New Hampshire Pharmacy Law Changes Related to Compounding

HB 0313 Session Year 2013

An Act relative to the regulation of the compounding of drugs by pharmacists.

Status: PASSED / ADOPTED WITH AMENDMENT 5/2/2013

Approved: June 25, 2013

Effective Date: January 1, 2014

New Hampshire

NH defined compounding in Statute.

NH RSA 318:1

III-a. "Compounding" means the preparation, mixing, assembling, packaging or labeling of a drug or device as a result of a practitioner's prescription drug order or initiative based on the pharmacist-patient-prescriber relationship in the course of professional practice or, for the purpose of, or as an incident, to research, teaching, or chemical analysis, but not selling or dispensing. "Compounding" also includes the preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns. "Compounding" shall not include the reconstitution of powdered formulations before dispensing or the addition of flavoring.

New Hampshire

NH changed the definition of Manufacturing

VIII. “Manufacturing” means the production, preparation, propagation, conversion or processing of a drug or device, either directly or indirectly, by large volume extraction from substances of natural origin, or independently by means of chemical or biological synthesis, and includes any packaging or repackaging of a substance or labeling or relabeling of its container, and the promotion and marketing of such drugs and devices ***for resale***. [~~“Manufacturing” also includes the preparation and promotion of commercially available products from bulk compounds for resale by pharmacists to anyone other than a patient via a prescription, practitioners, or other persons.~~] ***Manufacturing shall be governed by Good Manufacturing Practices as adopted and enforced by the federal Food and Drug Administration.***

New Hampshire

Amended NH RSA 318:14 To Read

318:14 Pharmacy. A licensed pharmacist shall have the right to conduct a pharmacy for the compounding***, according to the provisions of RSA 318:14-a,*** of medicines upon physicians', dentists', optometrists', podiatrists', veterinarians', advanced practice registered nurses', naturopathic doctors', and physician assistants' prescriptions [~~and for the manufacture,~~] ***or valid orders for the*** sale[~~,~~] and distribution of drugs, medicines, and poisons.

New Hampshire

New Section RSA 318:14-a Compounding

I. Products that are not commercially available may be compounded for hospital or office use but shall not be resold or dispensed. Nonprescription items may be compounded upon order by a practitioner for sale as long as the labeling complies with RSA 318:47-a and the product is not a copy of, or similar to, prescription or nonprescription products. All compounding shall be done in compliance with the United States Pharmacopeia as defined by board of pharmacy rules.

New Hampshire

New Section RSA 318:14-a Compounding

II. The compound drug product shall bear the label of the pharmacy responsible for compounding and dispensing the product directly to the patient for administration, and the prescription shall be filed at that pharmacy. Compounded prescription labels shall include the phrase “compounded per subscriber request” or a similar statement on the prescription label or through the use of an auxiliary label attached to the prescription container.

New Hampshire

New Section RSA 318:14-a Compounding

III. A pharmacist shall offer a compounded drug product to a practitioner for administration to an individual patient, in limited quantities. The compounded drug products are for practitioner administration only and shall not be re-dispensed. The pharmacist shall maintain records to indicate what compounded drug products were provided to the medical office or practice. Compounding pharmacies may advertise or otherwise promote the fact that they provide prescription compounding services, in accordance with state law and rules of the board, as well as applicable federal laws.

New Hampshire

New Section RSA 318:14-a Compounding

IV. Where a commercial drug shortage exists because a manufacturer is the only entity currently manufacturing a drug product of a specific strength, dosage form, or route of administration for sale in the United States, and the manufacturer cannot supply the drug product to the public or to practitioners for use, a pharmacist may compound a limited quantity using the active pharmaceutical ingredient and sell to a patient with a valid prescription from a valid prescriber. When the compounded drug product is sold to a medical office or practice it is for the practitioner to administer to patients, and shall not be for resale.

New Hampshire

New Section RSA 318:14-a Compounding

- V. The board shall adopt rules under RSA 541-A concerning the regulation of compounding.
- VI. Labeling requirements pursuant to paragraph II shall not apply when medication is dispensed to institutionalized patients as provided under RSA 318:47-b.

New Hampshire

Amended NH RSA 318:42(II) To Read

II. Physicians, dentists, optometrists, podiatrists, veterinarians, advanced practice registered nurses, naturopathic doctors, and physician assistants from possessing, compounding ***in accordance with RSA 318:14-a***, personally administering, or distributing prescription drugs to meet the immediate medical needs of their patients. For advanced practice registered nurses and physician assistants, compounding shall be limited according to RSA 318:42, VIII.

New Hampshire

Amended NH RSA 318:47-a To Read

318:47-a Prescription Labels. Whenever a pharmacist dispenses a noncontrolled drug pursuant to a prescription, he shall affix to the container in which such drug is dispensed a label showing at least the name and address of the pharmacy and the name or initials of the dispensing pharmacist or pharmacist-in-charge; the prescription identification number assigned by the pharmacy; the date dispensed; any directions as may be stated on the prescription; the name of the prescribing practitioner; the name of the patient; all pertinent auxiliary labels; and, unless otherwise indicated by the prescribing physician, dentist, veterinarian, or advanced practice registered nurse, the name, strength, and quantity of the drug dispensed. All drugs dispensed to a patient that have been filled using a centralized prescription processing system shall bear a label containing an identifiable code that provides a complete audit trail of the dispensing of the drug and pharmaceutical care activities. No person shall alter, deface, or remove any label so affixed. ***A compounded drug product shall also be labeled as provided in RSA 318:14-a, II. The compound drug product shall bear the label of the pharmacy responsible for compounding and dispensing the product directly to the patient for administration, and the prescription shall be filed at that pharmacy. Compounded prescription labels shall include the phrase "compounded per subscriber request" or a similar statement on the prescription label or through the use of an auxiliary label attached to the prescription container."***

Source: Dr. Thomas Andrew – NH Medical Examiner's Office

New Hampshire

Amended NH RSA 318-B:13 by adding new paragraph

IV. A compounded drug product shall also be labeled as provided in RSA 318:14-a.

Source: Dr. Thomas Andrew – NH Medical Examiner's Office

New Hampshire

As required in 318:14-a (V)

The Board is working to adopt new Compounding Rules. The new rules will add roughly 30 pages specific to compounding. The draft rules closely follow USP 795 and USP 797.

Source: Dr. Thomas Andrew – NH Medical Examiner's Office

Thank You

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