section 585 of the FD&C  
Act on Drug Product Tracing and  
Wholesale Drug Distributor and Third-  
Party Logistics Provider Licensing  
Standards and Requirements:  
Questions and Answers  
Guidance for Industry

***DRAFT GUIDANCE***

**This guidance document is being distributed for comment purposes only.**

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document contact CDER Office of Compliance at 301-796-3100 or [drugtrackandtrace@fda.hhs.gov](mailto:drugtrackandtrace@fda.hhs.gov).

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

**October 2014  
Procedural**

- **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.
- **Third-party logistics provider licensing:** Third-party logistic providers, those who provide storage and logistical operations related to drug distribution, to obtain a state or federal license.

The law requires FDA to develop standards, guidance documents, and pilot programs and to conduct public meetings, in addition to other efforts necessary to support efficient and effective implementation. FDA is developing a schedule for implementing the law's requirements.

This system will enhance the U.S. Food and Drug Administration's ability to help protect consumers from exposure to drugs that may be counterfeit, stolen, contaminated, or otherwise harmful. The system will improve detection and removal of potentially dangerous drugs from the drug supply chain to protect U.S. consumers. Failure to comply with the requirements of the law can result in penalties.

The development of the system will be phased in with new requirements over a 10-year period. These requirements will include providing product and transaction information at each sale with lot level information, in paper or electronic format, and placing unique product identifiers on individual drug packages.

#### For more information

- **[Title II of the Drug Quality and Security Act](#)**  
[\(/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm376829.htm\)](#)
- **[FDA Voice Blog: Creating a New System to Improve the Security of the Drug Supply](#)**  
[\(http://blogs.fda.gov/fdavoices/index.php/2014/04/creating-a-new-system-to-improve-the-security-of-the-drug-supply/\)](#)
- **[FDA issues draft guidance on identifying suspect drug products in the supply chain](#)**  
[\(/Drugs/DrugSafety/ucm400520.htm\)](#)

#### Spotlight

- **[Are you ready for the Drug Supply Chain Security Act?](#)**  
[\(/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm427033.htm\)](#)
- **[DSCSA Implementation: Product Tracing Requirements — Compliance Policy \(PDF - 56KB\)](#)**  
[\(/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM427867.pdf\)](#)

#### Webinars

- **[DSCSA Overview](#)**  
[\(/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/ucm388150.htm\)](#)
- **[Identification of Suspect Product and Notification](#)**  
[\(/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/ucm402366.htm\)](#)

(1)

# The Effect of Section 585 of the FD&C Act on Drug Product Tracing and Wholesale Drug Distributor and Third- Party Logistics Provider Licensing Standards and Requirements: Questions and Answers

## Guidance for Industry

*Additional copies are available from:*

*Office of Communications  
Division of Drug Information, WO51, Room 2201  
Center for Drug Evaluation and Research  
Food and Drug Administration  
10903 New Hampshire Ave., Silver Spring, MD 20993  
Phone: 301-796-3400; Fax: 301-847-8714  
druginfo@fda.hhs.gov*

*<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>*

*and/or*

*Office of Communication, Outreach and  
Development, WO71, Room 3128  
Center for Biologics Evaluation and Research  
Food and Drug Administration  
10903 New Hampshire Ave., Silver Spring, MD 20993  
Phone: 800-835-4709 or 240-402-7800  
ocod@fda.hhs.gov*

*<http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>*

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

**October 2014  
Procedural**

*Contains Nonbinding Recommendations*

*Draft — Not for Implementation*

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  - C. Third-Party Logistics Provider Standards and Licensing..... 5*

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2 **The Effect of Section 585 of the FD&C Act on Drug Product**  
3 **Tracing and Wholesale Drug Distributor and Third-Party Logistics**  
4 **Provider Licensing Standards and Requirements:**  
5 **Questions and Answers**  
6  
7 **Guidance for Industry<sup>1</sup>**  
8

9  
10 This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current  
11 thinking on this topic. It does not create or confer any rights for or on any person and does not operate to  
12 bind the FDA or the public. You can use an alternative approach if the approach satisfies the  
13 requirements of the applicable statutes and regulations. If you want to discuss an alternative approach,  
14 contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate  
15 FDA staff, call the appropriate number listed on the title page of this guidance.  
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19 **I. INTRODUCTION**  
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21 The Food and Drug Administration (FDA) is issuing these questions and answers to assist  
22 industry and State and local governments in understanding the effects of section 585 (Uniform  
23 National Policy) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)<sup>2</sup> added by Title II of  
24 the Drug Quality and Security Act (DQSA), which was enacted on November 27, 2013. Title II,  
25 which is also referred to as the Drug Supply Chain Security Act (DSCSA), establishes a Federal  
26 system for tracing prescription drug products through the pharmaceutical distribution supply  
27 chain and requires trading partners to pass, receive, and maintain certain product and distribution  
28 information. The DSCSA also requires FDA to establish Federal standards for licensing of  
29 wholesale drug distributors and third party logistics providers; the Agency is currently drafting  
30 these regulations. Section 585 sets forth a uniform national policy preempting States<sup>3</sup> from  
31 establishing or continuing in effect certain standards and requirements.

32 FDA is issuing this guidance to (1) help industry and States understand the immediate effects of  
33 the law and (2) clarify section 585's effect on State product tracing and standards and  
34 requirements for wholesale distributor and third-party logistics provider (3PL) licensing.  
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36 FDA's guidance documents, including this guidance, do not establish legally enforceable  
37 responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should

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<sup>1</sup> This guidance has been prepared by the Office of Compliance in the Center for Drug Evaluation and Research (CDER) in cooperation with the Center for Biologics Evaluation and Research (CBER) and the Office of Regulatory Affairs (ORA) at the Food and Drug Administration.

<sup>2</sup> For brevity, in this guidance, references to section 585 of the FD&C Act are cited as section 585.

<sup>3</sup> Section 585 uses the phrase "State and political subdivision of a State." For purposes of this document, the word *States* will mean States and political subdivisions of States.

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38 be viewed only as recommendations, unless specific regulatory or statutory requirements are  
39 cited. The use of the word *should* in Agency guidances means that something is suggested or  
40 recommended, but not required.

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42 **II. BACKGROUND**

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44 On November 27, 2013, the DSCSA (Title II of Public Law 113-54) was signed into law. The  
45 DSCSA outlines critical steps to build an electronic, interoperable system to identify and trace  
46 certain prescription drugs as they are distributed in the United States. The DSCSA adds sections  
47 581 through 585 as Subchapter H of the FD&C Act. These sections establish definitions (section  
48 581), requirements for supply chain participants (section 582), standards for and licensing of  
49 wholesale drug distributors (section 583) and third-party logistics providers (section 584), and a  
50 Uniform National Policy (section 585).

51

52 Section 585, as added by section 205 of the DQSA, states:

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54 (a) PRODUCT TRACING AND OTHER REQUIREMENTS.—Beginning on  
55 the date of enactment of the Drug Supply Chain Security Act, no State or political  
56 subdivision of a State may establish or continue in effect any requirements for tracing  
57 products through the distribution system (including any requirements with respect to  
58 statements of distribution history, transaction history, transaction information, or  
59 transaction statement of a product as such product changes ownership in the supply chain,  
60 or verification, investigation, disposition, notification, or recordkeeping relating to such  
61 systems, including paper or electronic pedigree systems or for tracking and tracing drugs  
62 throughout the distribution system) which are inconsistent with, more stringent than, or in  
63 addition to, any requirements applicable under section 503(e) (as amended by such Act)  
64 or this subchapter (or regulations issued thereunder), or which are inconsistent with—

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(1) any waiver, exception, or exemption pursuant to section 581 or 582; or

66

(2) any restrictions specified in section 582.

