UPCOMING CHANGES FOR DSCSA/DQSA

Tuesday
October 8, 2019

STAY ENGAGED  STAY INFORMED
Kate Gainer, PharmD
Executive Vice President & CEO
Iowa Pharmacy Association
Scott Mooney
Vice President of Distribution Operations
McKesson
Iowa Pharmacists Association 2/2/2: Drug Supply Chain Security Act (DSCSA)

Scott Mooney
Vice President of Distribution Operations
DSCSA Evolution

The DSCSA path

- 3PL and wholesale distributor reporting to FDA
  - 2014–2015

- Product tracing and verification
  - Authorized trading partners
  - 2015

- Product identification (serialization)
  - 2017–2018
  - Begin affixing

- Product verification (down-to package level)
  - 2019+
  - Returns

- Dispenser Purchase Requirements
  - 2020+

- Electronic interoperable system (product tracing down-to package level)
  - 2023

Licensure standards for 3PLs and wholesale distributors

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2017/2018 was all about labeling product — NOT passing serialized data.
Product-Labeling Guidance Issued

- Manufacturers received enforcement discretion, allowing them to delay affixing new 2D bar codes until Nov. 2018
- Manufacturers and repackagers received grandfathering guidance, allowing them to continue selling serialized product (until it expires) if packaged before Nov. 2018
- FDA issued draft guidance for human-readable data on Sept. 2018

FDA reinforced that linear bar code requirements remain, and were unaffected by DSCSA.
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Licensure standards for 3PLs and wholesale distributors
New DSCSA returns requirements start Nov 27, 2019

1) Distributors must associate the original DSCSA transaction information, transaction history and transactional statement with a saleable return

This requirement remains in effect and is unaffected by the enforcement discretion from the FDA

2) Distributor must verify that the product identifier affixed to the product corresponds with the data the manufacturer assigned the product when serial is present.

Manufacturers can send serialized data for their shipments to their trading partners to be used for verification of future saleable returns

--OR--

Make serial data available for query, using a verification router service requesting data for the distributors

McKesson is evaluating how we will react to the enforcement discretion from the FDA. There are risks if we do and if we do not verify so the evaluation is presently underway.
A customer communication will be made in **May** and **August of 2019**

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**McKesson return policy:**
**March, 2015**

B. "Saleable" Merchandise is defined as Merchandise returned to McKesson meeting all of the following criteria:

a) Merchandise is resaleable by McKesson without Special handling, refurbishing or other expense;

b) Merchandise has proper dating determined as follows:

   i. For Merchandise that has been deemed permanently short-dated by McKesson or manufacturers/vendors, has dating of current month plus three (3) months remaining until expiration, or

   ii. For all other Merchandise, has dating of current month plus six (6) months remaining until expiration

c) If prescription ("Rx") Merchandise, customer has attested that each specific unit of returned Rx Merchandise was purchased from McKesson and that the conditions specified by the manufacturer/vendor for storage, protection, handling and shipping have been maintained at all times.

**Effective November 27, 2019 returned Rx Merchandise must also include the original invoice number in order to be Saleable. In compliance with the Drug Supply Chain Security Act.**
Returns Verification

Must query manufacturer when ATTP does not have data

Manufacturer

The FDA announced enforcement discretion on THIS and only this requirement for 12 months

McKesson Repository (ATTP)

If serial data exists in ATTP then responds to query

Warehouse management systems

- Serialized product that can’t be verified must be quarantined and investigated
- Initial (successful) pilot conducted in 2016; follow-up pilots are now ongoing

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Dispenser Purchase Requirements: November 2020

• DSCSA states that dispensers may only purchase product affixed with a 2D bar code after November 27, 2020

...UNLESS...

Product is subject to grandfathering or a waiver, exemption, or exception (WEE) which was granted by the FDA

Grandfathering or a WEE can be evidenced by the presence of a transaction statement (from the seller) indicating that the transaction is DSCSA compliant. (*This was documented by the FDA in its “Final Grandfathering Guidance”*)
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Serialized DSCSA Data Exchange

- Transaction History sunsets in DSCSA transaction data
  - Replaced with ability to “facilitate the gathering” of transactions
- Serial number, lot number, and expiry become mandatory as a part of DSCSA transaction data
- Method of exchanging DSCSA data with ASNs will change to EPCIS—which is better suited for serial numbers
- What’s meant by “interoperable” in the DSCSA is under significant discussion across industry
QUESTIONS?
See You Next Month!

E-PRESCRIBING

Tuesday
November 12, 2019

Questions? Contact David Schaaf at dschaaf@iarx.org or 515-270-0713