

Are you ready for the Drug Quality Security Act dispenser enforcement deadline beginning Nov 1, 2015?

HCI's product tracking system has allowed us to become an industry leader in DQSA/DSCSA compliance and proprietary software related solutions. In addition we provide a range of value added services and online insight tools that can help our clients monitor order status, spot utilization trends, maintain their DQSA/DSCSA compliant repository electronically and more.

DQSA Dispenser requirements became effective on July 1st, 2015. FDA postponed enforcement of the requirements until November 1st, 2015. **Are you ready to meet these requirements?**

- Trading partners must be authorized licensed trading partners.
- Dispensers must receive transaction information, transaction history, and transaction statement from the previous owner prior to, or at the time of receipt of prescription drugs.
- Dispensers must capture transaction information (including lot level information if provided), transaction history, and transaction statements, necessary to investigate a suspect product and maintain such information, history, and statements for not less than 6 years after the transaction.
- When a dispenser transfers ownership of a product, they must provide the subsequent owner with transaction history, transaction information, and a transaction statement for the product. This requirement does not apply to sales by a dispenser to another dispenser to fulfill a specific patient need, dispensing to patients, or returns.
- A dispenser may enter into a written agreement with a third party, including an authorized wholesale distributor to maintain the transaction information, transaction history, and transaction statements required. If a dispenser enters into such an agreement, the dispenser must maintain a copy of the written agreement and shall not be relieved of the obligations of the dispenser.
- A dispenser must have systems in place to enable the dispenser to comply with the FDA requirements of suspect drugs.
- A dispenser must keep records of an investigation of a suspect product for not less than 6 years after the conclusion of an investigation.

We recognize our customers need for understanding of the law and compliance solutions. As an integral partner in the pharmaceutical supply chain we developed a robust useful tool and repository for your record requirements in an electronic format. Our goal is to provide you an opportunity to utilize our proprietary services to maintain and store your data retention requirements. With this advanced technology, you are not only compliant since January 1st, 2015 for all products purchased from HCI, but well beyond the November 2017 requirement of electronic records.

Call us today to schedule your complimentary training webinar.

Important Links:

http://www.healthcoalition.com/www/PDFs/DQSA_DSCSA_Letter.pdf

<https://www.govtrack.us/congress/bills/113/hr3204/text>