67 (b) Wholesale Distributor and Third-Party Logistics Provider Standards—

68 (1) IN GENERAL.—Beginning on the date of enactment of the Drug Supply  
69 Chain Security Act, no State or political subdivision of a State may establish or continue  
70 any standards, requirements, or regulations with respect to wholesale prescription drug  
71 distributor or third-party logistics provider licensure that are inconsistent with, less  
72 stringent than, directly related to, or covered by the standards and requirements  
73 applicable under section 503(e) (as amended by such Act), in the case of a wholesale  
74 distributor, or section 584, in the case of a third-party logistics provider.

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(2) State Regulation of Third-Party Logistics Providers.—No State shall  
76 regulate third-party logistics providers as wholesale distributors.

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III. QUESTIONS AND ANSWERS

A. Product Tracing

1. How does section 585(a) affect State tracing requirements?

Beginning on November 27, 2013, the date of enactment of the DSCSA, States were preempted from establishing or continuing in effect any requirements for tracing prescription drugs through the pharmaceutical distribution supply chain that are inconsistent with, more stringent than, or in addition to any requirements applicable under section 503(e) of the FD&C Act (21 U.S.C. 353(e) (as amended by the DSCSA)) or Subchapter H (added by the DSCSA) or regulations issued thereunder.

Section 585 enumerates the types of requirements that States are preempted from establishing or continuing in effect in any manner that is inconsistent with, more stringent than, or in addition to Federal law, including: statements of distribution history, transaction history, transaction information, or transaction statement of a product as the product changes ownership in the supply chain, verification, investigation, disposition, notification, or recordkeeping relating to the distribution systems, including paper or electronic pedigree systems or for tracking and tracing drugs throughout the distribution system.

In addition, no State may establish, continue in effect, or apply any requirement that is inconsistent with any waiver, exception, or exemption granted by FDA pursuant to sections 581 or 582 of the FD&C Act or any restrictions specified in section 582.

2. What product tracing requirements apply before January 1, 2015?

Prior to January 1, 2015, the Federal pedigree requirements of section 503(e)(1) of the FD&C Act, remain in effect. Therefore, until January 1, 2015, States may not regulate tracing in any way that is inconsistent with, more stringent than, or in addition to the requirements of section 503(e)(1) of the FD&C Act.

3. What product tracing requirements apply on or after January 1, 2015?

Beginning January 1, 2015, the Federal tracing requirements of section 582 of the FD&C Act established under the DSCSA, go into effect. After that date, States may not regulate tracing in any way that is inconsistent with, more stringent than, or in addition to those requirements.

4. Which State requirements are preempted?

Any requirements for tracing drugs through the pharmaceutical distribution supply chain that are inconsistent with, more stringent than, or in addition to any requirements applicable under section 503(e) of the FD&C Act, as amended by the DSCSA, or under subchapter H (or regulations issued thereunder) are preempted.

126 **B. Wholesale Drug Distributor Standards and Licensing**

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**1. How does section 585(b) affect State wholesale drug distributor standards and licensing?**

Beginning on November 27, 2013, States were preempted from establishing or continuing any standards, requirements, or regulations with respect to wholesale distributor licensure that are inconsistent with, less stringent than, directly related to, or covered by the standards<sup>4</sup> or requirements applicable under section 503(e) of the FD&C Act (as amended by the DSCSA). Thus, States may not impose standards, requirements, or regulations with respect to wholesale drug distributors that fall below the minimum standards established by Federal law.

**2. Will States need to change their wholesale drug distributor licensing laws before the new Federal wholesale drug distributor regulations take effect?**

Each State will have to analyze its own laws to determine the impact of section 585; however, FDA understands that, in general, the current Federal standards, requirements, and regulations have been the basis for most current State laws. Therefore it is likely those State laws would not fall below the minimum standards established by federal law and would not need to be changed.

The new wholesale drug distributor regulations issued under section 583 will take effect two years after they are finalized by FDA. By that time, States should have reanalyzed their licensing laws in order to determine if those laws fall below the minimum standards established by federal law.

**3. Can States continue to license wholesale drug distributors before the new Federal regulations for wholesale drug distributor standards and licensing go into effect?**

Yes. States can continue to license wholesale drug distributors before the regulations issued according to section 583 (as added by 204 of the DSCSA) become effective, as long as the State regulations are not inconsistent with, less stringent than, directly related to, or covered by Federal law. The DSCSA contemplates that states will continue to license wholesale drug distributors before the new regulations go into effect. For example, section 503(e)(1)(A) (as amended) requires a wholesale drug distributor to be licensed by the State from which the drug is distributed or else by the Secretary of Health and Human Services if the distributing wholesale drug distributor's State chooses not to have a licensing program. In addition, the distributor must be licensed by the State into which the drug is distributed (if required by that State).

**4. What wholesale drug distributor standards and licensing requirements apply after the new Federal regulations go into effect?**

When the new Federal licensure regulations of the FD&C Act become effective (see section 583(a), (e)), States will be preempted from continuing or establishing licensure in any way that

<sup>4</sup> Please refer to section 583(b) of the FD&C Act for additional information on content requirements for wholesale drug distributor licensing standards.

170 falls below the minimum standards established by those Federal regulations.<sup>5</sup> When the final  
171 regulations are published, States will know whether they need to change any standards,  
172 requirements, or regulations that they may have established that are inconsistent with, less  
173 stringent than, directly related to, or covered by those Federal regulations.  
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175 **C. Third-Party Logistics (3PL) Provider Standards and Licensing**  
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177 **1. How does section 585(b) affect 3PL standards and licensing?**  
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179 Beginning on November 27, 2013, States are preempted from establishing or continuing any  
180 standards, requirements, or regulations with respect to 3PLs that are inconsistent with, less  
181 stringent than, directly related to, or covered by the standards<sup>6</sup> or requirements applicable under  
182 section 584 of the FD&C Act. Thus, States may not impose standards, requirements, or  
183 regulations with respect to 3PLs that fall below the minimum standards established by Federal  
184 law.  
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186 **2. Can States license 3PLs before the new Federal regulations for 3PL standards and**  
187 **licensing go into effect?**  
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189 Yes. States can license 3PLs before the new Federal regulations issued according to section 584  
190 become effective. The DSCSA contemplates that States can license 3PLs before the new Federal  
191 regulations become effective. For example, section 584(b) of the FD&C Act requires 3PLs to  
192 report “the State by which the facility is licensed” beginning 1 year after the date of enactment of  
193 the DSCSA.  
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195 **3. What 3PL standards and licensing requirements apply after Federal regulations go**  
196 **into effect?**  
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199 Once the new Federal licensing regulations for 3PLs become effective (see section 584(d)),  
200 States will be preempted from continuing or establishing licensure in any way that falls below  
201 the minimum standards established by those regulations.<sup>7</sup> When the final regulations are  
202 published, States will know whether they need to change any standards, requirements, or  
203 regulations that they may have established that are inconsistent with, less stringent than, directly  
204 related to, or covered by those Federal regulations.  
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<sup>5</sup> The licensing regulations for wholesale drug distributors are to be issued not later than 2 years after the date of enactment of the Drug Supply Chain Security Act (section 583(a)); the final regulation will take effect “2 years after the date that such final regulation is published” (section 583(e)(3)).

