State Laws that Could Delay Product Launch or Distribution

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Seton Hall Life Sciences Compliance Program

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Agenda

I. General Licensing Overview
- Overview
- Who is Required to be Licensed?
- Distribution Models
- Controlled Substance & Device Licensing

II. Licensing Prerequisites
- Designated Representative Responsibilities
- Corporate Officer Responsibilities
- Other Prerequisites
- Pharmaceutical Detailer Licensure

III. Licensing Maintenance
- Reportable Changes

IV. Drug Supply Chain Security Act
- Overview
- Impact

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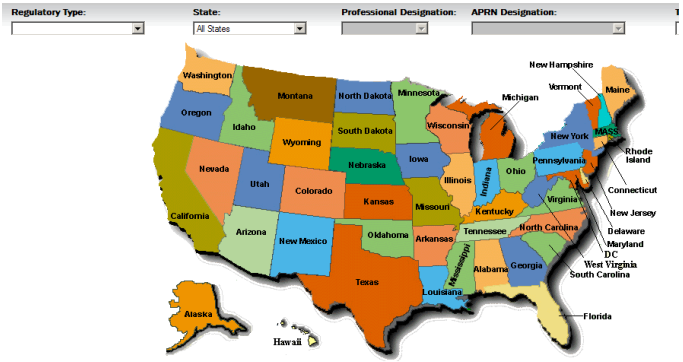
- All 50 States and the District of Columbia impose some form of licensure and registration requirement on companies seeking to manufacture, distribute, and/or sample drug products within their borders.

  - Licensing protects the public from counterfeit drugs.
  - State licensure requirements aid in the oversight of the industry.
  - In the absence of federal law, states have the primary responsibility to ensure that companies doing business within their borders hold legitimate licenses.



Who May Need a License

- Manufacturers*
- Wholesale Distributors*
- Third-Party Logistics Providers
- Virtual Manufacturers
- Sales Representatives/Detailers

*Numerous states, including Idaho, Minnesota, Oregon and Washington, have different licensure requirements for manufacturers and distributors.

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Who is a Wholesale Distributor?

"Any one engaged in wholesale distribution of prescription drugs, including, but not limited to, manufacturers; repackers; own-label distributors; private-label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies that conduct wholesale distributions."

21 C.F.R. § 205.3(g)

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Who Qualifies as a Manufacturer?

- A person who prepares, derives, manufactures, or produces a drug, device, or cosmetic;
- The holder of an NDA, an ANDA, a BLA, or a NADA;
- A private label distributor for whom the private label distributor's prescription drugs are originally manufactured and labeled for the distributor and have not been repackaged;
- A manufacturer who has entered into a written agreement with another prescription drug manufacturer that authorizes either manufacturer to distribute the prescription drug identified in the agreement as the manufacturer of that drug;
- A member of affiliated group which member distributes prescription drugs, whether or not obtaining title to the drugs, only for the manufacturer of drugs who is also a member of the affiliated group; or
- A person permitted as a third party logistics provider, only while providing warehousing, distribution, or other logistics services.

Fla. Stat. § 499.003(31)

Numerous states, including the following, distinguish between manufacturer and wholesaler licenses:

- Arizona
- California
- Georgia
- Idaho
- Maryland
- Minnesota
- Oregon
- Washington

Potential Ramifications of Manufacturer vs. Wholesaler Licensure:

