POLICY (TEMPLATE)

POLICY TITLE: Drug Supply Chain Security Act Compliance (DSCSA: "Track and Trace")

PUBLICATION DATE: 7/1/15
VERSION: V.1

POLICY PURPOSES:

a. To ensure that pedigree requirements regarding drug supply transfers are protected
b. To aid trading partners in identifying a suspect pharmaceutical product
c. To initiate notifications regarding illegitimate product.

DEFINITION(S):

On November 27, 2013, the Drug Quality and Security Act (DQSA) was signed into law, and Title II of the DQSA, the Drug Supply Chain Security Act (DSCSA) sets forth new definitions and requirements related to product tracing.

Beginning in 7/1/2015, trading partners (defined as manufacturers, wholesale distributors, repackagers, and dispensers) are required to provide the subsequent purchaser with product tracing information when engaging in transactions involving certain prescription drugs. Trading partners are also required to capture the product tracing information and maintain that data for not less than six years after the transaction occurs. Trading partners are manufacturers, repackagers, wholesale distributors, or dispensers including physician offices.

A "dispenser" is defined 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).

EXCEPTION: *The dispenser requirements for product tracing and verification shall not apply to* ***licensed health care practitioners*** *authorized to prescribe or administer medication under State law or* ***other licensed individuals under the supervision or***

direction of such practitioners who dispense or administer product in the usual course of professional practice*.*

Trading partners must have systems in place that enable them, upon determining that a product in their possession or control is suspect or upon receiving a request for verification from the FDA, to quarantine suspect product and promptly conduct an investigation, in coordination with other trading partners, as applicable, to determine whether a suspect product is illegitimate.

A trading partner must wait until FDA 325 responds to the termination request before the trading partner notifies other trading partners that 326 a notification is terminated. FDA intends to respond to requests for termination within 10 327 business days of submission. In some cases, FDA may contact a trading partner to notify the 328 partner that additional time is needed to respond to the request for termination. If a trading 329 partner believes that exigent circumstances require expedited consideration of a termination 330 request (e.g., a potential drug shortage), the trading partner must describe those circumstances in 331 the termination request to FDA.

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

TRANSACTION INFORMATION (TI)—The term “transaction information” means the:
(A) proprietary or established name or names of the product;
(B) strength and dosage form of the product;
(C) National Drug Code number of the product;
(D) container size;
(E) number of containers;
(F) lot number of the product;
(G) date of the transaction;
(H) date of the shipment, if more than 24 hours after the date of the transaction;
(I) business name and address of the person from whom ownership is being transferred; and
(J) business name and address of the person to whom ownership is being transferred.

TRANSACTION STATEMENT (TS)—The “transaction statement” is a statement, in paper or electronic form, that the entity transferring ownership in a transaction:
(A) is authorized as required under the Drug Supply Chain Security Act;
(B) received the product from a person that is authorized as required under the Drug Supply Chain Security Act;
(C) received transaction information and a transaction statement from the prior owner of the product, as required under section 582;
(D) did not knowingly ship a suspect or illegitimate product;
(E) had systems and processes in place to comply with verification requirements under section 582;
(F) did not knowingly provide false transaction information; and

(G) did not knowingly alter the transaction history.

POLICY STATEMENT: Starting January 1, 2015, section 582 of the FD&C Act requires trading partners, upon determining that a product in their possession or control is illegitimate, to notify FDA and all immediate trading partners (that they have reason to believe may have received the illegitimate product) not later than 24 hours after making the determination.

On 7/1/15, dispensers will receive TH/TI/TS and must capture information and maintain documentation for 6 years

SCOPE:

This policy applies to the following _____ Health System entities/facilities:

ATTACHMENT(S):, EXHIBIT(S):, OR APPENDIX(ES):
(Insert link to Policy, if appropriate)

REFERENCE(S):

1. Guidance for Industry Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification


Guidance for the Drug Industry.pdf

2. Drug Quality and Security Act – Overview and Implementation


DQSA - Drug Quality and Security Act Title

3. Draft Guidance for Industry DSCSA Implementation: Identification of Suspect Product and Notification

Drug Quality and Security Act - Identifi

4. Drug Supply Chain Security Act (DSCSA) – Updates and Actions for Health System Pharmacy

GAD.SPPM DSCSA_Final-1.pdf

5. Following Pharmaceutical Products Through the Supply Chain

Following-Pharmaceutical-Product Through

6. Impact of the Drug Supply Chain Security Act on Pharmacy Management: 2015 to 2023 (ASHP)

DSCSA-Compliance(ASHP)..pdf

7. DSCSA Implementation: Product Tracing Requirements — Compliance Policy Guidance for Industry

DSCSA_ Product_Tracing_Req

8. Impact of the Drug Supply Chain Security Act on Pharmacy Management: 2015 to 2023

DSCSA-Compliance(ASHP)..pdf