<sup>6</sup> Please refer to section 584(d)(2)(C) – (H) of the FD&C Act for additional information on content requirements for third-party logistics provider licensing standards.

<sup>7</sup> The licensing regulations for 3PLs are to be issued not later than 2 years after the date of enactment of the Drug Supply Chain Security Act (section 584(d)(1)); the final regulation will take effect “1 year after the date that such final regulation is issued” (section 584(d)(3)(C)).

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*Contains Nonbinding Recommendations*

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**4. Can States license 3PLs using their licensing program for wholesale drug distributors?**

Section 585(b)(2) does not permit states to license 3PLs as wholesale drug distributors. States would need to establish separate licensing programs for wholesale drug distributors and 3PLs.

**U.S. Food and Drug Administration**  
Protecting and Promoting Your Health

## Registered Outsourcing Facilities

Facilities Registered As Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act)

Updated as of 12/19/14

[Information Concerning Outsourcing Facility Registration \(/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm389118.htm\)](http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm389118.htm)

This table lists the outsourcing facilities that have submitted registration information that has been determined to be complete by the data lock date for the latest weekly update of the table.

Facility Name	Initial Date of Registration as an Outsourcing Facility <sup>1</sup>	Date of Most Recent Registration as an Outsourcing Facility <sup>1</sup>	End Date of Last FDA Inspection Related to Compounding <sup>2</sup>	Was a Form FDA-483 issued? <sup>3</sup>
Absolute Pharmacy, Lutz, FL	9/3/2014	9/3/2014	11/19/2014	Yes
Advanced Pharma, Inc., Houston, TX	1/22/2014	12/1/2014	3/17/2014	Yes ( <a href="#">/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElec</a> )
Alexander Infusion LLC dba Avanti Health Care, New Hyde Park, NY	4/21/2014	4/21/2014	7/9/2014	Yes ( <a href="#">/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElec</a> )
ALK-Abelló, Inc., Port Washington, NY	6/3/2014	6/3/2014	2/25/2014	Yes
Allergy Laboratories, Inc., Oklahoma City, OK	12/30/2013	12/30/2013	4/26/2013	Yes ( <a href="#">/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElec</a> )
Amerilab LLC, Edmond, OK	5/23/2014	5/23/2014	Not yet inspected	N/A
Anazao Health Corporation, Las Vegas, NV	9/23/2014	9/23/2014	Not yet inspected	N/A
Avella of Deer Valley, Phoenix, AZ	2/24/2014	2/24/2014	2/25/2013	Yes ( <a href="#">/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElec</a> )
Banner Health, Chandler, AZ	12/26/2013	12/26/2013	3/5/2014 (incomplete)	No
California Pharmacy and Compounding Center, Newport Beach, CA	4/30/2014	12/1/2014	8/25/2014; 10/17/2014	Yes (8/25/2014 ( <a href="#">/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/OI</a> ) and (10/17/2014))
Cantrell Drug Company, Litte Rock, AR	12/16/2013	12/16/2013	11/4/2013	Yes ( <a href="#">/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElec</a> )
Central Admixture Pharmacy Services, Inc., Allentown, PA	2/28/2014	2/28/2013	6/11/2014	Yes ( <a href="#">/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElec</a> )
Central Admixture Pharmacy Services, Inc., San Diego, CA	6/4/2014	6/4/2014	8/8/2014	Yes ( <a href="#">/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElec</a> )
Complete Pharmacy and Medical Solutions, Miami Lakes, FL	6/6/2014	6/6/2014	8/12/2014	Yes ( <a href="#">/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElec</a> )
Delta Pharma, Inc., Ripley, MS	8/6/2014	8/6/2014	10/2/2013	Yes ( <a href="#">/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElec</a> )

WHOL 68

WHOL 78

WHOL 1101

WHOL 1425

WHOL 1299

WHOL 1268

	Edge Pharmacy Services LLC, Colchester, VT	1/21/2014	1/21/2014	8/20/2014	Yes
	Essential Pharmacy Compounding Division of Kohll's Pharmacy, Omaha, NE	7/17/2014	7/17/2014	Not yet inspected	N/A
WHOL 1475	Exela Pharma Sciences, LLC., Lenoir, NC	6/6/2014	6/6/2014	11/21/2014	Yes (/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElec
WHOL 1222	Greer Laboratories, Inc., Lenoir, NC	2/24/2014	2/24/2014	11/15/2013	Yes (/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElec
WHOL 338	Healix Infusion Therapy, Inc., Sugar Land, TX	2/12/2014	12/1/2014	5/16/2014	Yes (/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElec
	Infusion Options Inc., Brooklyn, NY	1/24/2014	1/24/2014	4/23/2014	Yes (/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElec
	Institutional Pharmacy Solutions, LLC, Virginia Beach, VA	3/4/2014	3/4/2014	Not yet inspected	N/A
	Institutional Pharmacy Solutions, LLC, Irwindale, CA	3/6/2014	3/6/2014	6/20/2014	No
	IV Specialty Ltd, Austin, TX	2/26/2014	2/26/2014	7/22/2014	Yes (/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElec
	JCB Laboratories, North Wichita, KS	1/21/2014	12/1/2014	2/27/2013	Yes (/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElec
WHOL 409	Jubilant HollisterStier LLC, Spokane, WA	6/3/2014	6/3/2014	4/15/2014	Yes
	Kings Park Slope, Inc., Brooklyn, NY	12/23/2013	12/23/2013	3/14/2014	Yes (/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElec
	KRS Global Biotechnology, Inc., Boca Raton, FL	12/15/2013	12/15/2013	3/17/2014	Yes (/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElec
	LEESAR INC, Fort Myers, FL	4/30/2014	4/30/2014	8/8/2014	Yes (/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElec
	Leiter's Compounding, (Great Oaks Blvd), San Jose, CA	1/31/2014	1/31/2014	10/7/2014	Yes
	Lowlite Investments, Inc. dba Olympia Pharmacy, Orlando, FL	3/17/2014	3/17/2014	3/21/2013	Yes (/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElec
	Medistat RX, LLC, Foley, AL	12/1/2014	12/1/2014	9/18/2014	Yes
	Medi-Fare Drug & Home Health Center, Inc., Blacksburg SC	12/17/2013	12/17/2013	9/12/2014	Yes (/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElec
	Nephron Sterile Compounding Center, LLC (NSCC), West Columbia, SC	7/15/2014	7/15/2014	Not yet inspected	N/A
	OPS International, Inc. dba Olympia Pharmacy, Orlando, FL	3/10/2014	3/10/2014	12/4/2014	Yes

