Notice of Agency Rulemaking Proposal

AGENCY: 02 – 502 Maine Department of Professional and Financial Regulation, Office of Professional and Occupational Regulation, **Board of Pharmacy**

CHAPTER NUMBER AND TITLE:
Chapter 4-A Administration of Drugs and Vaccines (Amend)
Chapter 41, Sales of Nonprescription Drugs Through Vending Machine Outlets (New) Chapter 42, Compounding Drugs for Veterinarian Office Use (New)

TYPE OF RULE *(check one)*: X Routine Technical ☐ Major Substantive

BRIEF SUMMARY:
Each rule proposed is in response to laws enacted from the 129th and 130th Legislature. Chapter 4-A sets forth minimum requirements for treatment protocols, administration and recordkeeping requirements, and standards for the administration of drugs and vaccines and the operation of drug and vaccine administration clinics. Chapter 41 sets forth requirements for licensing, management and safe operation of non prescription drug vending machine outlets. Chapter 42 This chapter establishes the terms and conditions for the compounding and distribution of animal drugs for nonfood-producing animals and nonpatient-specific use in veterinary offices.

Date, time and location of PUBLIC HEARING *(if any)*: December 1, 2022, @ 8:30 a.m. (EST)

Location: Public hearing will be fully virtual using Zoom. Information to present testimony on the proposed rulemaking or to listen in will be posted on the Board's website at Information to join the Zoom meeting online

COMMENT DEADLINE: December 11, 2022, @ 5:00 p.m. (EST)

CONTACT PERSON FOR THIS FILING: Submit written comments: Geraldine.L.Betts@maine.gov
Geraldine L. Betts, Administrator, 35 State House Station, Augusta ME 04333, 207-624-8625, TTY users call Maine relay 711

CONTACT PERSON FOR SMALL BUSINESS IMPACT STATEMENT *(if different)*:
FINANCIAL IMPACT ON MUNICIPALITIES OR COUNTIES *(if any)*: None

STATUTORY AUTHORITY FOR THIS RULE:
Chapter 4-A - 32 M.R.S. §§ 13720, 13723, 13831, 13832, 13833, 13834(1), 13835
Chapter 41 - 32 M.R.S. §§ 13751, 13792(2)
Chapter 42 - 32 M.R.S. §§ 13720, 13723, 13722(1)(B-2)

SUBSTANTIVE STATE OR FEDERAL LAW BEING IMPLEMENTED *(if different)*: N/A

AGENCY WEBSITE: www.maine.gov/professionallicensing
EMAIL FOR OVERALL AGENCY RULEMAKING LIAISON: Kristin Racine, OPOR Staff Attorney

Rule-Making Fact Sheet

(5 MRSA §8057-A)

AGENCY: Department of Professional and Financial Regulation
Office of Professional and Occupational Regulation
Board of Pharmacy

CHAPTER NUMBER AND RULE TITLE:

1) **Chapter 4-A,** Administration of Drugs and Vaccines (Amend)
2) **Chapter 41,** Sales of Nonprescription Drugs Through Vending Machine Outlets (New)
3) **Chapter 42,** Compounding Drugs for Veterinarian Office Use (New)

STATUTORY AUTHORITY:

1) 32 M.R.S. §§ 13720, 13723, 13831, 13832, 13833, 13834(1), 13835
2) 32 M.R.S. §§ 13751, 13792(2)
3) 32 M.R.S. §§ 13720, 13723, 13722(1)(B-2)

DATE, TIME AND PLACE OF PUBLIC HEARING: December 1, 2022 @ 8:30 a.m. This will be a virtual public hearing on Zoom. **Click here to the Zoom online meeting link and for copies of the Proposed Rules**

COMMENT DEADLINE: December 11, 2022 @ 5:00 p.m. (EST)

PRINCIPAL REASON(S) OR PURPOSE FOR PROPOSING THIS RULE:

1) Chapter 4-A – This chapter sets forth minimum requirements for treatment protocols, administration and recordkeeping requirements, and standards for the administration of drugs and vaccines and the operation of drugs and vaccine administration clinics.

2) Chapter 41 – This chapter sets forth requirements for licensing, management and safe operation of vending machine outlets.

3) Chapter 42 – This chapter establishes the terms and conditions for compounding drugs for veterinarian office use pursuant to 32 M.R.S. § 13722(1)(B-2). This chapter was developed in consultation with the Maine State Board of Veterinary Medicine.

