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PREPARING FOR THE NOVEMBER 2023

DRUG SUPPLY CHAIN AND SECURITY ACT REQUIREMENTS

Objective: Provide direction to pharmacists on preparing to meet the compliance standards of the Drug Supply Chain and Security Act (DSCSA), which is scheduled to take full effect by Nov. 27, 2023.

DSCSA Overview:

The DSCSA, Title II of the Drug Quality and Security Act (DQSA) enacted by the United States Congress on Nov. 27, 2013, sets forth requirements for trading partners (i.e., manufacturers, wholesale distributors, repackagers, dispensers, and third-party logistics providers) regarding the tracing of prescription pharmaceutical products during distribution throughout the United States.[1] These interoperable, electronic tracing systems will allow the Food and Drug Administration (FDA) to protect U.S. consumers by readily identifying compromised prescription pharmaceutical products, including those that may be counterfeit, stolen, contaminated, dangerous, or harmful, and removing them from the pharmaceutical supply chain. In addition, the DSCSA will require wholesale distributors and third-party logistics providers to obtain national licensure and report licensure status to the FDA annually.[2]

What are the Responsibilities of Pharmacists ("Dispensers") Under DSCSA?

The DSCSA defines a dispenser as "a retail pharmacy, hospital pharmacy, a group of chain pharmacies under common ownership and control that do not act as a wholesale distributor, or any other person authorized by law to dispense or administer prescription drugs, and the affiliated warehouses or distribution centers of such entities under common ownership and control that do not act as a wholesale distributor and does not include a person who dispenses only products to be used in animals in accordance with section 512(a)(5)."[3]

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Current Responsibility Overview:

The key responsibilities of pharmacists in 2022 under DSCSA are:[4,5] As of the end of 2022, pharmacists must ensure most products are traceable at the lot-level and the following key responsibilities are met:

1. Engage in business only with licensed, registered trading partners:
   a. Manufacturers and repackagers are required to have a current registration
   b. Wholesale distributors and third-party logistics providers are required to be licensed
2. Properly manage product tracing documentation:
   a. Only accept prescription pharmaceutical products if they arrive with the transaction history (TH),* transaction information (TI), and transaction statements (TS)
   b. All product tracing information must be kept in a secure format for six years
   c. When selling prescription pharmaceutical products to a trading partner, include most product tracing information with the transaction

*As of Nov. 23, 2023, the TH requirement expires and has "no force or effect."[6]

3. Implement a system and process to properly manage suspect and illegitimate prescription pharmaceutical products
   a. Quarantine any suspect prescription pharmaceutical product(s)
   b. Collaborate with the manufacturer of suspect or illegitimate prescription pharmaceutical product(s) to ensure patients do not receive the illegitimate product(s)
   c. Report findings of illegitimate prescription pharmaceutical product(s) to the FDA and involved trading partners

New Responsibilities for 2023:

By 2023, pharmacists should ensure that their organization has policies and procedures in place that allow for unit-level traceability under DSCSA, including:[3,5]

1. Ensuring that all required TI and TS are exchanged between trading partners via a secure, interoperable, electronic system
2. Checking for inclusion of a package identifier (PI) to identify the prescription pharmaceutical product at the package level
3. Verifying the product identifier on a package or sealed case by the trading partners via a secure, interoperable, electronic system is available
4. Ensuring that trading partners can provide TI and TS via a secure, interoperable, electronic system when requested by authorized agents
5. Ensuring that secure, interoperable, electronic systems allow for the prompt production of TI for each transaction going back to the manufacturer
6. Addressing saleable returns by ensuring that secure, interoperable, electronic systems are in place and the TI and TS are returned with the product

Advice to Practitioners

Key Considerations for DSCSA Compliance

1. Educate staff regarding DSCSA requirements
2. Purchase prescription pharmaceutical products only from verified primary wholesale distributors or manufacturers
3. Develop organizational policies and procedures for addressing DSCSA dispenser requirements, including:
   a. Ensuring most received prescription pharmaceutical product shipments contain tracing information (TI and TS)
   b. Verifying product appearance of prescription pharmaceutical products when they arrive on site, to include attention to proper spelling/labeling, terminology, lot number, and expiration date, checking for holograms or other indicia of legitimacy
   c. Managing suspect and illegitimate prescription pharmaceutical products, including a quarantine process
   d. Reporting suspect or illegitimate product to the FDA and responding to an FDA inquiry within 48 hours of receipt
   e. Ensuring transaction data is being safely stored
4. Establish clear expectations for vendors regarding DSCSA compliance

Five things to discuss with your partner(s):

1. Does your wholesale distributor transact serialized product?
2. How are you preparing for DSCSA 2023 compliance?
3. Are you prepared for full prescription pharmaceutical product traceability in a secure, electronic, interoperable manner?
4. What will you expect from dispensers in 2023?
5. Determine which of your key vendors have this on their radar (inventory vendor, EMR vendor, tracing data vendor, etc.)

