



National Association of State
Controlled Substances Authorities



How Variations in State Laws and Regulations Present Challenges & Opportunities to Industry and Regulators



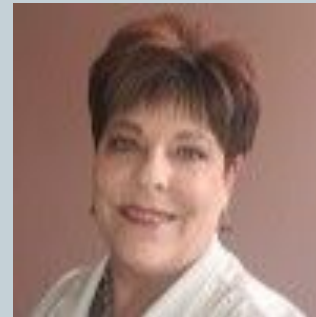
How Variations in State Laws and Regulations Present Challenges & Opportunities to Industry and Regulators



Moderators



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Disclaimer

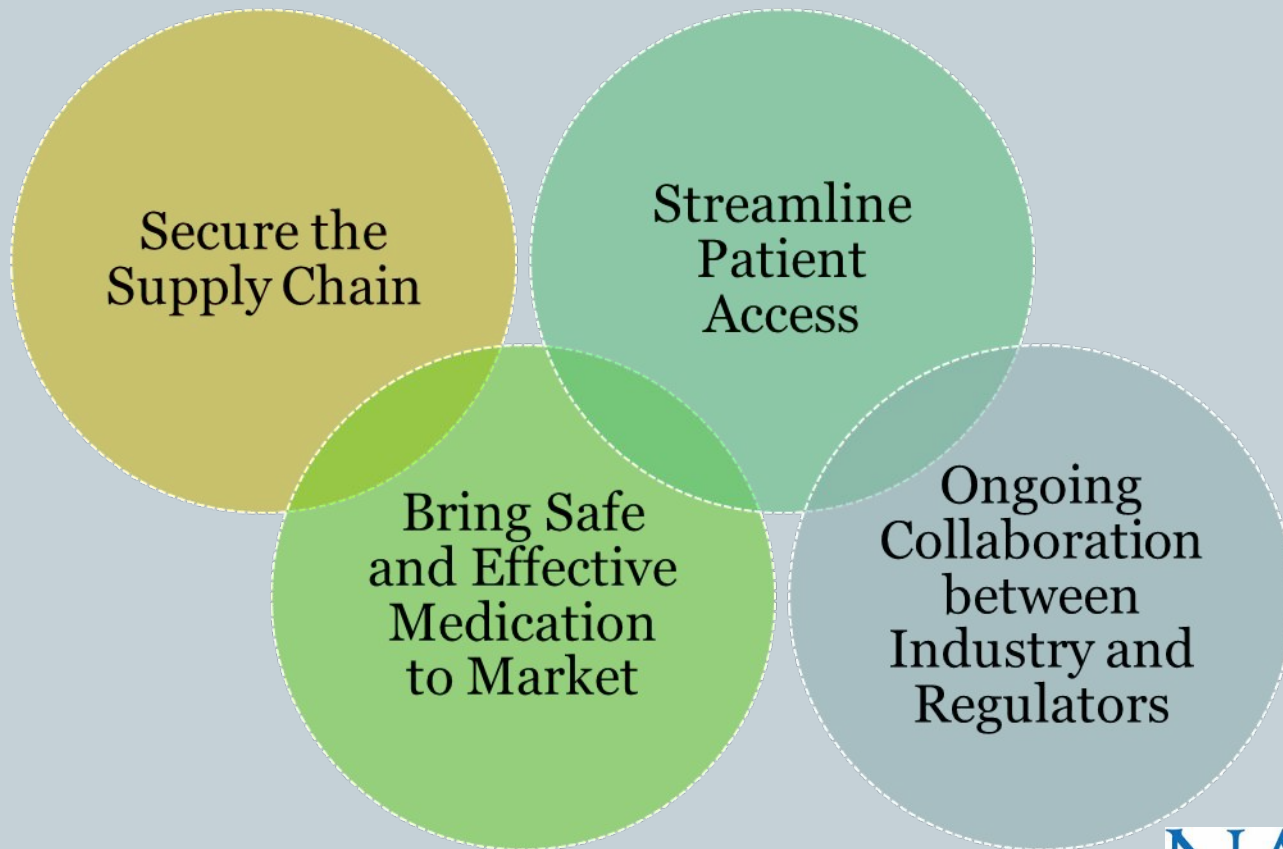


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Goals of Industry & Regulators

