CHAPTER 203
SB 104-FN – FINAL VERSION

03/05/2015 0508s
03/15/2015 1012s
06/11/2015 2110EBA

2015 SESSION

15-0199
10/01

SENATE BILL ***104-FN***

AN ACT relative to licensure of research organizations by the pharmacy board.

SPONSORS: Sen. Pierce, Dist 5; Sen. Bradley, Dist 3

COMMITTEE: Commerce

ANALYSIS

This bill provides for the licensure of research organizations conducting research relating to prescription drugs by the pharmacy board.

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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Matter which is either (a) all new or (b) repealed and reenacted appears in regular type.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 research organizations by the pharmacy board.

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

203:1 New Paragraphs; Pharmacists and Pharmacies; Definition; Research Organization; Researcher. Amend RSA 318:1 by inserting after paragraph XXIX the following new paragraphs:

XXX.(a) "Research organization" means an entity, including a biotechnology company or research institute, whose primary goal is to conduct fundamental research, industrial research, or experimental development relating to drug products, disease and drug diagnostics, and/or drug manufacturing technologies.

(b) A "research organization" shall not include:

(1) A "sponsor," "sponsor-investigator," or "contract research organization" as such terms are defined in 21 C.F.R. section 312.3;

(2) An "applicant" as such term is defined in 21 C.F.R. section 314.3; a "manufacturer," "processor," "packer," or "distributor" as such terms are used in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. section 301 et. seq.); or

(3) A "manufacturer" or "applicant" as such terms are used in 21 C.F.R. section 601.2.

XXXI. "Researcher" means a qualified person representing a research organization licensed by the board pursuant to RSA 318:51-c.

203:2 New Paragraph; Rulemaking; Research Organizations. Amend RSA 318:5-a by inserting after paragraph IV-a the following new paragraph:

IV-b. The standards for licensure of research organizations.

203:3 Rulemaking; Research Organization. Amend RSA 318:5-a, VII to read as follows:

VII. The establishment of all fees and fines required under this chapter, including application fees for nonresidents***. Fees for licensure of research organizations shall not be greater than the fees charged for registering pharmacies***;

203:4 New Paragraph; Possessing Prescription Drugs; Research Organization. Amend RSA 318:42 by inserting after paragraph XVII the following new paragraph:

XVIII. A research organization licensed by the board pursuant to RSA 318:51-c, and researchers representing such organization, from possessing prescription drugs for research operations.

203:5 New Section; Licensure of Research Organizations. Amend RSA 318 by inserting after section 51-b the following new section:

318:51-c Licensure of Research Organizations.

I. No research organization shall procure or conduct research operations with prescription drugs by researchers without first having obtained a license from the board. Such license shall expire annually on June 30. An application together with a reasonable fee as 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 board of pharmacy:

(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 space and security equipment as to properly carry on the research operations described in the application.

III. The license granted under this section shall at all times be displayed in a conspicuous place in the research organization facility for which it is issued.

IV. No license shall be issued under this section to research organizations for sale, dispensing, or distribution of prescription drugs.

(a) Prescription drugs are to be used solely for research purposes only.

(b) Use of controlled drugs is prohibited under the license for research organizations issued under this section.

(c) No research organization shall distribute prescription drugs directly to a consumer or a patient, or operate in such a manner as to endanger the public health.

(d) The research organization shall effectively destroy all prescription drugs in due course by means of conducting routine research operations or disposal by approved methods.

(e) The research organization shall maintain up-to-date and accurate records indicating:

(1) The amount of prescription drug destroyed.

(2) The date on which the prescription drug was destroyed.

(3) The manner or method by which the prescription drug was destroyed.

(f) Inventories and disposal transactions shall be maintained for 2 years and made available for inspection by the board's inspectors within a period of 72 hours from notice.

V. No license shall be granted to any research organization if any of its managing officers or researchers have within 5 years been convicted of a violation of any law of the United States, or of any state, relating to drugs, as defined by this chapter or RSA 318-B, or is an impaired person.

VI. Any licensee under this section is subject to the provisions of RSA 318:29.

VII.(a) The licensee shall, within 30 days of any change of information supplied in the original license application, notify the board.

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

(1) Current New Hampshire license number of the research organization.

(2) Name of managing officers and researchers, old and new, if applicable.

(3) Address of the research organization, old and new, if applicable.

VIII. A new license shall be required for a change of ownership of an established research organization to a successor business entity which results in a change in the controlling interest in the research organization.

203:6 Contingent Renumbering. If SB 202-FN of the 2015 regular legislative session becomes law, RSA 318:1, XXX and XXXI, as inserted by section 1 of this act, shall be renumbered as RSA 318:1, XXXI and XXXII, respectively, RSA 318:51-c, as inserted by section 5 of this act, shall be renumbered as RSA 318:51-f, and the references to RSA 318:51-c in RSA 318:1, XXXI, as inserted by section 1 of this act, and RSA 318:42, XVIII, as inserted by section 4 of this act, shall be renumbered as RSA 318:51-f.

203:7 Effective Date. This act shall take effect July 1, 2015.

Approved: July 6, 2015
Effective Date: July 1, 2015