Three things you should be doing now to prepare for DSCSA 2023:

1. Identifying a team to be charged with 2023 compliance preparedness. Team members may include members from Pharmacy, IT, Compliance, and Legal
2. Assessing technology needs
3. Revisiting compliance with current standards to determine where you are positioned for 2023

In Summary:

By Nov. 23, 2023:

1. Policies and procedures must be in place to allow for unit-level traceability (i.e., product identification) of most prescription pharmaceutical products
2. All communications between trading partners, authorities, and dispensers must be conducted via a secure, interoperable, electronic system

References:

1. **ASHP Impact of the Drug Supply Chain Security Act on Pharmacy Management 2015 to 2023:** https://www.ashp.org/-/media/assets/practice-management/docs/sppm-dsc-dscsa-ashp-resource-paper.ashx?la=en
2. **FDA Drug Supply Chain Security Act (DSCSA):** https://www.fda.gov/drugs/drug-supply-chain-integrity/drug-supply-chain-security-act-dscsa
3. **FDA Title II of the Drug Quality and Security Act:** https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/title-ii-drug-quality-and-security-act
4. **FDA Pharmacists: Utilize DSCSA Requirements to Protect Your Patients:** https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/pharmacists-utilize-dscsa-requirements-protect-your-patients
5. **NABP How Pharmacies Can Prep Now for the 2023 DSCSA Requirements:** https://nabp.pharmacy/news/blog/how-pharmacies-can-prep-now-for-the-2023-dscsa-requirements/
6. **HDA Enhanced Drug Distribution Security Traceability in 2023 and Beyond Position Statement:** https://www.hda.org/~/media/pdfs/government-affairs/position-statements/2020-09-29-enhanced-rx-distribution-traceability-in-2023-position-statement.ashx?la=en

Additional Resources

1. **ASHP Drug Supply Chain Resource:** https://www.ashp.org/dscsa?loginreturnUrl=SSOCheckOnly
2. **Drug Supply Chain Security Act:** https://www.govinfo.gov/content/pkg/PLAW-113publ54/pdf/PLAW-113publ54.pdf
3. **Drug Supply Chain Security Act Law and Policies:** https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/drug-supply-chain-security-act-law-and-policies
4. **Drug Supply Chain Security Act Product Tracing Requirements Frequently Asked Questions:** https://ww.fda.gove/drug-supply-chain-security-act-dscsa/drug-supply-chain-security-act-product-tracing-requirements-frequently-asked-questions
5. **Decision Tree Graphic: Should this Drug Package or Case Have a Product Identifier Under the DSCSA?:** https://www.fda.gov/media/116363/download
6. **Verify Wholesale Drug Distributor Licenses:** https://www.fda.gov/drugs/drug-supply-chain-integrity/verify-wholesale-drug-distributor-licenses
7. **DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs Guidance for Industry:** https://www.fda.gov/regulatory-information/search-fda-guidance-documents/dscsa-standards-interoperable-exchange-information-tracing-certain-human-finished-prescription-drugs
8. **Identifying Trading Partners Under the Drug Supply Chain Security Act:** https://www.fda.gov/regulatory-information/search-fda-guidance-documents/identifying-trading-partners-under-drug-supply-chain-security-act
9. **Exemption and Exclusion From Certain Requirements of the Drug Supply Chain Security Act for the Distribution of FDA-Approved Naloxone Products During the Opioid Public Health Emergency Guidance for Industry:** https://www.fda.gov/regulatory-information/search-fda-guidance-documents/exemption-and-exclusion-certain-requirements-drug-supply-chain-security-act-distribution-fda
10. Enhanced Drug Distribution Security in 2023 Under the DSCSA - YouTube
11. **FDA Drug Supply Chain Security Act Implementation Plan:** http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChain SecurityAct/ucm382022.htm
12. **FDA Guidance for Industry: DSCSA Implementation: Identification of Suspect Product and Notification:** https://www.fda.gov/regulatory-information/search-fda-guidance-documents/drug-supply-chain-security-act-implementation-identification-suspect-product-and-notification
13. **FDA Guidance for Industry: DSCSA Implementation: Product Tracing Requirements – Compliance Policy:** https://www.fda.gov/regulatory-information/search-fda-guidance-documents/dscsa-implementation-product-tracing-requirements-compliance-policy
14. **FDA Website: Are you Ready for the Drug Supply Chain Security Act?:** http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChain SecurityAct/ucm427033.htm
15. **FDA Website: Know Your Source: Protecting Patients from Unsafe Drugs:** http://www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm389121.htm
16. **FDA Email Contacts:**
    DrugTrackandTrace@fda.hhs.gov
    CDERDrugSupplyChainIntegrity@fda.hhs.gov
    WDD3PLRequirements@fda.hhs.gov