Pharm D Solutions dba PDS Compounding, West Houston, TX	8/6/2014	8/6/2014	Not yet inspected	N/A
Pharmaceutic Labs, LLC, Albany, NY	3/10/2014	3/10/2014	Not yet inspected	N/A
Pharmagen Laboratories Inc., Stamford, CT	1/21/2014	1/21/2014	8/23/2013	Yes ( <a href="#">/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElec</a>
Pharmakon Pharmaceuticals, Noblesville, IN	1/23/2014	12/5/2014	3/13/2014; 4/8/2014	Yes (3/13/2014 ( <a href="#">/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/O</a> ) (4/8/2014 ( <a href="#">/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/OR</a>
Pharmalogic CSP Inc., Bridgeport, WV	7/1/2014	7/1/2014	Not yet inspected	N/A
PharMedium Services, LLC, Cleveland, MS	12/11/2013	12/1/2014	2/22/2013	Yes ( <a href="http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy">http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy</a>
PharMedium Services, LLC, Edison, NJ	12/11/2013	12/1/2014	2/28/2013	Yes ( <a href="http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy">http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy</a>
PharMedium Services, LLC, Memphis, TN	12/11/2013	12/1/2014	3/22/2013	Yes ( <a href="http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy">http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy</a>
PharMedium Services, LLC, Sugar Land, TX	12/11/2013	12/1/2014	2/27/2013	Yes ( <a href="http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy">http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy</a>
Pine Pharmaceuticals, LLC, Tonawanda, NY	6/17/2014	6/17/2014	10/16/2014	No
Premier Pharmacy Labs Inc., Weeki Wachee, FL	4/16/2014	12/29/2014	5/9/2014	Yes ( <a href="#">/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElec</a>
Professional Pharmacy & Compounding Services LLC, Miami, FL	6/13/2014	6/13/2014	Not yet inspected	N/A
RC Compounding Services LLC, Poland, OH	2/12/2014	2/12/2014	2/7/2013	Yes ( <a href="#">/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElec</a>
Region Care, Inc., Great Neck, NY	12/24/2013	12/24/2013	3/20/2014	Yes ( <a href="#">/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElec</a>
SCA Pharmaceuticals, Little Rock, AR	12/13/2013	12/13/2013	4/1/2014	Yes ( <a href="#">/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElec</a>
SSM St. Clare Health Center, Fenton, MO	2/18/2014	2/18/2014	8/14/2014	Yes ( <a href="#">/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElec</a>
Syenz Laboratory, LLC, Norwood, NJ	9/9/2014	9/9/2014	Not yet inspected	N/A
Texas Health Infusion, The Woodlands, TX	8/8/2014	8/8/2014	Not yet inspected	N/A
Triangle Compounding Pharmacy Inc., Cary, NC	1/24/2014	1/24/2014	9/22/2014	Yes ( <a href="#">/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElec</a>
Unique Pharmaceuticals, Ltd., Temple TX	1/17/2014	12/2/2014	4/2/2014; 6/20/2014	Yes (4/4/2014 ( <a href="#">/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/OR</a> ) 6/20/2014 ( <a href="#">/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/OR</a>
US Compounding, Inc., Conway, AR	12/20/2013	12/20/2013	3/27/2014	Yes ( <a href="#">/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElec</a>

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 WHOL 720  
 WHOL 454  
 WHOL 397  
 WHOL 1497

US Specialty Formulations LLC, Bethlehem, PA	1/31/2014	12/1/2014	Not yet inspected	N/A
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**Notes**

1. The "initial date of registration as an outsourcing facility" is the date the facility was first registered (i.e., the date FDA determined that the initial registration information submitted for the facility was complete, and for firms first registering on or after October 1, 2014, the establishment fee was paid in full).

Under section 503B(b) of the FD&C Act, after the initial registration, a facility that elects to continue to be registered with FDA as an outsourcing facility must re-register annually. Beginning in fiscal year (FY) 2015 (October 1, 2014 to September 30, 2015), a facility that elects to register (or re-register) with FDA as an outsourcing facility must pay an annual establishment fee. The "date of most recent registration as an outsourcing facility" reflects the date FDA determined the most recently submitted registration information was complete and the annual establishment fee for that fiscal year paid in full.

Unless a previously registered outsourcing facility re-registers and pays the annual establishment fee in full during the registration period (between October 1 and December 31 of each calendar year), the facility will be removed from the list of registered outsourcing facilities on January 1 of the next calendar year.

2. Inspections identified in this table are associated with the facility at the listed address. A company may own or operate more than one registered outsourcing facility. FDA's web page [Compounding: Inspections, Recalls, and Other Actions \(Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm339771.htm\)](http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm339771.htm) may contain information about compounding facilities under the same ownership as the listed registered outsourcing facility.

Inspections may take place over several days, weeks, or longer. The date of the inspection is the date a Form FDA-483 listing the investigators' observations was issued. If no FDA Form-483 was issued, the date is the last day of the inspection.

3. A Form FDA-483 is issued when investigators observe any significant objectionable conditions. It does not constitute a final Agency determination of whether any condition is in violation of the FD&C Act or any relevant regulations.

4. This table reflects only FDA actions. It does not include State Board of Pharmacy actions, if any. To determine whether a registered outsourcing facility has been the subject of a State enforcement action, check with the State Board of Pharmacy for the state in which the facility is located. Some states post disciplinary or other actions on their web sites. For more information, please see [Compounding: Inspections, Recalls, and other Actions \(Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm339771.htm\)](http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm339771.htm).

5. "Closed" means the inspection has been closed without further action. "Open" means that FDA has not made a determination as to whether further action will be taken. If an action has been taken, it will be listed. Possible FDA actions include: warning letter; seizure; or injunction.

6. The information in this column was provided by the registered outsourcing facility at the time of registration and has not been verified by FDA. "N/A", indicates the registered outsourcing facility has not provided this information. In the future, FDA intends to provide information about whether the outsourcing facility also intends to compound nonsterile drugs from bulk drug substances. That information is not currently available to the Agency.



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Mark J. Hardy, PharmD, R.Ph.  
Executive Director

**Senate Bill No 2086 – Wholesale  
House Industry, Business & Labor Committee – Peace Garden Room  
8:00 AM - Monday – March 16, 2015**

Chairman Keiser, members of the House Industry, Business & Labor Committee, for the record I am Mark J. Hardy, PharmD, Executive Director of the North Dakota State Board of Pharmacy. I appreciate the opportunity to be here to speak with you today.

Senate Bill No 2086 services three purposes:

- 1) To clarify that a third-party logistics provider needs to be licensed in North Dakota and creates a separate structure for this type of business activity, which is consistent with the Federal Drug Quality and Security Act of 2013.
- 2) It creates a category for the new business type created by the Federal Drug Quality and Security Act of 2013 of Outsourcing Facility and
- 3) Provides a provision that was brought to us by the North Dakota Midwest Association for Medical Equipment Services [MAMES] who works with medical equipment services.

The federal Drug Quality and Security Act of 2013 included a provision which impacts North Dakota Wholesale Drug statutes. This legislation stated that third-party logistic providers could not be licensed as Wholesaler Distributors. Therefore, we are proposing to add a new category which can be found on page 11 under section 5. That requires licensure separate from the Wholesale Drug statutes that still maintains that the third-party logistic providers must meet the standards which are expected of our Wholesale Distributors. The Board feels licensure of third-party logistic providers is an important provision as it ensures proper standards for prescription drugs at each chain of custody. Common third-party logistic providers are UPS and FedEx, at which large warehouses store and secure the drugs. Thus, it is very important that these locations follow proper procedures and protocols to ensure quality and safeguards are in place.

