Summary of Proceedings
50-State Inter-governmental Meeting on the Drug Supply Chain Security Act (DSCSA)
November 17, 2015

On November 17, 2015, the U.S. Food and Drug Administration (FDA) convened the first inter-governmental working meeting of state government officials (including the District of Columbia and Puerto Rico) on the Drug Supply Chain Security Act (DSCSA). Attendees included officials from the state Boards of Pharmacy, other state regulatory authorities and organizations that represent state officials, including the National Association of Boards of Pharmacy (NABP) and the Association of State and Territorial Health Officials (ASTHO).

The purpose of this meeting was to have an interactive discussion regarding topics related to the implementation of the DSCSA and to identify potential areas for FDA and state collaboration specific to the DSCSA. Discussion topics included, but were not limited to, national licensing standards, product tracing requirements, federal and state licensing of wholesale distributors and third-party logistics providers (3PLs), and challenges facing states regarding inspections and licensing.

FDA hopes to have more inter-governmental working meetings with state officials on DSCSA in the future. This meeting was initiated because of the variety of ongoing questions and issues that have emerged at both the state and federal levels following the passage of the DSCSA in November 2013.

The meeting included discussions of the following topics:

Overview of DSCSA Implementation

FDA began the meeting by providing an overview of the DSCSA. This included a review of the law's scope and major provisions, an update on the uniform national standards, a description of key points for state authorities and a view of FDA's The DSCSA Resources for State Officials web page. FDA also described in detail two of the six guidance documents issued by the Agency on the DSCSA and the recently launched Annual Reporting Database for Wholesale Distributors and 3PLs:

- Draft Guidance: "DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs: How to Exchange Product Tracing Information," which provides details for industry on how to exchange product tracing information;

- Draft Guidance: "Identification of Suspect Product and Notification," which provides recommendations on how to identify and determine whether a product is a suspect product and sets forth a process to notify and consult with FDA to terminate notifications about illegitimate product;

- FDA's Annual Reporting Database for Wholesale Distributors and 3PLs, which gathers current state licensure status from wholesale distributors and 3PLs and allows state officials to access the information, including company contact information and significant disciplinary actions.

Panel 1: Wholesale Distributor and Third-Party Logistics Provider (3PL) Licensing

The first session panel was comprised of officials from FDA and three state regulatory agencies (California, Florida and Oklahoma). Issues addressed during this panel discussion related to wholesale distributor and 3PL licensing. FDA began the panel discussion with an update on the regulations and licensure timeline, a comparison of wholesale distributor and 3PL licensing requirements contained in the DSCSA, and a suggested to-do list for state licensing authorities once the federal regulations are final.

Following the FDA update, each state official on the panel was given an opportunity to discuss any specific issues that have been raised in their states by industry and state officials regarding licensure. Issues raised by state panelists included:

- The need for more information from FDA on the timing of the federal regulations because of the effect they have on when and how the states will introduce related state legislation and regulation;
- Clarification on federal 3PL licensing requirements; and
- The desire for more state-to-state communication between licensing officials regarding areas of mutual interest.

FDA heard the concerns raised by panelists and members of the audience and answered questions where possible. Other DSCSA issues raised by audience members during the first panel's session included, but were not limited to, clarification on certain definitions, preemption, inspection authority, exemptions from licensure, and the requirements of human drugs for animal use.

Panel 2: FDA and State Collaboration

The second panel consisted of officials from FDA and the Virginia and Oregon Boards of Pharmacy. The purpose of this panel was to have an interactive discussion on ways the FDA and state licensing officials can more effectively collaborate. This panel also discussed the topic of inspections of wholesale distributors and 3PLs. Audience comments were made regarding some states' limited ability to inspect, and audience members commented that the frequency of wholesale distributor and 3PL inspections varies from state to state. Following a brief presentation and discussion of FDA's Annual Reporting Database for Wholesale Distributors and 3PLs, the following questions were asked to start the conversation on collaboration efforts:

- On which DSCSA implementation issues would the states like to collaborate more closely with FDA?
- What is the best way to use the 21 CFR Part 20.88 Information Sharing Agreements (similar to compounding)?
- What are the preferable methods for FDA-State collaboration (additional 50-State meetings, quarterly conference calls, etc.)?

Panel members from the states and audience members suggested having not only more FDA to state communication on DSCSA issues but also having the FDA potentially assist with more state to state communication. Potential formats for more communication and interaction among federal and state officials include regular conference calls, webinars and additional in-person meetings.

FDA Action Items:

- FDA will consider the issues presented during the meeting by the states when developing guidance documents and proposed regulations.
- FDA will consider how a modified 20.88 Information Sharing Agreement could be developed for use in states on the DSCSA similar to how it is used for compounding issues.
- FDA will explore the suggestions made regarding the best ways for the FDA and states to collaborate.
- FDA will continue to update The DSCSA: Resources for State Officials web page with the latest guidance documents, regulations, contact information, etc.
- FDA will consider comments and suggestions regarding the wholesale distributor/3PL licensure database.