- Surety Bonds
- Background Checks
- VAWD
- Pedigree Requirements

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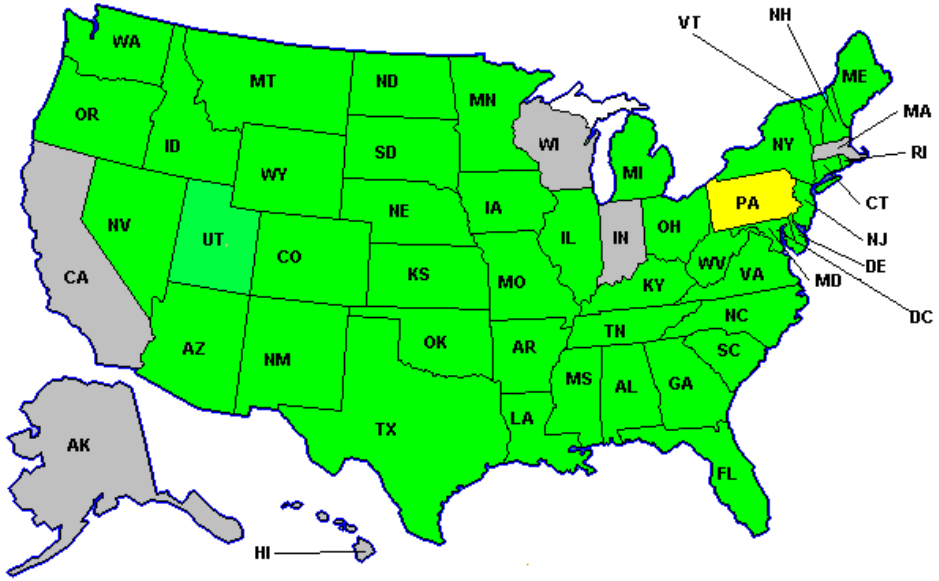
Licensure Considerations for Manufacturers

- Does the pharmaceutical company do its own shipping?



- AK, HI & MA do not license non-resident manufacturers and wholesalers of legend drugs.
- PA licensure is not required unless the entity has sales representatives operating in PA. Non-resident companies may in the alternative provide a list of sales representatives.
- CA, CT, IN, & WI exempt non-resident manufacturers who meet certain criteria and distribute only their own products.

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Who is a Third-Party Logistics Provider?

A Third Party Logistics Provider is…

"…an entity that provides or coordinates warehousing, or other logistics services of a product in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of a product, but does not take ownership of the product, nor have responsibility to direct the sale or disposition of the product."

21 USC § 360eee (22)

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Controlled Substances: Licensure Considerations

Factors that Affect CS Licensure

- Resident vs. Nonresident
  - Ex: Indiana
- Physically Handling and Distributing Controlled Substances
  - Ex: Michigan
- Responsibility for the Controlled Substance
  - Ex: New York

Controlled Substances: Licensure Considerations

Various State Approaches to CS Licensure

- Same Application
  Ex: Rhode Island
- A separate section of the same Application
  Ex: Montana and Oregon
- Completely separate application
  Ex: Louisiana
- One license, the same license w/ “CS,” or a completely separate license
  Ex: Arkansas, Alabama, Michigan, respectively

Device Licensure: Unique Challenges

- All states have existing regulatory programs and requirements governing the distribution chain for drugs
- Approximately half of states have no regulatory oversight for medical device distribution
- Of states that do regulate device distribution, regulatory landscape varies greatly
- Prescription Drug Marketing Act provides federal guidelines and minimum requirements for states' regulation of drug distribution→ no comparable guidelines exist for regulation of medical device distribution

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Taking A Closer Look: The Numbers

- **26** states require in-state prescription device manufacturers/ distributors to obtain a license before doing business in the state

- **19** states require out-of-state prescription device manufacturers/ distributors to obtain a license

