CHAPTER 180
SB 202-FN – FINAL VERSION

03/05/2015 0549s
6May2015… 1474h
05/28/2015 1997EBA

2015 SESSION

15-0906
10/01

SENATE BILL ***202-FN***

AN ACT relative to licensure of outsourcing facilities by the pharmacy board.

SPONSORS: Sen. Carson, Dist 14; Sen. Bradley, Dist 3; Sen. Reagan, Dist 17; Rep. Sytek, Rock 8; Rep. Sherman, Rock 24; Rep. B. Griffin, Hills 6

COMMITTEE: Executive Departments and Administration

ANALYSIS

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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Explanation: Matter added to current law appears in ***bold italics.***
Matter removed from current law appears [~~in brackets and struckthrough.~~]
Matter which is either (a) all new or (b) repealed and reenacted appears in regular type.

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STATE OF NEW HAMPSHIRE

In the Year of Our Lord Two Thousand Fifteen

AN ACT relative to licensure of outsourcing facilities by the pharmacy board.

Be it Enacted by the Senate and House of Representatives in General Court convened:

180:1 Purpose. It is 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. The general court recognizes that the federal Drug Quality and Security Act (DQSA) was signed into law November 27, 2013 and that the federal Food and Drug Administration (FDA), pursuant to section 503B of the Federal Food, Drug and Cosmetic Act, as amended by the DQSA, is in the process of establishing final guidelines for the regulation of outsourcing facilities, identified as 503B facilities. It is the intent of this act to establish a licensing requirement for FDA registered 503B outsourcing facilities and to establish interim requirements for such facilities. Once federal guidelines are finalized and adopted, it is the intent of the general court that such requirements shall be further adopted by the New Hampshire pharmacy board to maintain regulatory consistency for outsourcing facilities with the federal government.

180:2 New Paragraph; Definition Added. Amend RSA 318:1 by inserting after paragraph XXIX the following new paragraph:

XXX. "Outsourcing facility" means 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.

180:3 New Sections; Licensing of Outsourcing Facilities; Rulemaking. Amend RSA 318 by inserting after section 51-b the following new sections:

318:51-c Licensing of Outsourcing Facilities Identified as Section 503B Facilities by the United States Food and Drug Administration.

I. No person shall compound legend drugs or controlled drugs, as defined in RSA 318-B:1, VI, and no person acting as or employed by an outsourcing facility shall supply such drugs, without first having obtained a license from the board. Such license shall expire annually on June 30. An application together with a fee established by the board shall be filed annually on or before July 1.

II. No license shall be issued under this section unless the applicant has furnished proof satisfactory to the pharmacy board:

(a) That the applicant is of good moral character or, if that applicant is an association or corporation, that the managing officers are of good moral character.

(b) That the applicant has sufficient land, buildings, and security equipment as to properly carry on the business described in the application.

III. 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 chapter or RSA 318-B, or to any person who is a drug-dependent person.

IV. Any person licensed pursuant to this section shall be subject to the provisions of RSA 318:29.

V.(a) 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.

(b) The notice required pursuant to subparagraph (a) shall contain:

(1) Current New Hampshire license number of the outsourcing facility.

(2) Name of the outsourcing facility, old and new, if applicable.

(3) Address of the outsourcing facility, old and new, if applicable.

(4) Names, addresses, and titles of new corporate officers, partners, or owners.

(c) 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.

VI. 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.

318:51-d Requirements for Outsourcing Facilities.

I. Outsourcing facilities shall maintain a human drug compounding outsourcing facility registration from the United States Food and Drug Administration (FDA) and shall comply with applicable Current Good Manufacturing Practices (CGMP) requirements as defined in the Final Guidance for Industry-Human Drug Compounding Outsourcing Facilities under Section 503B of the Food, Drug, and Cosmetic Act, when compounding or manufacturing drug products for sale in New Hampshire.

II. Facilities are subject to inspection by the FDA on a risk-based schedule.

III. Outsourcing facilities shall be in compliance with applicable United States Drug Enforcement Administration (DEA) regulations.

IV. As part of the New Hampshire outsourcing facility license application process, 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.

V. Outsourcing facilities shall be required to test all finished drug products compounded

from bulk active pharmaceutical ingredients (API) to determine whether they meet final product specifications before their release for distribution. No products shall be released for use until this testing is conducted and the results confirm that the finished drug product meets specifications. Copies of the test results shall be included with each batch sent to New Hampshire customers and available for inspection by the pharmacy board.

VI. Outsourcing facilities compounding drug products from sterile, commercially available raw materials shall confirm sterility through process control validated by testing of at least 20 percent of the lots of each product shipped into New Hampshire. Results of these tests shall be provided to New Hampshire customers in receipt of the compounded preparations and available for inspection by the pharmacy board.

318:51-e Rulemaking. The board shall adopt rules pursuant to RSA 541-A relative to:

I. The application procedure for licensing of outsourcing facilities;

II. Content of the application;

III. The standards for licensing of outsourcing facilities;

IV. The establishment of fees for licensing outsourcing facilities;

V. Standards for denial and revocation of license;

VI. Inspection requirements;

VII. Dispensing and distribution requirements of prescription drugs;

VIII. Record keeping requirements; and

IX. Requirements for outsourcing facilities.

180:4 Repeal. RSA 318:51-d, relative to requirements for outsourcing facilities, is repealed.

180:5 Contingency; Effective Date of Repeal. Section 4 of this act shall take effect on the date that the pharmacy board certifies to the director of legislative services and the secretary of state the effective date of rules adopted by the board under RSA 318:51-e, IX, which replace the requirements of RSA 318:51-d, or June 30, 2017, whichever is later.

180:6 Application. The pharmacy board shall have authority to extend any current license held by outsourcing facilities beyond July 1, 2015, until such time as the rules for licensing requirements and application requirements adopted pursuant to RSA 318:51-e are in effect.

180:7 Effective Date.

I. Section 4 of this act shall take effect as provided in section 5 of this act.

II. The remainder of this act shall take effect July 1, 2015.

Approved: June 26, 2015

Effective Date: I. Section 4 shall take effect as provided in section 5

II. Remainder shall take effect July 1, 2015