Compounding of pharmaceuticals has been a very hot topic on a national scale in the pharmacy industry. It has long been known that locations were compounding non-patient specific prescriptions and shipping them to various facilities.

These types of activities were not legal and recently came to light with the meningitis outbreak tied to the New England Compounding Center in Massachusetts. The FDA has decided that they should regulate these types of facilities as Outsourcing facilities at which they are able to compound medications that are non-patient specific and ship them accordingly. They hold these facilities to a very high standard level which is similar to a drug manufacturer.

We are asking to add a provision to our Wholesale Statutes in which these facilities be licensed and categorized as such. Currently, since the law has passed, we have maintained that these types of facilities must be licensed under our wholesale provisions before they can do any shipping of non-patients specific compounds into North Dakota.

Currently we have 15 facilities that are licensed which are marked on the enclosed list of the FDA registered outsourcing facilities.

Also on page 11 in section 4 subsection 2.; you will note that in the unforeseen circumstance in which a contaminated product was identified, upon request the outsourcing facility must provide lists of distribution of products to the state within forty-eight hours.

We set the fee in Section 3 for outsourcing facilities to be \$200 which is less than the current \$400 wholesale license fee in which they are currently licensed. Thus the fiscal note contains a net loss in revenue.

Lastly, on page 8 in Section 2 the North Dakota MAMES brought forward these current standards for Durable Medical Equipment Retailers. Since the passage of this legislation, they noticed one situation in which there was cause for concern for those items that were considered thirteen month capped rental items by the Center of Medicare and Medicaid Services. The current law reads that they had to have a new prescription every year, which is interpreted as 12 months. We have clarified that and agree with the Association in which there is no need to have a yearly prescription and those prescriptions can be perpetual moving forward.

Again, I thank you for the opportunity to present this bill and will answer any questions you may have.

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# Drug Supply Chain Security Act (DSCSA)

## Title II of the Drug Quality and Security Act of 2013

The Drug Quality and Security Act (DQSA), was signed into law by President Obama on November 27, 2013. [Title II of DQSA, the Drug Supply Chain Security Act \(/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm376829.htm](#) outlines critical steps to build an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the United States.

Ten 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.

Drug manufacturers, wholesale drug distributors, repackagers, and many dispensers (primarily pharmacies) will be called on to work in cooperation with FDA to develop the new system over the next 10 years.

Among key provisions implemented over the next 10 years are requirements for:

- **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, wholesaler 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:** Manufacturers, wholesaler 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, wholesaler 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, wholesaler 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.

pg 3

- **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.
- **Third-party logistics provider licensing:** Third-party logistic providers, those who provide storage and logistical operations related to drug distribution, to obtain a state or federal license.

The law requires FDA to develop standards, guidance documents, and pilot programs and to conduct public meetings, in addition to other efforts necessary to support efficient and effective implementation. FDA is developing a schedule for implementing the law's requirements.

This system will enhance the U.S. Food and Drug Administration's ability to help protect consumers from exposure to drugs that may be counterfeit, stolen, contaminated, or otherwise harmful. The system will improve detection and removal of potentially dangerous drugs from the drug supply chain to protect U.S. consumers. Failure to comply with the requirements of the law can result in penalties.

The development of the system will be phased in with new requirements over a 10-year period. These requirements will include providing product and transaction information at each sale with lot level information, in paper or electronic format, and placing unique product identifiers on individual drug packages.

#### For more information

- **[Title II of the Drug Quality and Security Act \(/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm376829.htm\)](#)**
- **[FDA Voice Blog: Creating a New System to Improve the Security of the Drug Supply \(http://blogs.fda.gov/fdavoice/index.php/2014/04/creating-a-new-system-to-improve-the-security-of-the-drug-supply/\)](http://blogs.fda.gov/fdavoice/index.php/2014/04/creating-a-new-system-to-improve-the-security-of-the-drug-supply/)**
- **[FDA issues draft guidance on identifying suspect drug products in the supply chain \(/Drugs/DrugSafety/ucm400520.htm\)](#)**

#### Spotlight

- **[Are you ready for the Drug Supply Chain Security Act? \(/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm427033.htm\)](#)**
- **[DSCSA Implementation: Product Tracing Requirements — Compliance Policy \(PDF - 56KB\) \(/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM427867.pdf\)](#)**

#### Webinars

- **[DSCSA Overview \(/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/ucm388150.htm\)](#)**
- **[Identification of Suspect Product and Notification \(/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/ucm402366.htm\)](#)**

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# The Effect of Section 585 of the FD&C Act on Drug Product Tracing and Wholesale Drug Distributor and Third- Party Logistics Provider Licensing Standards and Requirements: Questions and Answers Guidance for Industry

## ***DRAFT GUIDANCE***

**This guidance document is being distributed for comment purposes only.**

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document contact CDER Office of Compliance at 301-796-3100 or [drugtrackandtrace@fda.hhs.gov](mailto:drugtrackandtrace@fda.hhs.gov).

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

**October 2014  
Procedural**

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# The Effect of Section 585 of the FD&C Act on Drug Product Tracing and Wholesale Drug Distributor and Third- Party Logistics Provider Licensing Standards and Requirements: Questions and Answers

## Guidance for Industry

*Additional copies are available from:*

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1  
2 **The Effect of Section 585 of the FD&C Act on Drug Product**  
3 **Tracing and Wholesale Drug Distributor and Third-Party Logistics**  
4 **Provider Licensing Standards and Requirements:**  
5 **Questions and Answers**  
6  
7 **Guidance for Industry<sup>1</sup>**  
8

9  
10 This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current  
11 thinking on this topic. It does not create or confer any rights for or on any person and does not operate to  
12 bind the FDA or the public. You can use an alternative approach if the approach satisfies the  
13 requirements of the applicable statutes and regulations. If you want to discuss an alternative approach,  
14 contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate  
15 FDA staff, call the appropriate number listed on the title page of this guidance.  
16

17  
18  
19 **I. INTRODUCTION**  
20

21 The Food and Drug Administration (FDA) is issuing these questions and answers to assist  
22 industry and State and local governments in understanding the effects of section 585 (Uniform  
23 National Policy) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)<sup>2</sup> added by Title II of  
24 the Drug Quality and Security Act (DQSA), which was enacted on November 27, 2013. Title II,  
25 which is also referred to as the Drug Supply Chain Security Act (DSCSA), establishes a Federal  
26 system for tracing prescription drug products through the pharmaceutical distribution supply  
27 chain and requires trading partners to pass, receive, and maintain certain product and distribution  
28 information. The DSCSA also requires FDA to establish Federal standards for licensing of  
29 wholesale drug distributors and third party logistics providers; the Agency is currently drafting  
30 these regulations. Section 585 sets forth a uniform national policy preempting States<sup>3</sup> from  
31 establishing or continuing in effect certain standards and requirements.

32 FDA is issuing this guidance to (1) help industry and States understand the immediate effects of  
33 the law and (2) clarify section 585's effect on State product tracing and standards and  
34 requirements for wholesale distributor and third-party logistics provider (3PL) licensing.  
35

36 FDA's guidance documents, including this guidance, do not establish legally enforceable  
37 responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should

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<sup>1</sup> This guidance has been prepared by the Office of Compliance in the Center for Drug Evaluation and Research (CDER) in cooperation with the Center for Biologics Evaluation and Research (CBER) and the Office of Regulatory Affairs (ORA) at the Food and Drug Administration.