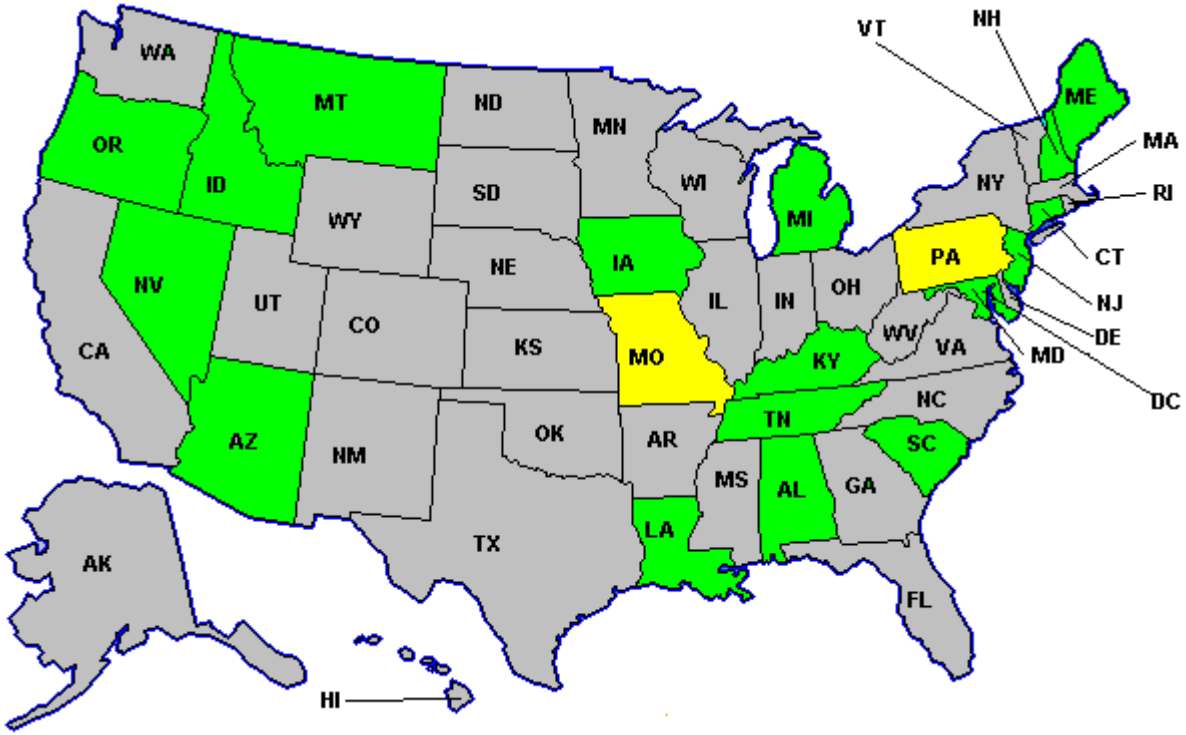
- **11** states require out-of-state prescription device manufacturers/ distributors that sell, but do not ship, to obtain a license

States that License Out-of-State Prescription Device Manufacturers/Distributors that Ship

Green—Yes

Grey—No

Yellow—See Below



- D.C. – License not required
- PA – License required for in-state entities. Out-of-state entities only required to hold license if sales representatives operate within state
- Missouri – License only required if device is utilized to introduce prescription drug into body

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Designated Representative Qualifications

Designated Representative requirements vary by state

- Example: Texas.
  - Currently the most stringent designated representative requirements.
  - Only state with a 3 year experience requirement.

ATTACHMENT A
APPLICANT QUALIFICATIONS

To qualify for the issuance or renewal of a license as a wholesale distributor and/or manufacturer of prescription drugs under these sections, the designated representative of an applicant or license holder must:

(1) Be at least 21 years of age.
(2) Have been employed full-time for at least three years by a pharmacy or a wholesale distributor in a capacity related to the dispensing or distributing of prescription drugs, including recordkeeping for the dispensing or distributing of prescription drugs.
(3) Be employed by the applicant full-time in a managerial-level position.
(4) Be actively involved in and aware of the actual daily operation of the wholesale distributor.
(5) Be physically present at the applicant's place of business during regular business hours, except when the absence of the designated representative is authorized, including sick leave and vacation leave.
(6) Serve as a designated representative for only one applicant at any one time.
(7) Not have been convicted of a violation of any federal, state, or local laws relating to wholesale or retail prescription drug distribution or the distribution of controlled substances.
(8) Not have been convicted of a felony under a federal, state, or local law.

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Designated Representative / Corporate Officer Responsibilities

- Provide work-related and personal information for completion of applications.
  - Ex: Florida
- Sign (and notarize) applications, affirmations, attachments, etc.
- Comply with fingerprint/background check requirements.
- Comply with state reporting requirements.
- Designated Representative - active and on-site
- Stay informed of changing state laws and regulations.

