

STATE OF MAINE

—
IN THE YEAR OF OUR LORD
TWO THOUSAND TWENTY-ONE

—
S.P. 11 - L.D. 4

An Act To Amend the Maine Pharmacy Act

Emergency preamble. Whereas, acts and resolves of the Legislature do not become effective until 90 days after adjournment unless enacted as emergencies; and

Whereas, this legislation clarifies the definition of compounding under the Maine Pharmacy Act to include the compounding of drugs for distribution to licensed veterinarians for limited office use on behalf of their animal patients; and

Whereas, this legislation requires the Maine Board of Pharmacy to adopt rules establishing the terms and conditions for compounding for veterinarian office use; and

Whereas, this legislation prohibits compounding for veterinarian office use until rules are adopted; and

Whereas, it is important that this legislation take effect as soon as possible so that the rules can be adopted in an expedient manner; and

Whereas, in the judgment of the Legislature, these facts create an emergency within the meaning of the Constitution of Maine and require the following legislation as immediately necessary for the preservation of the public peace, health and safety; now, therefore,

Be it enacted by the People of the State of Maine as follows:

Sec. 1. 10 MRSA §8003-H is enacted to read:

§8003-H. Licensure by endorsement

The Office of Professional and Occupational Regulation, referred to in this section as "the office," including the licensing boards and commissions within the office, shall establish a process to issue a license by endorsement to an applicant who presents proof of licensure by another jurisdiction of the United States as long as the other jurisdiction maintains substantially equivalent license requirements for the licensed profession or occupation and as long as:

1. Good standing. The applicant is in good standing in all jurisdictions in which the applicant holds or has held a license. For purposes of this subsection, "good standing"

means that the applicant does not have a complaint, allegation or investigation pending, does not have a license that is suspended or subject to practice restrictions and has never surrendered a license or had a license revoked;

2. No cause for denial. No cause for denial of a license exists under section 8003, subsection 5-A, paragraph A or under any other law; and

3. Fee. The applicant pays the fee, if any, pursuant to section 8003, subsection 2-A, paragraph D.

The office, or a licensing board or commission within the office, may require an applicant to pass a jurisprudence examination if such an examination is required to be passed for licensure pursuant to law or rule of the office, licensing board or commission.

The office, including the licensing boards and commissions within the office, shall adopt rules to implement this section. Rules adopted pursuant to this paragraph are routine technical rules pursuant to Title 5, chapter 375, subchapter 2-A.

Sec. 2. 32 MRSA §13702-A, sub-§4, as enacted by PL 2007, c. 402, Pt. DD, §2, is amended to read:

4. Compounding. "Compounding" means the preparation, mixing, assembling, packaging or labeling of a drug or device by a pharmacist ~~for the pharmacist's patient either for dispensing as the result of a practitioner's prescription drug order, or for the purpose of, or as an incident to, research, teaching or chemical analysis and not for sale or dispensing.~~ "Compounding" includes the preparation of drugs or devices in anticipation of prescription drug orders to be received by the pharmacist based on routine, regularly observed prescribing patterns.:

A. For the pharmacist's patient for dispensing as the result of a practitioner's prescription drug order;

B. For the purpose of, or as an incident to, research, teaching or chemical analysis and not for sale or dispensing;

C. In anticipation of prescription drug orders to be received by the pharmacist based on routine, regularly observed prescribing patterns for the pharmacist's patient; or

D. For nonpatient-specific drugs for distribution to licensed veterinarians for veterinarian office use for nonfood-producing animals, as that term is defined in board rule.

Sec. 3. 32 MRSA §13702-A, sub-§23, as enacted by PL 2007, c. 402, Pt. DD, §2, is amended to read:

23. Pharmacist in charge. "Pharmacist in charge" means ~~the~~ a pharmacist who ~~is responsible for the licensing of the~~ accepts responsibility for the operation of a licensed pharmacy in conformance with applicable laws.

Sec. 4. 32 MRSA §13721, sub-§1, ¶A, as enacted by PL 1987, c. 710, §5, is amended to read:

A. The licensing by examination or by ~~reciprocity~~ endorsement of applicants who are qualified to engage in the practice of pharmacy under this Act;

Sec. 5. 32 MRSA §13722, sub-§1, ¶B-1, as enacted by PL 1999, c. 130, §6, is amended to read:

B-1. Establish standards for the use, maintenance and supervision of automated pharmacy systems;

Sec. 6. 32 MRSA §13722, sub-§1, ¶B-2 is enacted to read:

B-2. Establish the terms and conditions for compounding drugs for veterinarian office use by rule, including, at a minimum:

(1) Requirements and specifications of minimum professional and technical equipment, environments, supplies and procedures and quality assurance requirements;

(2) Labeling requirements;

(3) Limits on the supply for administration to the veterinarian's patient and the supply for dispensing to the veterinarian's client;

(4) Record-keeping requirements; and

(5) Procedures for notifications regarding defective drug products and adverse events.