IS MATERIAL INCORPORATED BY REFERENCE IN THE RULE? ___YES _X__NO [§8056(1)(B)]

ANALYSIS AND EXPECTED OPERATION OF THE RULE: [*see* §8057-A(1)(B) &(D)]

1) This chapter eliminates the requirement for submission of a vaccine administration treatment protocol to and approval by the Board of Pharmacy and requires pharmacies to maintain a protocol on the premises and to make it available to the board or an agent of the board upon request. This chapter outlines the requirements for administration of drug clinics and the one-time approval by the Board for a drug administration clinic.
2) This chapter establishes licensing for vending machine drug outlets and standards for the sale of nonprescription drugs by vending machines.
3) This chapter establishes the terms and conditions for the compounding and distribution of animal drugs for nonfood-producing animals and nonpatient-specific use in veterinary offices.

BRIEF SUMMARY OF RELEVANT INFORMATION CONSIDERED DURING DEVELOPMENT OF THE RULE (including up to 3 primary sources relied upon) [*see* §§8057-A(1)(E) & 8063-B]. None

ESTIMATED FISCAL IMPACT OF THE RULE: [*see* §8057-A(1)(C)] None.

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

392 MAINE BOARD OF PHARMACY

Chapter 4-A: ADMINISTRATION OF DRUGS~~,~~ AND VACCINES AND OPERATION OF A DRUG OR VACCINE ADMINISTRATION CLINIC INSIDE, OUTSIDE OR OFF THE PREMISES OF A LICENSED RETAIL PHARMACY, RURAL HEALTH CLINIC OR FREE CLINIC

Summary: This chapter sets forth minimum requirements for treatment protocols, administration and recordkeeping requirements, and standards for the administration of drugs~~, and vaccines, and other injectable FDA approved~~ and the operation of drug and vaccine administration clinics.

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1. Minimum Requirements for Treatment Protocol Issued Pursuant to 32 M.R.S.~~A~~ § 13833

For purposes of this section, a treatment protocol is a written collaborative agreement between a practitioner as described in 32 M.R.S.~~A~~ § 13833 and a pharmacist who holds a certificate of administration or pharmacy as described in this section. A treatment protocol authorizes the administration and injection of drugs and vaccines by a pharmacist who holds a certificate of administration pursuant to 32 M.R.S.~~A~~ §§ 13831-13835 and must include, at a minimum, the following provisions:

1. **Authorized Practitioner**

The treatment protocol must state the name, professional title, license number and contact information of the authorized practitioner issuing the protocol.

2. **Time Period**

The treatment protocol must state the beginning and ending dates of the period of time during which the protocol will be in effect, and the date on which the treatment protocol was issued. The treatment protocol may not have a beginning date prior to the date of issuance.

3. **Scope of Coverage – Pharmacists**

The treatment protocol may cover specific, named pharmacists who hold a certificate of administration, or may cover on a blanket basis all pharmacists holding a certificate of administration who are employed by or under contract to a specific pharmacy or pharmacies. Thus, the protocol must either:

A. State the name and contact information of the individual pharmacists holding a certificate of administration who are covered by the treatment protocol; or

B. State the name and physical address of the pharmacy or pharmacies whose employee or contract certified pharmacists holding a certificate of

administration will be covered by the treatment protocol without further identification.

A treatment protocol that covers on a blanket basis all pharmacists who hold a certificate of administration and are employed by or under contract to a specific pharmacy or pharmacies only applies to the administration and injection of drugs and vaccines by such pharmacists in the course of the pharmacists' employment or performance of contractual duties for a pharmacy identified in the treatment protocol.

4. **Scope of Coverage – Drugs and Vaccines**

The treatment protocol must identify the drugs and vaccines that may be administered pursuant to the protocol. For each drug and vaccine named, the protocol must specify the maximum permitted dose and the route of administration.

~~[NOTE: Drugs and vaccines that may be administered pursuant to this chapter are described in 32 MRSA §§ 13831]~~

5. **Standards for Observation**

The treatment protocol must include standards for observation of the person receiving the drug or vaccine to determine whether the person has an adverse reaction. The treatment protocol must specify a minimum post-administration patient retention period.

6. **Adverse Reactions**

The treatment protocol must include procedures to be followed by the pharmacist who holds a certificate of administration when administering epinephrine, diphenhydramine, or both, to a person who has an adverse reaction to a drug or vaccine administered by the pharmacist. The treatment protocol must include guidelines as to when contact with the local emergency services system or other follow-up health care providers is necessary or recommended.

7. Notification

A. The treatment protocol must require a pharmacist holding a certificate of administration who administers a drug or vaccine pursuant to this treatment protocol to provide notice of the administration within 3 business days to the authorized practitioner who issued a prescription, treatment protocol or written standing order pursuant to 32 M.R.S.~~A~~ §13831(2) which authorized administration to the patient or to the patient population of which the patient is a member~~;~~.

