CHAPTER 264 HB 615 - FINAL VERSION

14Mar2019... 0773h 13Jun2019... 2460-EBA

2019 SESSION

19-0672 10/01

HOUSE BILL 615

AN ACT relative to the regulation of pharmacies and pharmacists.

SPONSORS: Rep. Merchant, Sull. 4

COMMITTEE: Executive Departments and Administration

ANALYSIS

This bill makes various changes to the regulation of pharmacies and pharmacists by the board of pharmacy, including procedures of the board, exceptions to possessing prescription drugs, license expirations and renewals, and establishing the licensure of drug distribution agents.

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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Matter which is either (a) all new or (b) repealed and reenacted appears in regular type.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 Nineteen

AN ACT relative to the regulation of pharmacies and pharmacists.

	Be it Enacted by the Senate and House of Representatives in General Court convened:
1	264:1 Pharmacy Board. Amend RSA 318:5, I to read as follows:
2	I. The board shall have a president, vice-president, $and a$ secretary, [and a treasurer] who
3	shall be elected from among their number annually in the month of September.
4	264:2 New Paragraph; Rulemaking. Amend RSA 318:5-a by inserting after paragraph XIX the
5	following new paragraph:
6	XX. The standards and procedures for licensure of drug or device distribution agents.
7	264:3 Impersonating an Applicant. Amend RSA 318:20 to read as follows:
8	318:20 Impersonating Applicant.
9	I. No one shall impersonate an applicant before the board of pharmacy applying for
10	licensure under the provisions of this chapter.
11	II. No third party shall sign an application, complete an application, call to check
12	on the status of an application, or submit an application and documentation on behalf of
13	an applicant.
14	III. No third party shall complete an online renewal, paper renewal, or make any
15	changes or updates to an original application on behalf of an applicant.
16	IV. Authorization and release forms shall not be accepted as a form of release.
17	264:4 Application Fee for Pharmacist License. Amend RSA 318:23 to read as follows:
18	318:23 Application Fee for Pharmacist License. Each person applying for a license to practice
19	the profession of pharmacy in this state by way of examination shall pay a reasonable application fee
20	to be established by the pharmacy board. This fee shall include the cost of [standard examination
21	forms, the cost of administering the examination, and the cost of] investigating the applicant's
22	qualifications to become a pharmacist in this state.
23	264:5 Renewal of License. Amend RSA 318:25 to read as follows:
24	318:25 [Relicensure] Renewal of License. Pharmacist licenses shall expire [annually]
25	biennially in even-numbered years at midnight on December 31. Every licensed pharmacist who

- I. [Annually reapply for licensure as of January 1] Biennially, in even-numbered years, apply for license renewal no later than midnight on December 31;
 - II. Pay a reasonable fee established by the board;

wishes to continue to practice the profession of pharmacy shall:

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1 III. Satisfy any continuing education requirements established by the board; and 2 IV. Provide such data relating to his practice, residence, and status as deemed necessary by 3 the board. 264:6 Impaired Pharmacist Program; Biennial License. Amend RSA 318:29-a, VI(b) to read as 4 follows: 5 6 (b) The board may allocate an amount determined by the board from each pharmacist 7 [annual] biennial license renewal fee it collects to provide funding for the impaired pharmacist 8 program as set forth in subparagraph VI(a). 9 264:7 Pharmacy Permit Renewal. Amend RSA 318:38, II to read as follows: 10 II. All pharmacy permits shall expire when there is a change of ownership of the pharmacy 11 or at midnight on December 31 [of each] biennially in each odd-numbered year. Every pharmacy 12 that wishes to continue to operate as such shall renew its permit [annually as of January 1] no later than December 15 biennially in odd-numbered years or immediately when the permit expires 13 14 for any other reason. It shall be deemed a violation of the provisions of this chapter for any 15 pharmacy to be open or operated beyond the expiration date of its permit. 16 264:8 New Subparagraph; Dealing in or Possessing Prescription Drugs; Dental Hygienists. 17 Amend RSA 318:42, II by inserting after subparagraph (b) the following new subparagraph: 18 Nothing in this section shall prohibit a dental hygienist from possessing, 19 administering, dispensing, or prescribing a fluoride supplement, topically applied fluoride, and 20 chlorhexidine gluconate oral rinse pursuant to RSA 317-A:21-c, I(g). 21 264:9 Dealing in or Possessing Prescription Drugs; Registered Nurse, Physician Assistant. 22Amend RSA 318:42, VIII to read as follows: 23 VIII. A registered nurse or physician assistant from: 24 Making dilutions from concentrated solutions or pre-weighed or pre-measured 25 packets. 26 (b) Adding prepared sterile additives. 27 Reconstituting or diluting medications following manufacturers specific 28 directions. 29 (d) Entering an institutional pharmacy in an institutional setting specially designated 30 for this purpose by the institution in the absence of a pharmacist to obtain those drugs needed in an 31 emergency situation. 32 264:10 Renewal; License of Manufacturers and Wholesalers. Amend RSA 318:51-a, I to read as follows: 33 I. No person shall manufacture legend drugs or controlled drugs as that term is defined in 34 35 RSA 318-B:1, VI and no person as a wholesaler, distributor, or reverse distributor shall supply the 36 same without first having obtained a license to do so from the board. Such license shall expire 37 [annually] biennially on June 30 of every even-numbered year. An application together with a