Compounding drugs for veterinarian office use is not permitted until rules are adopted by the board pursuant to this paragraph. Rules adopted pursuant to this paragraph are routine technical rules as defined in Title 5, chapter 375, subchapter 2-A;

Sec. 7. 32 MRSA §13732, sub-§1, ¶C, as enacted by PL 1987, c. 710, §5, is repealed.

Sec. 8. 32 MRSA §13733, as amended by PL 2007, c. 402, Pt. DD, §14, is repealed.

Sec. 9. 32 MRSA §13733-A is enacted to read:

§13733-A. Licensure by endorsement

In order to obtain a license as a pharmacist by endorsement, an applicant for licensure must meet the requirements of Title 10, section 8003-H and any applicable rules adopted pursuant to that section.

Sec. 10. 32 MRSA §13752, sub-§2, ¶C, as amended by PL 2007, c. 402, Pt. DD, §24, is further amended to read:

C. Identity of the pharmacist licensed to practice in the State who will be the pharmacist in charge of the pharmacy, when one is required by this chapter, and such further information as the board may determine necessary. The board shall adopt rules identifying the duties and responsibilities of the pharmacist in charge, which must include, at a minimum, responsibility for ensuring the pharmacy's compliance with all state and federal laws, rules and regulations pertaining to the practice of pharmacy, the distribution of drugs by the pharmacy and the licensure of pharmacy personnel. A pharmacist may be the pharmacist in charge for only one pharmacy, ~~except upon the pharmacist applying for and receiving written authorization from~~ as otherwise determined by the board by rule. The position of pharmacist in charge may not be held by a qualified assistant pharmacist; and

Sec. 11. 32 MRSA §13752, sub-§2, ¶D, as enacted by PL 1999, c. 130, §11, is amended to read:

D. ~~A certification~~ Attestation by the pharmacist identified as the pharmacist in charge that the pharmacist has read and understands the requirements and duties of a pharmacist in charge set forth in board rules.

Sec. 12. 32 MRSA §13753, sub-§1, as amended by PL 2007, c. 402, Pt. DD, §26, is further amended to read:

1. Changes. All licensed pharmacies shall report to the board, by mail ~~or~~ fax or electronic communication as accepted by the board, the occurrence of any of the following changes:

- A. Permanent closing, which requires ~~14~~ 10 calendar days' prior notice to the public and to the board;
- B. Change of ownership, which requires ~~7~~ 10 calendar days' prior notice to the board;
- C. Change of pharmacist, in charge which requires notice no later than ~~7~~ 10 calendar days after the change; and
- D. Any other matters and occurrences as the board may require by rule.

Sec. 13. 32 MRSA §13833, first ¶, as amended by PL 2011, c. 577, §6, is further amended to read:

~~The~~ A pharmacist shall administer drugs and vaccines in compliance with a treatment protocol established by a practitioner authorized under the laws of this State to order administration of those drugs and vaccines approved by the board. A copy of the original treatment protocol must be submitted to the board and any subsequent revisions to the treatment protocol must be kept on the premises of the pharmacy and be available to the board or the board's representative upon request. At a minimum the treatment protocol must include:

Sec. 14. 32 MRSA §13835, sub-§1, as amended by PL 2011, c. 577, §8, is further amended to read:

1. Criteria. Criteria for the operation of a vaccine administration clinic inside, outside or off the premises of a retail pharmacy, rural health clinic or free clinic licensed under section 13751. The rules must require ~~one-time board approval of the plan of operation for any vaccine administration clinics to be operated by a pharmacist or pharmacy and may not require board approval of each individual clinic;~~

Sec. 15. Consultation with State Board of Veterinary Medicine. The Maine Board of Pharmacy shall consult with the State Board of Veterinary Medicine in the establishment of the terms and conditions for compounding drugs for veterinarian office use pursuant to the Maine Revised Statutes, Title 32, section 13722, subsection 1, paragraph B-2.

Emergency clause. In view of the emergency cited in the preamble, this legislation takes effect when approved.