New Hampshire 503B Legislation

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Executive Director
New Hampshire Board of Pharmacy

SENATE BILL ***202-FN***

- Introduced in March 2015
- This bill establishes the requirement for licensure by the pharmacy board of outsourcing facilities operating pursuant to section 503B of the Federal Food, Drug, and Cosmetic Act.

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Purpose: In the interest of the residents of New Hampshire to strengthen the oversight of outsourcing facilities that provide compounded drugs for patient use in New Hampshire by requiring such facilities to be licensed and regulated by the New Hampshire pharmacy board.

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- This bill defined “Outsourcing facility” as a facility at one geographic location or address that is engaged in the compounding of sterile drugs, has elected to register as an outsourcing facility, and complies with all of the requirements of section 503B of the Federal Food, Drug, and Cosmetic Act.

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- Requires Outsource Facilities to license with the Board prior to shipping into the state
- No license shall be issued unless the applicant has furnished proof satisfactory to the pharmacy board:
  a. applicant is of good moral character
  b. applicant has sufficient land, buildings, and security equipment to properly carry on the business described in the application.

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- No license shall be granted to any person who has within 5 years been convicted of a violation of any law of the United States, or of any state, relating to drugs, as defined in this NH Pharmacy laws, or to any person who is a drug-dependent.

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- Any person licensed pursuant to this section shall be subject to the provisions of RSA 318:29.
- The outsourcing facility to which a license has been issued shall, within 30 days of any change of information supplied in the original application, notify the board.

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- A new license shall be required for a change of ownership of an established outsourcing facility to a successor business entity which results in a change in the controlling interest in the outsourcing facility

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- The outsourcing facility to which a license has been issued shall, within 30 days of any written warnings or disciplinary action from any state or federal licensing or enforcement agency, notify the board and provide a copy of the action.

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- Outsourcing facilities shall maintain a human drug compounding outsourcing facility registration from the FDA and shall comply with applicable Current Good Manufacturing Practices (CGMP) requirements

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- Facilities are subject to inspection by the FDA
- Outsourcing facilities shall be in compliance with applicable DEA regulations.
- The pharmacist-in-charge shall certify to the board that the facility is in full compliance with all applicable FDA and DEA regulations and guidelines, and state law and rules.

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- Outsource facilities are required to test 100% of all high risk sterile products shipped into NH (results must be shipped with products)
- Outsourcing facilities are required to test at least 20% of all low to medium risk products shipped into NH.

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- The Pharmacy Board Shall adopt Rules
  - Application Procedure
  - Content of application
  - Standards for licensure
  - Establish fees
  - Standards for denial and revocation of licensure
  - Inspection Requirements
  - Dispensing requirements
  - Record Keeping Requirements

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- Senate Bill 202-FN passed June 26, 2015
- The law became effective July 1, 2015
- The Board has started licensing 503B's (Currently # facilities Licensed)
- Next Step – draft rules as required in the bill

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Inter-governmental Working Meeting on Drug Compounding and DSCSA

U.S. Food and Drug Administration
Silver Spring, Maryland

November 16-17, 2015