**Policy Name: Drug Supply Chain Security**

**Act – Title II (DSCSA)**



**Policy Number: 4270-315**

**Issuing Department: Pharmacy**

**Effective Date: 1/1/2015 (New)**

**Policy Statement:** The DSCSA outlines critical steps to build a system which will identify and trace certain prescription drugs as they are distributed within the United States. This system will enhance FDA’s ability to help protect U.S. consumers by improving detection and removal of potentially dangerous products from the pharmaceutical distribution supply chain.

Livingston HealthCare will follow procedures to procure and distribute medications according to the DSCSA Title II.

**Definitions:**

*Suspect product:* a product for which there is reason to believe it (A) is potentially counterfeit, diverted, or stolen; (B) is potentially intentionally adulterated (C) is potentially the subject of a fraudulent transaction; or (D) appears otherwise unfit for distribution.

*Illegitimate product:* a product for which credible evidence shows that it is a suspect product

*Authorized Trading Partners:*

* Manufacturers/repackagers – valid registration
* Wholesalers/3PL – valid State or Federal license
* Dispenser – valid State license

*Covered Products:* Prescription drug in finished dosage form for administration to a patient without further manufacturing

*Excluded Products*:

* Blood or blood components intended for transfusion
* Radioactive drugs or biologics
* Imaging drugs
* Certain IV products
* Medical gas
* Homeopathic drugs
* Compounded drugs

*Transaction*: Transfer of product where a change of ownership occurs

**Procedure:**

Responsibilities of dispenser (pharmacy):

1. Use only authorized trading partners
2. Assure there is Lot-level product tracing: provide transaction information, history, and statement. (beginning 7/1/2015)
3. May sign an agreement for wholesalers and distributors to electronically store this transaction information.
4. Records must be retained for 6 years.
5. Establish systems for verification and handling of suspect or illegitimate product.
   1. Upon receiving request or when a product is suspect
      1. Immediately quarantine all product
         1. remove from circulation,
         2. store securely
         3. labeled appropriately – do not use
      2. Conduct an investigation
      3. Coordinate with other trading partners if necessary
      4. Follow any other instructions provided by the FDA when notified of suspect product.
      5. Notify the FDA - if product is determined to be illegitimate <http://www.accessdata.fda.gov/scripts/cder/email/drugnotification.cfm>
      6. Follow instructions on the website and/or form.
      7. Terminate any notifications to FDA using the following site/form

<http://www.accessdata.fda.gov/scripts/cder/email/drugnotification.cfm>

1. How to identify suspect product:
   1. Appearance (product or packaging seems suspicious- missing information, foreign language on labeling, different product name)
   2. Purchased from unknown source
   3. High demand or recent shortage
   4. Unusual pricing
   5. Previously reported as counterfeit or fraudulent
2. Exchange of transaction information for any change of ownership (does not include dispensing to a patient pursuant to a prescription)
   1. May be paper or Electronic
   2. Required information
      1. Transaction Information
         1. Proprietary or established name or names of the product
         2. strength and dosage form
         3. NDC number
         4. container size
         5. number of containers
         6. lot number
         7. date of the transaction
         8. date of the shipment, if more than 24 hours after the date of the transaction
         9. Business name and address of the person from whom and to whom ownership is being transferred.
      2. Transaction History (TH): A statement in paper or electronic form, including the transaction information for each prior transaction going back to the manufacturer of the product.
      3. Transaction Statement (TS): all conditions must be met.
         1. Entity transferring ownership in a transaction is authorized as required under DSCSA
         2. Received transaction information and a transaction statement from the prior owner of the product, as required under the law
         3. Did not knowingly ship a suspect or illegitimate product
         4. Have systems and processes in place to comply with verification requirements under the law
         5. Did not knowingly provide false transaction information; and
         6. Did not knowingly alter the transaction history.

**References**:

*Office of Communications*

*Division of Drug Information, WO51, Room 2201*

*Center for Drug Evaluation and Research*

*Food and Drug Administration*

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[*http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm*](http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm)

DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs: How to Exchange Product Tracing Information Guidance for Industry. FDA, Nov 2014. Procedural