



*Healthcare Distribution  
Management Association*

DATE: June 22, 2015  
TO: State Wholesale Drug Distributor Licensing Authorities  
FROM: HDMA State Government Affairs Department  
SUBJECT: Drug Supply Chain Security Act (DSCSA; Title II of the 2013 Drug Quality and Security Act; Public Law 113-54)

On July 1, federal requirements as stipulated by the DSCSA will go into effect for dispensers regarding exchange of transaction information, history and statements, as well as storage requirements for transaction data. HDMA and its primary pharmaceutical distributor members are reaching out to you in advance of this date to offer our assistance plus recognize the summer months may present an optimal timeframe for further engagement on DSCSA implementation.

Following passage of the DSCSA, HDMA immediately engaged supply chain stakeholders to educate and advocate for effective implementation of the legislation. While the FDA continues to craft rules that will ultimately offer further implementation guidance, HDMA wishes to offer the following interim recommendations:

- Encourage dispensers (primarily pharmacies and pharmacists) to contact and communicate with their wholesale distributors as it pertains to the July 1 deadline – each of our primary pharmaceutical distributor members are well positioned to assist with implementation;
- As you engage in implementation of DSCSA prior to further guidance from the FDA, form advisory councils or “work-groups” specific to this subject matter. As an example, in Oklahoma, under the direction of the state’s Board of Pharmacy Executive Director (John Foust), HDMA members and nearly 20 other supply chain stakeholders worked together in 2014 to develop legislation, regulations, and rules to efficiently implement DSCSA. The result, an example of reorganizing the pharmacy act into sections that mirror pertinent DSCSA definitions while creating regulatory allowances that should enable compliance with federal law, and;
- When stakeholder meetings are conducted in your state over the coming months, invite the primary pharmaceutical distributor community (i.e., HDMA) to address DSCSA implementation and compliance efforts in open forums to ensure further education on the subject matter and successful implementation.

For nearly a decade, primary pharmaceutical distributors advocated for a single, federal framework to trace prescription medicines throughout the supply chain. The previous 50-state patchwork of rules and regulations is now replaced with one federal traceability solution that will ensure regulatory clarity and

consistency, help prevent counterfeits, discourage gray market activities, and further enhance the safety and efficiency of the supply chain for all Americans.

In addition to the DSCSA traceability requirements, HDMA also supports strong, consistent distributor licensing as a critical component to ensuring that criminals do not infiltrate the supply chain and gain access to prescription medicines. These include, among others:

- Storage, handling and facility requirements;
- Surety bonds;
- Background checks for key personnel; and,
- Stronger penalties for felons, repeat violations, etc.

HDMA distributor members continually utilize innovations to change and enhance the business model that maintains the safety and integrity of the prescription drug products that patients depend on for their health and well-being. DSCSA further supports these objectives and HDMA is here to serve as a resource with respect to implementation. On our website, at [www.healthcaredistribution.org/issues/pharmaceutical-traceability](http://www.healthcaredistribution.org/issues/pharmaceutical-traceability), HDMA provides an array of DSCSA-related resources including anticipated compliance timelines, guidance documents, and presentations.

Again, HDMA and our distributor members are committed to a secure prescription drug supply chain and we look forward to working with FDA and the states as we go through the federal and state regulatory implementation process. HDMA appreciates your consideration of our interim recommendations and looks forward to hearing from you.

If you have any additional questions or would like more information, please contact Gary Riddle (VP, State Government Affairs) at 703-885-0236 or [glriddle@hdmanet.org](mailto:glriddle@hdmanet.org).