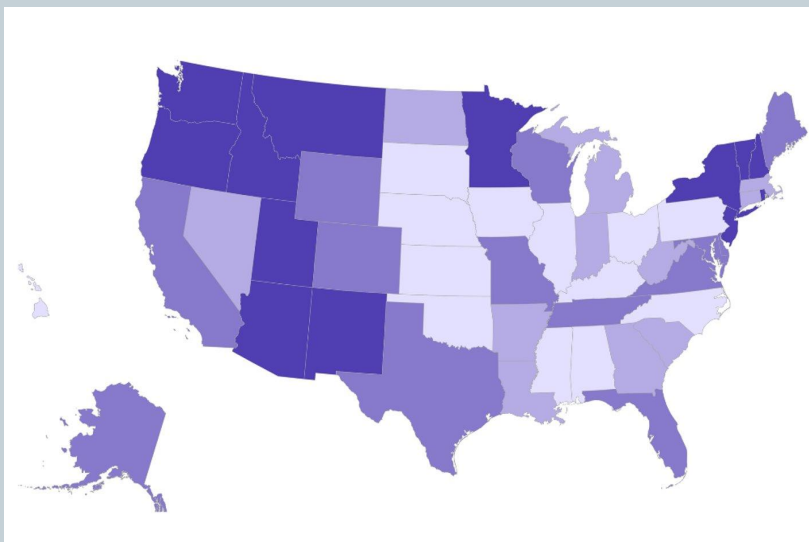


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Variations in State Regulations

Ongoing Challenges for Industry



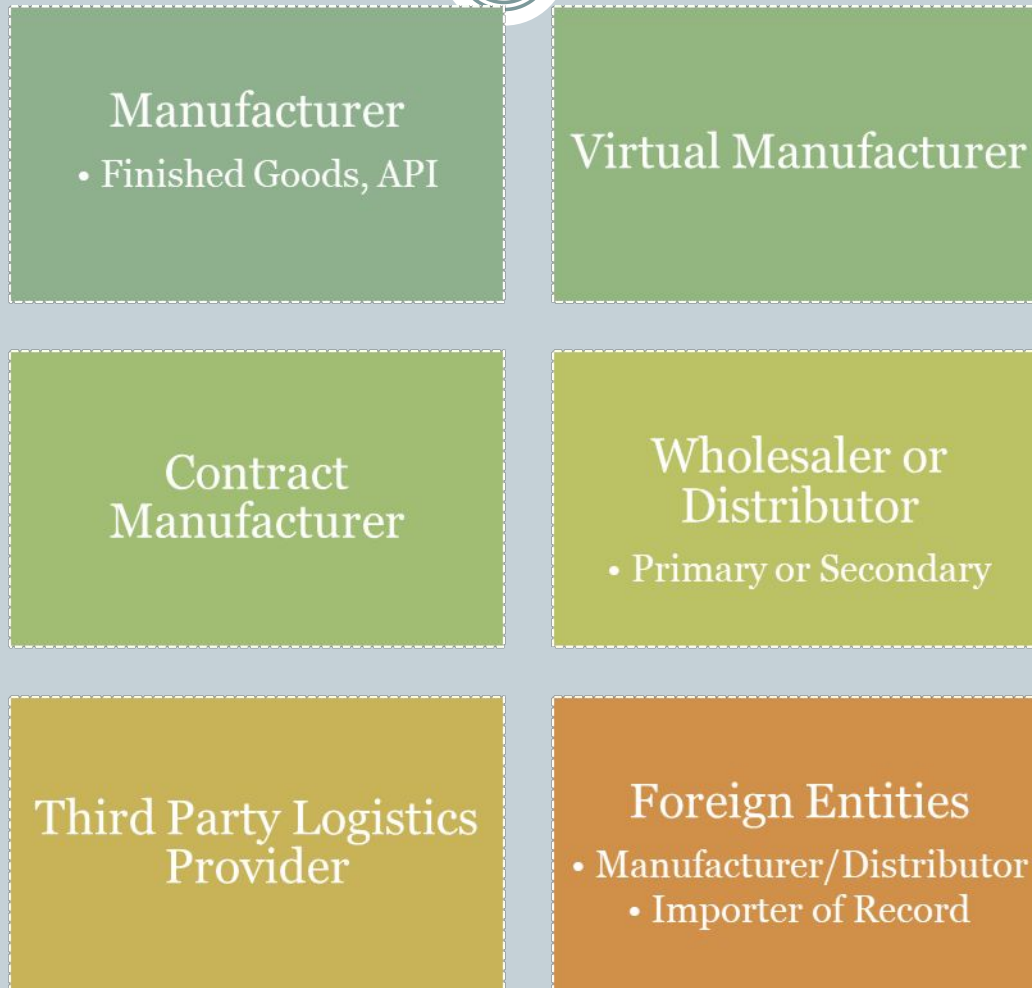
- “Patchwork” Among State Requirements
 - Definitions
 - Ex. Possession vs Ownership
 - Licensing Regulations and Laws
 - Requirements of Applications
 - Inspection Details
 - Licensure Responsibility to Supply Chain