Other Prerequisites to Licensure

- *Resident state license
  - *Most states will not issue a license without a resident state license or resident state exemption
- Resident State License Verification
  - Some states (ex. MT, NY, OR) require the resident state licensing agency to complete a *license verification form*
- FDA registration documentation
  - New York, for example, will not even inspect a facility until in receipt of proof of FDA product approval.
- Inspection report
- Fingerprinting/background checks for corporate officers and/or designated representative

Other Prerequisites to Licensure (contd.)/Timeline

- Surety Bond (ex. CA, NV, WI)
- Incorporation documentation
- Authority to Do Business Registration

  Obtained through the Secretary of State (Ex. AL, ND)

***In general, it takes anywhere from 6-8 months from the onset of an initial licensing project for a company to secure all of its licenses.**

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Pharmaceutical Detailer Licensure

- The District of Columbia requires licensure of sales representatives and others who market Rx drugs on a company's behalf.

- There is broad applicability. Companies who have promotional speaker programs are applying for licensure of physician speakers in D.C.

- A continuing education requirement exists for re-licensure.

What about Medical Science Liaisons?

Are they "promoting" products & therefore subject to licensure?

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Licensure Maintenance: Reportable Changes

- Ownership
  - Ex: Maine – 7 Days Prior; File New Application
- Name
  - Ex: Mississippi – 10 Days Prior; New License Required
- Location
  - Ex: Montana – 30 Days Prior; New License Required
- Designated Representative/Responsible Contact
  - Ex: Arizona
    - Resident Manufacturer: 24 hours
    - Wholesalers and Non-Resident Manufacturers: 10 days
  - Ex: South Carolina – Within 30 Days of Change
    - Notification of Permit Holder Change Form must be submitted

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Licensure Maintenance: Reportable Changes

- Corporate Officers
  - Ex: California Non-Resident Wholesalers – 30 days
  - Ex: Georgia – Prior to Change
    - Personnel Certification Form must be completed and submitted by new corporate officer(s)
- Disciplinary Action
  - Ex: Colorado
    - 3 days (license suspended, revoked or withdrawn)
    - 3 days (other disciplinary action within Colorado)
    - 30 days (disciplinary action in another state)

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Drug Supply Chain Security Act

Enacted on November 27, 2013

Title II of the Drug Quality and Security Act ("DQSA"), the Drug Supply Chain Security Act ("Act"), creates a more secure national pharmaceutical supply chain through the implementation of common standards and requirements for the licensing of wholesale distributors and third-party logistics providers.

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An entity engaged in wholesale distribution is required to be licensed by:

The resident state

or

The Secretary, if the resident state does not license wholesale distributors

and

Each state into which the entity distributes drug product if such state(s) requires the licensure of non-resident wholesale distributors

As of January 1, 2015 Reporting Requirements

- Must report *annually* to the Secretary:
  - Each state licensed and the corresponding license number(s)
  - Name, address and contact information of each facility and all trade names operating under
- Must report any significant disciplinary action taken against them by a state or the federal government within a reporting period

As of January 1, 2015 Federal Database

- A Database will be available on the FDA website that will:
  - Identify the authorized wholesale distributor's name, address and contact information
  - Each state the authorized wholesale distributor is properly licensed to engage in wholesale distribution

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Drug Supply Chain Security Act cont.

The Act also implements similar licensing requirements of third-party logistics providers ("3PLs"):

An entity operating as a 3PL is required to be licensed by:

The resident state

or

The Secretary, if the resident state does not license 3PLs

and

Each state into which the entity operates if such state(s) requires the licensure of 3PLs

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The Secretary shall establish regulations for the standards of licensure for wholesale distributors and 3PLs. These standards will include:

Wholesale Distributor Standards

- Storage and handling requirements
- Record keeping requirements
- Surety bond requirements
- Mandatory background checks and fingerprinting of facility managers or designated representatives (DR)
- Key personnel qualifications
- Mandatory physical inspection of any facility to be used in wholesale distribution
- Prohibition of certain persons from receiving or maintaining licensure as a wholesale distributor

- Process that a third-party accreditation program approved by the Secretary will issue a license to a 3PL
- Storage and handling requirements
- Record keeping requirements
- Written policies and procedures
- Mandatory background checks and fingerprinting of facility managers or designated representatives (DR)
- Key personnel qualifications
- Periodic physical inspection
- Report a list of all manufacturers, wholesale distributors and dispensers servicing
- Procedures that require a license to be renewed every 3 years

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Pedigree Requirements

- Title II: Drug Supply Chain Security
  - H.R. 3204, among other things, provides a timeline for manufacturers, wholesale distributors, repackagers, and third-party logistics providers to implement a national track and trace system that preempts state pedigree laws.
  - 10 years after enactment, all entities in the distribution supply chain will be required to implement an electronic track and trace system.
  - HR 3204 became on January 1, 2015.