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- reasonable fee as established by the board shall be filed [annually on or before July 1] biennially by midnight on June 30 of every even-numbered year.
- 3 264:11 Renewal; License for Limited Retail Drug Distributors. Amend RSA 318:51-b, I to read 4 as follows:
 - I. No person shall operate as a limited retail drug distributor, as defined in RSA 318:1, VII-a, without first having obtained a license to do so from the board. Such license shall expire [annually] biennially on June 30 of each odd-numbered year. An application together with a reasonable fee as established by the board shall be filed [annually on or before July 1] biennially by midnight June 15 of every odd-numbered year.
- 10 264:12 Renewal; License of Outsourcing Facilities. Amend RSA 318:51-c, I to read as follows:
 - 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] biennially on June 30 of each odd-numbered year. An application together with a fee established by the board shall be filed [annually on or before July 1] biennially by June 15 of every odd-numbered year.
 - 264:13 Renewal; License of Research Organizations. Amend RSA 318:51-f, I to read as follows:
 - 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] biennially on June 30 of each odd-numbered year. An application together with a reasonable fee as established by the board shall be filed [annually on or before July 1] biennially by June 15 of every odd-numbered year.
 - 264:14 New Section; Drug or Device Distribution Agents. Amend RSA 318 by inserting after section 51-f the following new section:
 - 318:51-g Licensure of Drug or Device Distribution Agents.
 - I. No person shall act as a prescription drug or device distribution agent, which includes controlled drugs as the term is defined in RSA 318-B:1, VI, without first having obtained a license to do so from the board.
- 28 II. Any person licensed pursuant to this section shall be subject to the provisions of RSA 29 318:29.
 - III. For purposes of this section:

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- (a) A drug or device distribution agent shall include virtual manufacturers, virtual wholesaler distributors, jobbers or brokers (including sales/marketing offices), and third-party logistics companies, and any other agent involved in the handling or distribution of prescription drugs, medical gases, or prescription medical devices or equipment in the supply chain that affects the pedigree of the products.
- 36 (b) "Broker or jobber" is any party that mediates between a buyer and a seller for the 37 sale or shipment of prescription drugs, gases, equipment, or devices.

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(c) "Pedigree" is a document or an electronic file containing information that records

2 each distribution of any given prescription drug, medical gas, or prescription medical device or 3 equipment. "Third-party logistics provider" is a person that contracts with a wholesale 4 (d) distributor or a manufacturer to provide or coordinate warehousing, wholesale distribution, or other 5 6 services on behalf of a manufacturer, but does not take title to the prescription drug, gas, device, or 7 equipment. 8 (e) "Virtual manufacturer" is anyone that owns the NDA or ANDA for a prescription 9 drug, gas, device, or equipment that contracts with others for the actual manufacturing. 10 "Virtual wholesale distributor" is anyone engaged in wholesale distribution of 11 prescription drugs, gases, devices, or equipment. 12 264:15 Repeals. The following are repealed: 13 I. RSA 318:45, relative to certain sales permitted. 14 II. RSA 318:46 and 318:47, relative to keeping and inspection of a record book. III. RSA 318:47-e, relative to procedures for dispensing emergency contraception. 15 16 RSA 318:51-a, V(b)(4), relative notification by manufacturers and wholesalers of IV. 17 corporate changes.

264:16 Effective Date. This act shall take effect 60 days after its passage.

Approved: July 19, 2019

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Effective Date: September 17, 2019