116th Annual Convention

Date: Saturday, October 18, 2014
Time: 10:30 am – 12:00 pm
Location: Austin Convention Center, Room 19AB, Level 4

Title: Understanding the Drug Quality and Security Act: New Requirements Effective 2015
ACPE # 207-000-14-207-L03-P · 0.15 CEUs
ACPE # 207-000-14-207-L03-T

Activity Type: Application-based
Speaker: Susan Pilch, Vice President of Policy and Regulatory Affairs, NCPA

Pharmacist and Pharmacy Technician Learning Objectives:
Upon completion of this activity, participants will be able to:
1. Summarize the Requirements of this new law effective in 2015.
2. Describe action items and necessary changes to your inventory control and documentation of drug products.
3. Describe areas of possible collaboration with your wholesaler for compliance.
4. Discuss areas of collaboration/dialogue with your network software vendor for compliance.

Disclosures:
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Susan Pilch, VP, NCPA Policy and Regulatory Affairs
Martha Russell, Asst. Genl. Counsel, Cardinal Health

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Martha Russell declares no conflicts of interest or financial interest in any product or service mentioned in this program, including grants, employment, gifts, stock holdings, and honoraria.

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Drug Quality and Security Act

- The Drug Quality and Security Act was signed by the President on November 27, 2013.
- Contains two main “titles”:
  - Title I Drug Compounding: establishes national standards for compounding pharmaceuticals (not discussed here).
  - Title II Drug Supply Chain Security Act (DSCSA): establishes a national system for tracing pharmaceutical products through the supply chain, sets national licensing standards for wholesale distributors and third-party logistics providers, and preempts existing state licensing and pedigree requirements.

Critical Background: What Prompted Federal Supply Chain Legislation??

- Each link the chain would have to “scan” each item to capture transaction data
- With each successive distribution—the e-pedigree would have to be updated—and would grow exponentially and pharmacies would have to maintain massive amounts of data
- Cost of compliance for small pharmacy = Extremely High

Background Continued......

- FDA Statements that the CA law would serve as a national “template”
- Long-standing FDA interest in this issue; first proposed in 2007
- Estimates that cost of compliance with California-type of system would have cost $100,000 per individual pharmacy in first year alone....
Drug Supply Chain Security Overview: 3 parts

1. **Traceability**: Establishes a two phased national system for tracing pharmaceutical products through the supply chain.

2. **Licensing**: Establishes uniform national licensing standards for wholesale distributors and third-party logistics providers.

3. **Preemption**: Immediately preempts all state laws and regulations for tracing products through the supply chain (i.e., pedigree requirements) AND state laws and regulations regarding wholesale distributor and 3PL licensure.

DSCSA Part 1 of 3 – Traceability

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DSCSA Part 1 of 3 – SCOPE

**Definition of “Products”**

- **The traceability requirements in Phase 1 and 2 apply to PRODUCTS.**
  - Products = prescription drugs in finished dosage form that are for human use.
  - no OTC, medical devices, API, or drugs indicated for animal use
- A number of prescription drugs are exempted from the definition of product, including:
  - Blood and blood components intended for transfusion
  - Radioactive drugs and radioactive biologics
  - Imaging drugs
  - Intravenous products
  - Medical gases
  - Homeopathic drugs
  - Compounded drugs
DSCSA Part 1 of 3 – SCOPE
Definition of “Transaction”

• The traceability requirements in Phase 1 and 2 apply to TRANSACTIONS.
  -- Transaction = changes in ownership.
  -- No 3PL involvement
• A number of transfers are exempted from the definition of transaction, including:
  -- Transfer of a product from one pharmacy to another (regardless of whether the two pharmacies are affiliated in any way) to fill a prescription for an identified patient.
  -- Distribution of minimal quantities of products by a licensed retail pharmacy to a licensed practitioner for office use*****
  -- Distribution of a product pursuant to a sale or merger of a pharmacy or WD
  -- Distribution of combination products (device + drug/device/biologic)
  -- Distribution for emergency medical reasons

DSCSA Part 1 of 3 – Traceability
A 2 phased approach

Part 1: Traceability
Establishes a two phased national system for tracing pharmaceutical products through the supply chain
  a) Phase 1: Product tracing – supply chain partners pass transactional data to subsequent purchasers (data exchange occurs with change of ownership only).
  b) Phase 2: Product identifier – supply chain partners trace product identifiers thru the supply chain.

DSCSA Part 1 of 3 – Traceability
Phase 1 of 2: Product Tracing

Phase 1
• Starting January 1, 2015:
  -- manufacturers are required to pass transaction data to subsequent purchasers.
  -- repackagers and wholesale distributors will be required to receive transaction data from manufacturers and pass transaction data to subsequent purchasers
• July 1, 2015: dispensers are required to receive transaction data and pass transaction data if they further distribute
DSCSA Part 1 of 3 – Traceability

Phase 1 of 2: Product Tracing

• What is “transaction data” that must be passed, received, and maintained by supply chain participants?

  Three items:
  • transaction information
  • transaction history
  • transaction statement
  – These include information about the product and transaction (Ti), the seller’s compliance (Ts), and the subsequent owners & transactions (Th).

Storing/Accessing Transaction Data

• The law allows a dispenser to have a third party (wholesale distributor) maintain the transaction data required to be captured and stored by the pharmacy.

• Law does not require the wholesaler to do this on behalf of a pharmacy and will require a written agreement between pharmacy and wholesaler(s).

• Some wholesalers to create web portal system for dispensers to access relevant information.