<sup>2</sup> For brevity, in this guidance, references to section 585 of the FD&C Act are cited as section 585.

<sup>3</sup> Section 585 uses the phrase "State and political subdivision of a State." For purposes of this document, the word *States* will mean States and political subdivisions of States.

*Contains Nonbinding Recommendations*

*Draft — Not for Implementation*

38 be viewed only as recommendations, unless specific regulatory or statutory requirements are  
39 cited. The use of the word *should* in Agency guidances means that something is suggested or  
40 recommended, but not required.  
41

42 **II. BACKGROUND**  
43

44 On November 27, 2013, the DSCSA (Title II of Public Law 113-54) was signed into law. The  
45 DSCSA outlines critical steps to build an electronic, interoperable system to identify and trace  
46 certain prescription drugs as they are distributed in the United States. The DSCSA adds sections  
47 581 through 585 as Subchapter H of the FD&C Act. These sections establish definitions (section  
48 581), requirements for supply chain participants (section 582), standards for and licensing of  
49 wholesale drug distributors (section 583) and third-party logistics providers (section 584), and a  
50 Uniform National Policy (section 585).  
51

52 Section 585, as added by section 205 of the DQSA, states:  
53

54 (a) **PRODUCT TRACING AND OTHER REQUIREMENTS.**—Beginning on  
55 the date of enactment of the Drug Supply Chain Security Act, no State or political  
56 subdivision of a State may establish or continue in effect any requirements for tracing  
57 products through the distribution system (including any requirements with respect to  
58 statements of distribution history, transaction history, transaction information, or  
59 transaction statement of a product as such product changes ownership in the supply chain,  
60 or verification, investigation, disposition, notification, or recordkeeping relating to such  
61 systems, including paper or electronic pedigree systems or for tracking and tracing drugs  
62 throughout the distribution system) which are inconsistent with, more stringent than, or in  
63 addition to, any requirements applicable under section 503(e) (as amended by such Act)  
64 or this subchapter (or regulations issued thereunder), or which are inconsistent with—  
65

- 66 (1) any waiver, exception, or exemption pursuant to section 581 or 582; or  
(2) any restrictions specified in section 582.

67 (b) **Wholesale Distributor and Third-Party Logistics Provider Standards—**

68 (1) **IN GENERAL.**—Beginning on the date of enactment of the Drug Supply  
69 Chain Security Act, no State or political subdivision of a State may establish or continue  
70 any standards, requirements, or regulations with respect to wholesale prescription drug  
71 distributor or third-party logistics provider licensure that are inconsistent with, less  
72 stringent than, directly related to, or covered by the standards and requirements  
73 applicable under section 503(e) (as amended by such Act), in the case of a wholesale  
74 distributor, or section 584, in the case of a third-party logistics provider.

75 (2) **State Regulation of Third-Party Logistics Providers.**—No State shall  
76 regulate third-party logistics providers as wholesale distributors.  
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**III. QUESTIONS AND ANSWERS**

**A. Product Tracing**

**1. How does section 585(a) affect State tracing requirements?**

Beginning on November 27, 2013, the date of enactment of the DSCSA, States were preempted from establishing or continuing in effect any requirements for tracing prescription drugs through the pharmaceutical distribution supply chain that are inconsistent with, more stringent than, or in addition to any requirements applicable under section 503(e) of the FD&C Act (21 U.S.C. 353(e) (as amended by the DSCSA)) or Subchapter H (added by the DSCSA) or regulations issued thereunder.

Section 585 enumerates the types of requirements that States are preempted from establishing or continuing in effect in any manner that is inconsistent with, more stringent than, or in addition to Federal law, including: statements of distribution history, transaction history, transaction information, or transaction statement of a product as the product changes ownership in the supply chain, verification, investigation, disposition, notification, or recordkeeping relating to the distribution systems, including paper or electronic pedigree systems or for tracking and tracing drugs throughout the distribution system.

In addition, no State may establish, continue in effect, or apply any requirement that is inconsistent with any waiver, exception, or exemption granted by FDA pursuant to sections 581 or 582 of the FD&C Act or any restrictions specified in section 582.

**2. What product tracing requirements apply before January 1, 2015?**

Prior to January 1, 2015, the Federal pedigree requirements of section 503(e)(1) of the FD&C Act, remain in effect. Therefore, until January 1, 2015, States may not regulate tracing in any way that is inconsistent with, more stringent than, or in addition to the requirements of section 503(e)(1) of the FD&C Act.

**3. What product tracing requirements apply on or after January 1, 2015?**

Beginning January 1, 2015, the Federal tracing requirements of section 582 of the FD&C Act established under the DSCSA, go into effect. After that date, States may not regulate tracing in any way that is inconsistent with, more stringent than, or in addition to those requirements.

**4. Which State requirements are preempted?**

Any requirements for tracing drugs through the pharmaceutical distribution supply chain that are inconsistent with, more stringent than, or in addition to any requirements applicable under section 503(e) of the FD&C Act, as amended by the DSCSA, or under subchapter H (or regulations issued thereunder) are preempted.

26 **B. Wholesale Drug Distributor Standards and Licensing**

27  
128 **1. How does section 585(b) affect State wholesale drug distributor standards and**  
129 **licensing?**

130  
131 Beginning on November 27, 2013, States were preempted from establishing or continuing any  
132 standards, requirements, or regulations with respect to wholesale distributor licensure that are  
133 inconsistent with, less stringent than, directly related to, or covered by the standards<sup>4</sup> or  
134 requirements applicable under section 503(e) of the FD&C Act (as amended by the DSCSA).  
135 Thus, States may not impose standards, requirements, or regulations with respect to wholesale  
136 drug distributors that fall below the minimum standards established by Federal law.

137  
138 **2. Will States need to change their wholesale drug distributor licensing laws before the**  
139 **new Federal wholesale drug distributor regulations take effect?**

140  
141 Each State will have to analyze its own laws to determine the impact of section 585; however,  
142 FDA understands that, in general, the current Federal standards, requirements, and regulations  
143 have been the basis for most current State laws. Therefore it is likely those State laws would not  
144 fall below the minimum standards established by federal law and would not need to be changed.

145  
146 The new wholesale drug distributor regulations issued under section 583 will take effect two  
147 years after they are finalized by FDA. By that time, States should have reanalyzed their  
148 licensing laws in order to determine if those laws fall below the minimum standards established  
149 by federal law.

150  
151 **3. Can States continue to license wholesale drug distributors before the new Federal**  
152 **regulations for wholesale drug distributor standards and licensing go into effect?**

153  
154 Yes. States can continue to license wholesale drug distributors before the regulations issued  
155 according to section 583 (as added by 204 of the DSCSA) become effective, as long as the State  
156 regulations are not inconsistent with, less stringent than, directly related to, or covered by  
157 Federal law. The DSCSA contemplates that states will continue to license wholesale drug  
158 distributors before the new regulations go into effect. For example, section 503(e)(1)(A) (as  
159 amended) requires a wholesale drug distributor to be licensed by the State from which the drug is  
160 distributed or else by the Secretary of Health and Human Services if the distributing wholesale  
161 drug distributor's State chooses not to have a licensing program. In addition, the distributor must  
162 be licensed by the State into which the drug is distributed (if required by that State).