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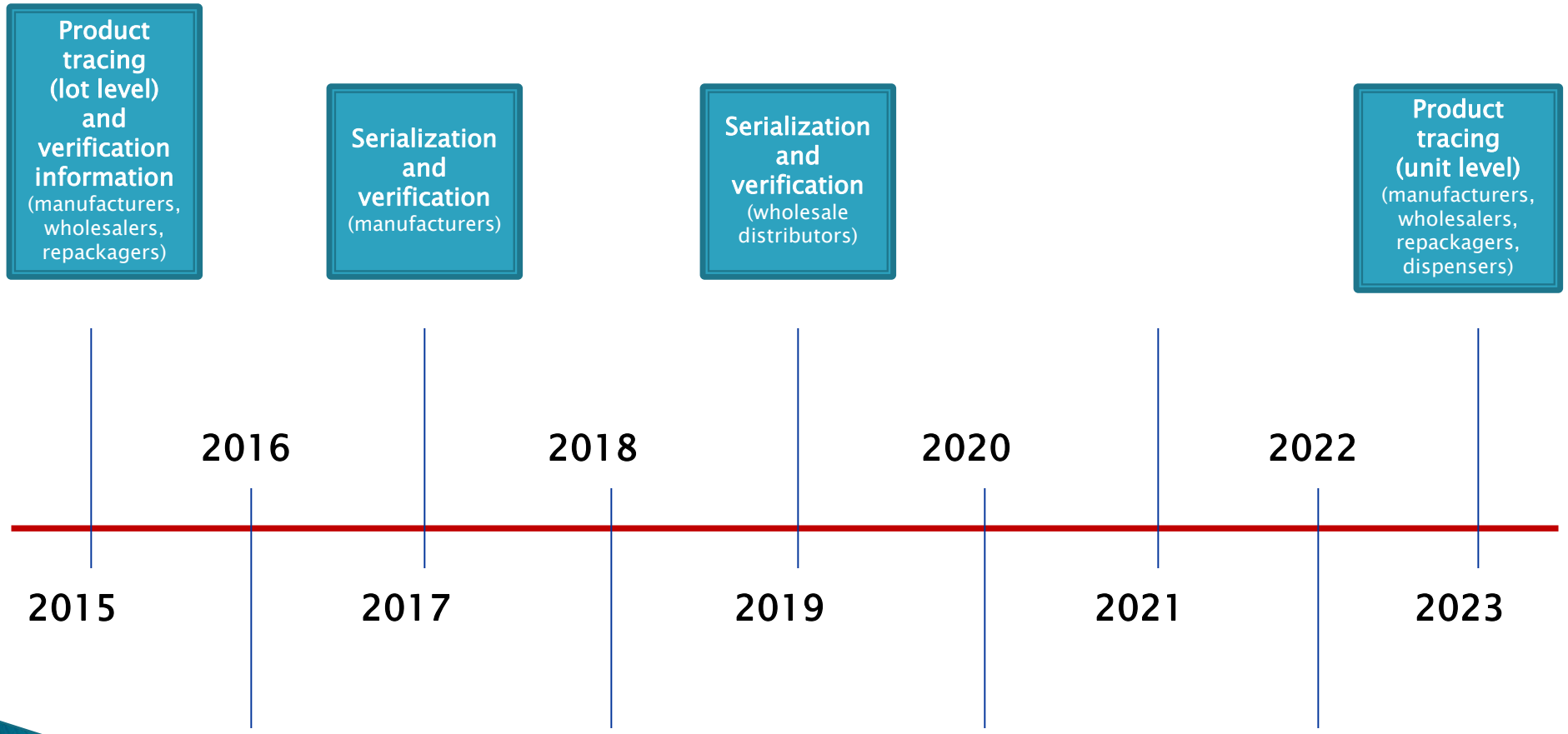
Track and Trace Timeline



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Questions?

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