## The Drug Supply Chain Security Act

The Distribution Industry at the Nexus of DSCSA Implementation

The Healthcare Distribution Alliance (HDA) and the distribution industry have led on federal traceability issues for nearly two decades, with the association playing a central role as a convener and intermediary between regulatory and industry stakeholders since enactment of the <u>Drug Supply Chain Security Act (DSCSA)</u>. Through each milestone, HDA has leveraged the industry's expertise, formed productive partnerships with industry groups and served as a forum for its members and supply chain partners to address critical technology and compliance questions.



#### **Convening Supply Chain Stakeholders To Advance Solutions**

HDA has brought supply chain and technology leaders together to develop collaborative, industry-driven solutions to complex implementation challenges — and in some cases, even creating novel technology systems to comply with certain requirements. HDA's task forces and working groups, including the Traceability Implementation Work Group, Verification Router Service Task Force, Bar Code Task Force and Exceptions Handling Work Group, have helped inform HDA's work on traceability implementation and contributed to industry guidelines that support DSCSA compliance, including:

- HDA Guidelines for Bar Coding in the Pharmaceutical Supply Chain
- Exceptions Handling Guidelines for the DSCSA



### Representing HDA Members and Engaging with Regulators

Informed by its industry work groups, HDA has voiced the interests of our members that are leading DSCSA implementation efforts for the industry. The association has regularly engaged with the Food and Drug Administration (FDA) by submitting <u>comments</u> and testimony and reflecting the industry's perspective on draft guidance and proposed rules related to DSCSA implementation. HDA also has regularly participated in public meetings and other events to ensure distributors' perspective is well understood.





# Spearheading Education and Thought-Leadership on a Complex Law

HDA has spearheaded DSCSA-related educational offerings as part of our industry leadership. The association's annual <u>Traceability Seminar</u> brings together supply chain leaders from every segment as well as regulators to learn more about relevant DSCSA implementation milestones as well as innovative approaches and lessons learned as distributors, manufacturers and dispensers implement serialization and traceability technologies.

Further, between 2015 and 2022, the HDA Research Foundation conducted a <u>Serialization</u> Readiness Survey to benchmark the readiness of manufacturers and distributors to meet the DSCSA's product serialization requirements.



#### **Supporting Trading Partners' Compliance Efforts**

DSCSA implementation is a clear example of how the distribution sector's collaborative spirit and logistics expertise benefit the entire healthcare sector. Throughout the implementation process, HDA has helped upstream and downstream partners across the supply chain better understand their responsibilities and prepare for the DSCSA's final implementation deadline of November 27, 2023.

- Manufacturer Data Quality: Best Practices Considerations for DSCSA: A report
  providing detailed information for manufacturers on best practices that can improve data
  quality to aid in DSCSA implementation.
- <u>DSCSAEdu Website:</u> A virtual resource hub developed for dispensers preparing for DSCSA implementation.

As the final deadline approaches, HDA and our members will continue to work with supply chain partners to address critical technology and compliance questions and engage with FDA. By working together, we can effectively implement this groundbreaking law to ensure a more safe and secure pharmaceutical supply chain for patients.

For more information about the distribution industry's approach to pharmaceutical traceability and DSCSA implementation visit: <a href="https://www.hda.org/pharmaceutical-traceability">www.hda.org/pharmaceutical-traceability</a>

