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Special FDA Update

FDA Enhanced Drug Distribution Security Update – June 2021

3 Areas of Concern for the FDA

1 **Trading Partners must be Authorized**

Including a valid state and/or federal license and complying with reporting requirements.

2 **Quarantine & Investigate Suspect Drugs**

Prevent, Detect and Respond when harmful drugs enter the supply chain

3 **Interoperable Electronic System**

Cannot use paper – entire supply chain must electronically exchange tracing information by 2023

[Click here for the full June 2021 FDA DSCSA Update.]

Verification Requirements:

All prescription drugs that seem suspect or are missing any of the 3 pieces of tracing information must be quarantined and investigated. Investigations include validating the transaction information and history, as well as, verifying lot and product identifier. Once a product is deemed illegitimate, dispensers are responsible to notify their trading partner and the FDA using Form 3911 within 48 hours. It is important to remember that a form 3911 must be filed by the dispenser no matter whether the trading partner reported it or not.

Road to Interoperability:

Compliance is a process and steps to interoperability are needed to be started now to ensure a smooth transition. By 2023, all verification will change to the package level. Furthermore, all documentation will move to electronic format only. All saleable returns will require the complete electronic tracing information to qualify for return.

New FDA Dispenser Engagement:

As of November 27, 2020, dispensers are fully engaged with all facets of securing the supply chain. The FDA is currently actively engaging dispensers to promote and achieve compliance. The fact that more pharmacies have added secondary trading partners over the past 18 months only adds to the vulnerability of the drug supply chain without the proper solution in place.

In the News

Counterfeit Drugs and Suspect products:

According to the FDA three pharmacies purchased counterfeit Janssen Symtuza. The drug is used to treat HIV. The counterfeit drug puts patients at risk of treatment failure.

Prior to the 2013 decision to create the DSCSA and many times since, articles have circulated the news about counterfeit drugs being smuggled and distributed in the U.S. These drugs lack the effectiveness and can cause adverse health risks including death. The DSCSA is designed to protect patients by protecting the supply chain.

FDA Drug Topics – June 1, 2021

Securing the Supply Chain:

According to the Department of Health, the Biden Administration is taking a hard look at securing the Pharmaceutical Supply Chain. They emphasized that shoring up the U.S. health security will require collaboration with government agencies as well as the private sector. Everyone will need to actively participate to ensure a secure supply chain and patient safety. Starting with this includes the manufacturer of medicines, active pharmaceutical ingredients and starting materials, all the way down to the dispenser.

HHS Press Release – June 8, 2021

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