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Licensing

Varying Definitions & Types



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State Licensing Challenges



Resident and Nonresident Licensing

- License type and definitions vary by state
- Reciprocity has significant impact depending on license type
- License verifications, inspection process, timelines and accreditation requirements

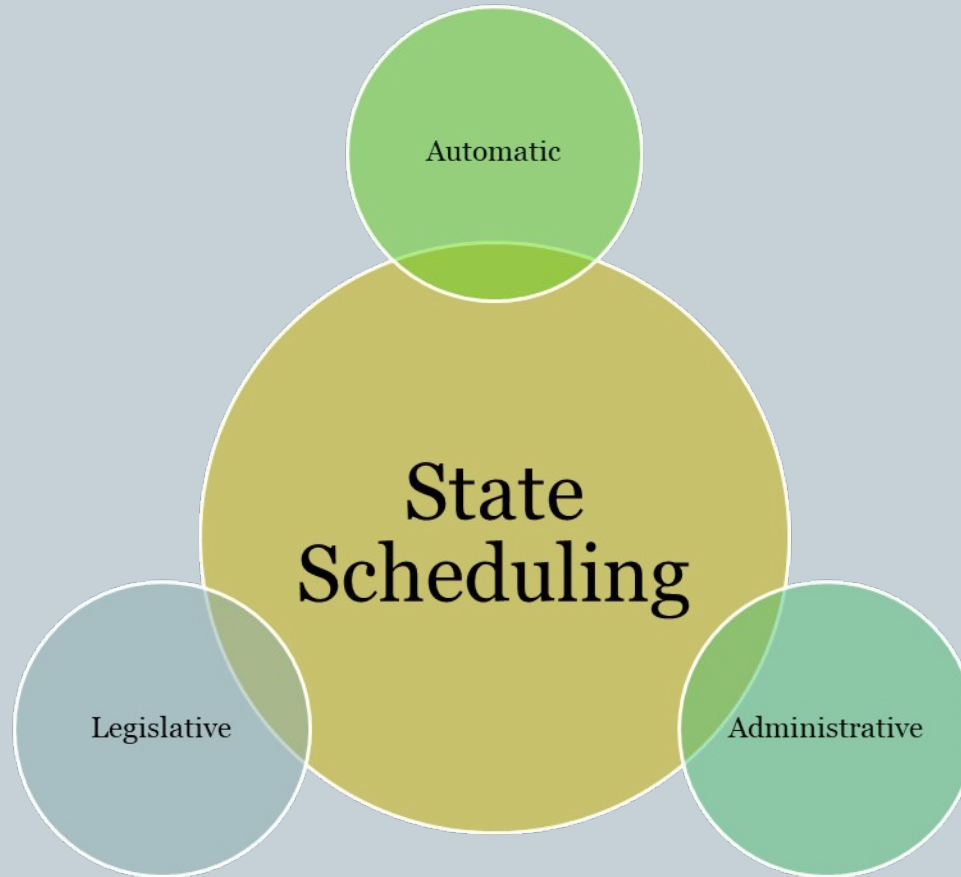
Change of Ownership Process

- Apps Required Prior to Close
- App Submission Prior to Close but cannot for legal purposes
- Required in limited timeframe post-close

Information Requirements

- Personal data submissions every year for the same person
- Sensitive information including SS#, date of birth, fingerprints, drivers license and/or passports

Controlled Substance New Drug Approvals/Scheduling Actions



Controlled Substance New Drug Approvals/Rescheduling/Reporting

- Bringing New Controlled Substance Products to Market
- FDA and DEA Approval and Recommended Scheduling
- Impact of State Scheduling Process on Supply Chain
- State considering requirements that differ from DEA Obligations
- Reporting Requirements



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New Challenges to the Industry in Licensing Compliance



- Disclosure of Vendor Partners to Obtain Licensure
- Additional information required for CMOs
 - Need to address information that is proprietary
 - Required information be provided that is out of the applicants control
- Expanding licensing requirements for Importers
 - State licensing category
 - Importer of Record
- Implementation of DSCSA Requirements for Wholesale Distributors – Change Once Again?