163  
164  
165 **4. What wholesale drug distributor standards and licensing requirements apply after**  
166 **the new Federal regulations go into effect?**

167  
168 When the new Federal licensure regulations of the FD&C Act become effective (see section  
169 583(a), (e)), States will be preempted from continuing or establishing licensure in any way that

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<sup>4</sup> Please refer to section 583(b) of the FD&C Act for additional information on content requirements for wholesale drug distributor licensing standards.

170 falls below the minimum standards established by those Federal regulations.<sup>5</sup> When the final  
171 regulations are published, States will know whether they need to change any standards,  
172 requirements, or regulations that they may have established that are inconsistent with, less  
173 stringent than, directly related to, or covered by those Federal regulations.  
174

175 **C. Third-Party Logistics (3PL) Provider Standards and Licensing**  
176

177 **1. How does section 585(b) affect 3PL standards and licensing?**  
178

179 Beginning on November 27, 2013, States are preempted from establishing or continuing any  
180 standards, requirements, or regulations with respect to 3PLs that are inconsistent with, less  
181 stringent than, directly related to, or covered by the standards<sup>6</sup> or requirements applicable under  
182 section 584 of the FD&C Act. Thus, States may not impose standards, requirements, or  
183 regulations with respect to 3PLs that fall below the minimum standards established by Federal  
184 law.  
185

186 **2. Can States license 3PLs before the new Federal regulations for 3PL standards and**  
187 **licensing go into effect?**  
188

189 Yes. States can license 3PLs before the new Federal regulations issued according to section 584  
190 become effective. The DSCSA contemplates that States can license 3PLs before the new Federal  
191 regulations become effective. For example, section 584(b) of the FD&C Act requires 3PLs to  
192 report “the State by which the facility is licensed” beginning 1 year after the date of enactment of  
193 the DSCSA.  
194

195 **3. What 3PL standards and licensing requirements apply after Federal regulations go**  
196 **into effect?**  
197

198  
199 Once the new Federal licensing regulations for 3PLs become effective (see section 584(d)),  
200 States will be preempted from continuing or establishing licensure in any way that falls below  
201 the minimum standards established by those regulations.<sup>7</sup> When the final regulations are  
202 published, States will know whether they need to change any standards, requirements, or  
203 regulations that they may have established that are inconsistent with, less stringent than, directly  
204 related to, or covered by those Federal regulations.  
205

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<sup>5</sup> The licensing regulations for wholesale drug distributors are to be issued not later than 2 years after the date of enactment of the Drug Supply Chain Security Act (section 583(a)); the final regulation will take effect “2 years after the date that such final regulation is published” (section 583(e)(3)).

<sup>6</sup> Please refer to section 584(d)(2)(C) – (H) of the FD&C Act for additional information on content requirements for third-party logistics provider licensing standards.

<sup>7</sup> The licensing regulations for 3PLs are to be issued not later than 2 years after the date of enactment of the Drug Supply Chain Security Act (section 584(d)(1)); the final regulation will take effect “1 year after the date that such final regulation is issued” (section 584(d)(3)(C)).

06  
07  
08  
**4. Can States license 3PLs using their licensing program for wholesale drug distributors?**

209 Section 585(b)(2) does not permit states to license 3PLs as wholesale drug distributors. States  
210 would need to establish separate licensing programs for wholesale drug distributors and 3PLs.  
211

**U.S. Food and Drug Administration**  
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## Registered Outsourcing Facilities

Facilities Registered As Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act)

Updated as of 12/19/14

[Information Concerning Outsourcing Facility Registration \(/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm389118.htm\)](#)

This table lists the outsourcing facilities that have submitted registration information that has been determined to be complete by the data lock date for the latest weekly update of the table.

Facility Name	Initial Date of Registration as an Outsourcing Facility <sup>1</sup>	Date of Most Recent Registration as an Outsourcing Facility <sup>1</sup>	End Date of Last FDA Inspection Related to Compounding <sup>2</sup>	Was a Form FDA-483 issued? <sup>3</sup>
Absolute Pharmacy, Lutz, FL	9/3/2014	9/3/2014	11/19/2014	Yes
Advanced Pharma, Inc., Houston, TX	1/22/2014	12/1/2014	3/17/2014	Yes ( <a href="#">/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElec</a> )
Alexander Infusion LLC dba Avanti Health Care, New Hyde Park, NY	4/21/2014	4/21/2014	7/9/2014	Yes ( <a href="#">/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElec</a> )
ALK-Abelló, Inc., Port Washington, NY	6/3/2014	6/3/2014	2/25/2014	Yes
W HOL 68				
Allergy Laboratories, Inc., Oklahoma City, OK	12/30/2013	12/30/2013	4/26/2013	Yes ( <a href="#">/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElec</a> )
W HOL 1178				
Amerilab LLC, Edmond, OK	5/23/2014	5/23/2014	Not yet inspected	N/A
AnazaoHealth Corporation, Las Vegas, NV	9/23/2014	9/23/2014	Not yet inspected	N/A
W HOL 1101				
Avella of Deer Valley, Phoenix, AZ	2/24/2014	2/24/2014	2/25/2013	Yes ( <a href="#">/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElec</a> )
Banner Health, Chandler, AZ	12/26/2013	12/26/2013	3/5/2014 (incomplete)	No
California Pharmacy and Compounding Center, Newport Beach, CA	4/30/2014	12/1/2014	8/25/2014; 10/17/2014	Yes (8/25/2014 ( <a href="#">/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/OI</a> and (10/17/2014)
W HOL 1425				
Cantrell Drug Company, Litte Rock, AR	12/16/2013	12/16/2013	11/4/2013	Yes ( <a href="#">/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElec</a> )
W HOL 1299				
Central Admixture Pharmacy Services, Inc., Allentown, PA	2/28/2014	2/28/2013	6/11/2014	Yes ( <a href="#">/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElec</a> )
W HOL 1268				
Central Admixture Pharmacy Services, Inc., San Diego, CA	6/4/2014	6/4/2014	8/8/2014	Yes ( <a href="#">/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElec</a> )
Complete Pharmacy and Medical Solutions, Miami Lakes, FL	6/6/2014	6/6/2014	8/12/2014	Yes ( <a href="#">/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElec</a> )
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Delta Pharma, Inc., Ripley, MS	8/6/2014	8/6/2014	10/2/2013	Yes ( <a href="#">/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElec</a> )

