



Tracing paths to success

Distributors use traceability law to help providers enhance patient safety, supply chain integrity

In 2013, the Drug Quality and Security Act established for the first time ever a national prescription drug traceability system that enhances patient safety and supply chain integrity. Getting a national solution to replace the patchwork of competing and overlapping state pedigree laws is a significant victory for distributors, manufacturers, and patients alike.

The Food and Drug Administration (FDA) is now tasked with the responsibility of implementing and enforcing the traceability law over the next several years. Healthcare distributors are taking a proactive role to ensure a smooth rollout takes place and that customers understand and are well prepared to take advantage of this important legislation.

Snapshot

The Drug Quality and Security Act

- Provides a national uniform solution that preempts the patchwork of state pedigree laws.
- Requires pharmaceutical manufacturers to provide transaction information, transaction history, and transaction statement details to initial purchasers in a single document—paper or electronic.
- Establishes national licensure standards for pharmaceutical wholesalers that ensures uniformity in all 50 states. The bill outlines key requirements, such as background checks, physical inspections, bonding requirements, and fingerprinting.

Setting the stage

Medical surgical distributors were involved in early track and trace legislation discussions, making sure customer interests were well represented. “Distributors long recognized the need to replace inconsistent state requirements that were costly, inefficient, and left the pharmaceutical supply chain’s integrity at risk,” says Linda Rouse O’Neill, Vice President, Government Affairs, HIDA. “Politics and policy finally aligned so this issue could move forward in Congress.”

Pam Scherrer, Director of Quality Assurance and Regulatory, MMS – A Medical Supply Company, emphasizes the importance of the work distributors accomplished prior to the traceability law’s passage and the ways it will improve supply chain integrity for providers. “We worked together to streamline recommended language and provide input from medical surgical distributors’ perspectives as the law was under consideration,” says Scherrer. “Our customers were very pleased, as were we, when the track and trace law passed. The new regulations provide standardization to our industry where it’s needed most and make customer sales easier.”

Next steps

With the various forms and documents distributors used to receive from trading partners, it was sometimes difficult for providers to determine from where a prescription drug originated. Drug manufacturers are now responsible for providing comprehensive documents that include all necessary traceability information, simplifying this entire process and enhancing patient safety.

“Our Regulatory Department is already stressing to our suppliers that all necessary data and system requirements must be in place so we can receive and pass required transaction information for our customers’ benefit,” says Scherrer. Her team is focusing on three key areas with suppliers and provider customers that she thinks are essential for successful data exchange:

Information accessibility:

“Ask and verify that providers can access transaction history information in a quick and easy way.” Distributors may provide data in either a single document, or through any combination of self-generated paper, electronic portal, or supplier-provided information on the product package.

Compliance expertise:

“Manufacturers have to be 100% compliant with the new traceability law, and front line supply chain employees should be just as knowledgeable and aware of key tracing requirements and dates.” Starting January 1, 2015, suppliers must comply with applicable traceability requirements and engage with only “authorized trading partners.” (Authorized trading partners are defined in the law as having a valid license under State law or under the new federal licensure requirements when they take effect in 2017.)

Open communication:

“We’re making sure our Customer Service and Account Managers are well-equipped to handle inquiries or related questions.” Through frequent communication, first points of contact can anticipate potential customer issues before they arise. It’s also important that there are open channels for directing unanswered questions to the proper people within your organization.

Thanks to the new track and trace law, compliance knowledge has become just as important as product knowledge in supply chain transactions. Distributors have anticipated this growing trend for several years and are well prepared and well positioned to help their customers benefit from these changes.