• Please note difference between access to information and storage of information.

DSCSA Part 1 of 3 – Traceability

Phase 2 of 2: Product Identifiers

• Phase 2
  – 10 years after enactment (November 2023), supply chain stakeholders will be required to electronically track product at the individual package level using the product identifier.
  • Product identifier: A product identifier is a standardized graphic that carries the product’s standardized numerical identifier, lot number, and expiration date in both human and machine readable format.
  – Unless FDA allows the use of other technologies, a 2D barcode shall be used for the package and case.
  – Data shall be exchanged in a secure, interoperable, electronic manner.
  – A series of assessments, public meetings, and at least one pilot program will be conducted to develop the precise requirements for, and ensure the technological feasibility of, Phase 2.
Phase II and Independent Community Pharmacy

• NCPA was able to secure significant protections for small dispensers (25 or fewer FTE) in Phase II

• Before any Phase II requirements can go into effect, HHS Secretary has to contract with a "private independent consulting firm with expertise to conduct a technology and software assessment that examines the feasibility of small dispensers conducting interoperable, electronic tracing of products at the package level. The consulting firm must agree to consult with small dispensers

• The assessment shall examine whether hardware/software is readily accessible and can be integrated into existing business practices and is not prohibitively expensive

• The Secretary shall prescribe alternative methods of compliance for small businesses to comply and a waiver process

DSCSA Part 1 of 3 – Traceability

Timeline

• Enactment (Day 1) to December 31, 2014: pedigree requirements as they exist today in the PDMA
  – Manufacturers and ADRs exempt from providing pedigrees
  – ADR: Authorized Distributor of Record

• January 1, 2015: manufacturers pass transaction data to subsequent purchasers. Repackagers and wholesale distributors required to receive transaction data from manufacturers and pass transaction data to subsequent purchasers.

• July 1, 2015: dispensers are required to receive transaction data and pass transaction data if they further distribute

DSCSA Part 1 of 3 – Traceability

Timeline continued...

• 2017: Four years after enactment, we are still in Phase 1, but the framework for Phase 2 begins. Manufacturers must affix a product identifier to each individual package and homogenous case.

• 2018: Beginning five years after enactment, repackagers must affix a product identifier to each individual package and homogenous case.

• 2019: Beginning six years after enactment, wholesale distributors must only accept products that contain the required product identifier; and verify product identifier before redistributing returned products.

• 2020: Beginning seven years after enactment, dispensers must only accept products that contain the required product identifier.
DSCSA Part 2 of 3 – Licensing

1. Traceability: Establishes a two phased national system for tracing pharmaceutical products through the supply chain.

2. Licensing: Establishes uniform national licensing standards for wholesale distributors and third-party logistics providers.

3. Preemption: Immediately preempts all state laws and regulations for tracing products through the supply chain (i.e., pedigree requirements) AND state laws and regulations regarding wholesale distributor and 3PL licensure.

DSCSA Part 2 of 3 – Licensing

• The Act sets out seven broad categories of licensing standards for wholesale distributors and for 3PLs.
  – Storage and handling, maintenance of records, bond, background checks, physical inspections.
  – November 2015: FDA will issue regulations to further define those standards.
  – Regulations will be FINAL by November 2015 and EFFECTIVE November 2017.
  • This gives states two years (November 2015 to November 2017) to revise their wholesale distribution and licensing requirements to match FDA's.
DSCSA Part 2 of 3 – Licensing

• States will continue to license wholesale distributors and 3PLs, but they will be required to do so utilizing the federal standards that FDA establishes.
• In the absence of a home state licensing program that satisfies the federal requirements, a federal licensing program will be established to license wholesale distributors and 3PLs.
• DSCSA does not discuss a state’s licensing of manufacturers or repackers (just says that they are not to be considered wholesale distributors).

DSCSA Part 3 of 3 – Preemption

1. Traceability: Establishes a two phased national system for tracing pharmaceutical products through the supply chain.

2. Licensing: Establishes uniform national licensing standards for wholesale distributors and third-party logistics providers.

3. Preemption: Immediately preempts all state laws and regulations for tracing products through the supply chain (i.e., pedigree requirements); preempts state laws and regulations regarding wholesale distributor and 3PL licensure in 2017.
Pedigree preemption: As of November 2013, eighteen states had state prescription drug pedigree requirements in effect. Immediately upon enactment, the DSCSA preempted all state pedigree laws and we were left with one standard federal solution.

**DSCSA Part 3 - Preemption**

- Licensing Preemption:
  - The Act also preempts state laws and regulations regarding wholesale distributor and 3PL licensure that are inconsistent with the standards established by the Act.
  - FDA will finalize these licensing standards in 2015 and they will be effective 2017.
  - States may continue to regulate wholesale distributors and 3PLs in areas that are not covered by the licensing standards in the Act.

**DSCSA Preparation**

- FDA Guidance
- State activity:
  - Florida
  - Oklahoma
  - Idaho
  - Oregon
  - New Mexico
- Cardinal Health is currently in the development stage for our proposed solutions for January 1, 2015 compliance.
  - web portal which will be utilized to provide transactional data to our downstream customers
Need to Know for Independent Community Pharmacy

- Requirements for receiving information/storage effective July 1, 2015
- Need to dialogue with wholesaler(s)—both primary and secondary about capabilities to assist pharmacy in accessing and storing information and your current technology vendor
- FDA Emphasis on Pharmacists “Knowing their Sources”
- Forthcoming FDA Guidance on “Treatment of Suspect Product”

Questions and Answers

Thank you!

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