Edge Pharmacy Services LLC, Colchester, VT	1/21/2014	1/21/2014	8/20/2014	Yes
Essential Pharmacy Compounding Division of Kohl's Pharmacy, Omaha, NE	7/17/2014	7/17/2014	Not yet inspected	N/A
Exela Pharma Sciences, LLC., Lenoir, NC	6/6/2014	6/6/2014	11/21/2014	Yes (/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElec
Greer Laboratories, Inc., Lenoir, NC	2/24/2014	2/24/2014	11/15/2013	Yes (/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElec
Healix Infusion Therapy, Inc., Sugar Land, TX	2/12/2014	12/1/2014	5/16/2014	Yes (/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElec
Infusion Options Inc., Brooklyn, NY	1/24/2014	1/24/2014	4/23/2014	Yes (/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElec
Institutional Pharmacy Solutions, LLC, Virginia Beach, VA	3/4/2014	3/4/2014	Not yet inspected	N/A
Institutional Pharmacy Solutions, LLC, Irwindale, CA	3/6/2014	3/6/2014	6/20/2014	No
IV Specialty Ltd, Austin, TX	2/26/2014	2/26/2014	7/22/2014	Yes (/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElec
JCB Laboratories, North Wichita, KS	1/21/2014	12/1/2014	2/27/2013	Yes (/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElec
Jubilant HollisterStier LLC, Spokane, WA	6/3/2014	6/3/2014	4/15/2014	Yes
Kings Park Slope, Inc., Brooklyn, NY	12/23/2013	12/23/2013	3/14/2014	Yes (/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElec
KRS Global Biotechnology, Inc., Boca Raton, FL	12/15/2013	12/15/2013	3/17/2014	Yes (/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElec
LEESAR INC, Fort Myers, FL	4/30/2014	4/30/2014	8/8/2014	Yes (/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElec
Leiter's Compounding, (Great Oaks Blvd), San Jose, CA	1/31/2014	1/31/2014	10/7/2014	Yes
Lowlite Investments, Inc. dba Olympia Pharmacy, Orlando, FL	3/17/2014	3/17/2014	3/21/2013	Yes (/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElec
Medistat RX, LLC, Foley, AL	12/1/2014	12/1/2014	9/18/2014	Yes
Medi-Fare Drug & Home Health Center, Inc., Blacksburg SC	12/17/2013	12/17/2013	9/12/2014	Yes (/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElec
Nephron Sterile Compounding Center, LLC (NSCC), West Columbia, SC	7/15/2014	7/15/2014	Not yet inspected	N/A
OPS International, Inc. dba Olympia Pharmacy, Orlando, FL	3/10/2014	3/10/2014	12/4/2014	Yes

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Pharm D Solutions dba PDS Compounding, West Houston, TX	8/6/2014	8/6/2014	Not yet inspected	N/A
Pharmaceutic Labs, LLC, Albany, NY	3/10/2014	3/10/2014	Not yet inspected	N/A
Pharmagen Laboratories Inc., Stamford, CT	1/21/2014	1/21/2014	8/23/2013	Yes (/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORAO
Pharmakon Pharmaceuticals, Noblesville, IN	1/23/2014	12/5/2014	3/13/2014; 4/8/2014	Yes (3/13/2014 (/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORAOI (4/8/2014 (/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORAO
Pharmalogic CSP Inc., Bridgeport, WV	7/1/2014	7/1/2014	Not yet inspected	N/A
PharMedium Services, LLC, Cleveland, MS	12/11/2013	12/1/2014	2/22/2013	Yes (http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy
PharMedium Services, LLC, Edison, NJ	12/11/2013	12/1/2014	2/28/2013	Yes (http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy
PharMedium Services, LLC, Memphis, TN	12/11/2013	12/1/2014	3/22/2013	Yes (http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy
PharMedium Services, LLC, Sugar Land, TX	12/11/2013	12/1/2014	2/27/2013	Yes (http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy
Pine Pharmaceuticals, LLC, Tonawanda, NY	6/17/2014	6/17/2014	10/16/2014	No
Premier Pharmacy Labs Inc., Weeki Wachee, FL	4/16/2014	12/29/2014	5/9/2014	Yes (/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORAO
Professional Pharmacy & Compounding Services LLC, Miami, FL	6/13/2014	6/13/2014	Not yet inspected	N/A
RC Compounding Services LLC, Poland, OH	2/12/2014	2/12/2014	2/7/2013	Yes (/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORAOElec
Region Care, Inc., Great Neck, NY	12/24/2013	12/24/2013	3/20/2014	Yes (/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORAOElec
SCA Pharmaceuticals, Little Rock, AR	12/13/2013	12/13/2013	4/1/2014	Yes (/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORAOElec
SSM St. Clare Health Center, Fenton, MO	2/18/2014	2/18/2014	8/14/2014	Yes (/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORAOElec
Syenz Laboratory, LLC, Norwood, NJ	9/9/2014	9/9/2014	Not yet inspected	N/A
Texas Health Infusion, The Woodlands, TX	8/8/2014	8/8/2014	Not yet inspected	N/A
Triangle Compounding Pharmacy Inc., Cary, NC	1/24/2014	1/24/2014	9/22/2014	Yes (/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORAOElec
Unique Pharmaceuticals, Ltd., Temple TX	1/17/2014	12/2/2014	4/2/2014; 6/20/2014	Yes (4/4/2014 (/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/O 6/20/2014 (/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/O
US Compounding, Inc., Conway, AR	12/20/2013	12/20/2013	3/27/2014	Yes (/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORAOElec

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US Specialty Formulations LLC, Bethlehem, PA	1/31/2014	12/1/2014	Not yet inspected	N/A
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**Notes**

1. The "initial date of registration as an outsourcing facility" is the date the facility was first registered (i.e., the date FDA determined that the initial registration information submitted for the facility was complete, and for firms first registering on or after October 1, 2014, the establishment fee was paid in full).

Under section 503B(b) of the FD&C Act, after the initial registration, a facility that elects to continue to be registered with FDA as an outsourcing facility must re-register annually. Beginning in fiscal year (FY) 2015 (October 1, 2014 to September 30, 2015), a facility that elects to register (or re-register) with FDA as an outsourcing facility must pay an annual establishment fee. The "date of most recent registration as an outsourcing facility" reflects the date FDA determined the most recently submitted registration information was complete and the annual establishment fee for that fiscal year paid in full.

Unless a previously registered outsourcing facility re-registers and pays the annual establishment fee in full during the registration period (between October 1 and December 31 of each calendar year), the facility will be removed from the list of registered outsourcing facilities on January 1 of the next calendar year.

2. Inspections identified in this table are associated with the facility at the listed address. A company may own or operate more than one registered outsourcing facility. FDA's web page [Compounding: Inspections, Recalls, and Other Actions \(Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm339771.htm\)](http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm339771.htm) may contain information about compounding facilities under the same ownership as the listed registered outsourcing facility.

Inspections may take place over several days, weeks, or longer. The date of the inspection is the date a Form FDA-483 listing the investigators' observations was issued. If no FDA Form-483 was issued, the date is the last day of the inspection.

3. A Form FDA-483 is issued when investigators observe any significant objectionable conditions. It does not constitute a final Agency determination of whether any condition is in violation of the FD&C Act or any relevant regulations.

4. This table reflects only FDA actions. It does not include State Board of Pharmacy actions, if any. To determine whether a registered outsourcing facility has been the subject of a State enforcement action, check with the State Board of Pharmacy for the state in which the facility is located. Some states post disciplinary or other actions on their web sites. For more information, please see [Compounding: Inspections, Recalls, and other Actions \(Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm339771.htm\)](http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm339771.htm).

5. "Closed" means the inspection has been closed without further action. "Open" means that FDA has not made a determination as to whether further action will be taken. If an action has been taken, it will be listed. Possible FDA actions include: warning letter; seizure; or injunction.

6. The information in this column was provided by the registered outsourcing facility at the time of registration and has not been verified by FDA. "N/A", indicates the registered outsourcing facility has not provided this information. In the future, FDA intends to provide information about whether the outsourcing facility also intends to compound nonsterile drugs from bulk drug substances. That information is not currently available to the Agency.

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