Areas for Collaboration & Solutions



Difficulties for Supply Chain:

- Varying requirements specific to information requirements, applications, proprietary information, timelines
- Change of ownership “CHOW”

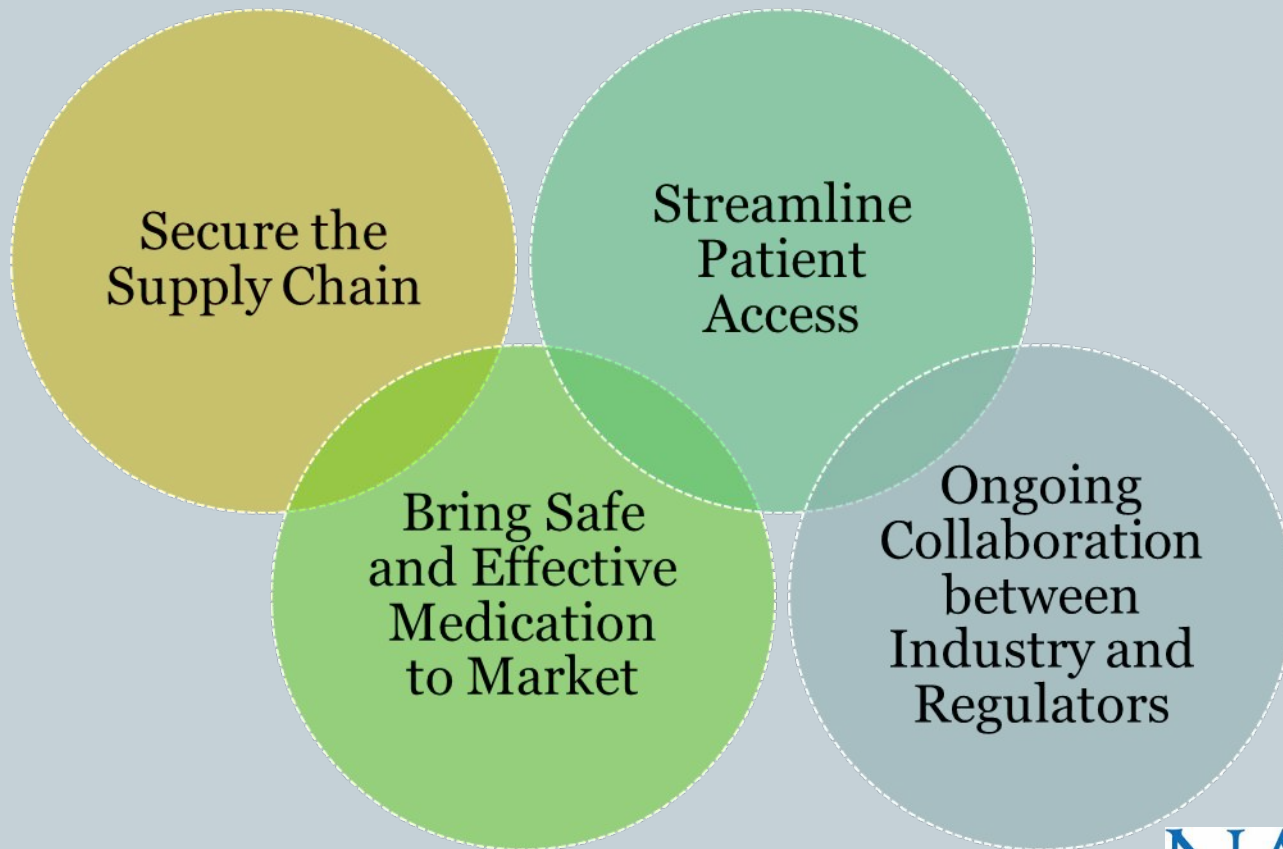
Collaborative Solutions:

- Expand Use of the 2 national accreditations: Value Add
 - Application – Indiana
 - Streamlined Process
 - Background checks/fingerprinting/bonds
- Short Term exemption or Transfer of license during Acquisitions
 - Both parties license is current and in good standing
 - Timelines for CHOW application process



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Goals of Industry & Regulators



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Questions?

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