B. Where the Maine Immunization Information System (ImmPact) or a successor system allows for entry of administration of a vaccine, reporting the administration of a vaccine through that system satisfies the requirements of this section.

~~B~~C. The treatment protocol must require a pharmacist who holds a certificate of administration to provide notice of an adverse reaction to a drug or vaccine administered by the pharmacist of which the pharmacist is aware, including a statement as to whether epinephrine or diphenhydramine was administered, within 3 business days to:

(1) The authorized practitioner who issued the prescription, treatment protocol or written standing order which authorized administration to the patient or to the patient population of which the patient is a member;

(2) The Vaccine Adverse Event~~s~~ Reporting System co-sponsored by the Centers for Disease Control and the Federal Drug Administration; and

(3) The Maine Center for Disease Control and Prevention.

[**NOTE**: A prescription, treatment protocol or written standing order from an authorized practitioner is not required for administration of influenza vaccines.]

~~8. **Submission to Board**~~

~~The pharmacist holding a certificate of administration or the pharmacy or pharmacies to which the treatment protocol is issued shall submit a copy of the protocol to the board no later than 20 calendar days after the effective date of the protocol. If the protocol is changed, a copy of the revised protocol must be submitted to the board no later than 20 calendar days after the effective date of the change.~~

2. Administration Requirements

A pharmacist who holds a certificate of administration shall observe the following administration requirements in addition to requirements contained in:

- An applicable prescription, treatment protocol or written standing order issued pursuant to 32 M.R.S.~~A~~ §13831(2); and

- The applicable treatment protocol issued pursuant to 32 M.R.S.~~A~~ §13833 and Section 1 of this chapter.

1. **Verification**

~~A. For administration of influenza vaccines, the pharmacist who holds a certificate of administration shall verify as necessary that the patient is 9 years of age or older.~~

~~B. For administration of all other vaccines pursuant to a prescription, the pharmacist who holds a certificate of administration shall verify~~

~~(1) That the patient is the person to whom the prescription was issued;~~

~~(2) That the patient is 18 years of age or older.~~

~~C. For administration of all other vaccines pursuant to a treatment protocol or standing written order, the pharmacist who holds a certificate of administration shall verify:~~

~~(1) That the patient is a member of the patient population (e.g., employee of designated employer, resident of designated municipality) covered by the treatment protocol or standing written order; and~~

~~(2) That the patient is 18 years of age or older.~~

A. For the administration of all drugs and vaccines pursuant to a prescription or treatment protocol or standing written order, the pharmacist who holds a certificate of administration shall verify:

(1) That the patient is the person to whom the prescription was issued; or

(2) That the patient is a member of the patient population (e.g., employee of designated employer, resident of designated municipality) covered by the treatment protocol or standing written order.

B. In addition, for the administration of vaccines, the pharmacist who holds a certificate of administration shall verify:

(1) For administration of a COVID-19 vaccine pursuant to 32 M.R.S. § 13831(2-A), that the patient is 3 years of age or older;

(2) For administration of influenza vaccines, that the patient is 7 years of age or older; or

(3) For the administration of all other vaccines pursuant to a prescription or treatment protocol or standing written order, that the patient is 18 years of age or older.

2. **Assessment**

Prior to administering a drug or vaccine, a pharmacist who holds a certificate of administration shall assess the patient for contraindications that would preclude vaccination.

3. **Drug or Vaccine Information ~~Statement~~**

A pharmacist who holds a certificate of administration, prior to administration, shall give each patient or the patient's legal representative the appropriate drug or vaccine information ~~statement~~ for the drug or vaccine to be administered. The pharmacist shall ~~orally~~ review with the patient or patient's legal representative the portions of the statement describing the risks of the vaccine and what to look for and what to do in the event of a severe reaction.

4. **Informed Consent**

After providing the drug or vaccine information ~~statement~~, but prior to administration, the pharmacist who holds a certificate of administration shall obtain in writing the informed consent of the patient or the patient's legal representative to administration of the drug or vaccine and to emergency administration of epinephrine, diphenhydramine or both if the patient has an adverse reaction to the drug or vaccine administered.

5. **Certificate of Vaccination**

A pharmacist holding a certificate of administration who administers a ~~drug or~~ vaccine shall issue a certificate of vaccination to the patient or patient's representative at the time the ~~drug or~~ vaccine is administered. The certificate shall be signed by the pharmacist and shall include the patient's name, date of vaccination and the location where the ~~drug or~~ vaccine was administered.

6. **Record of Individual Administration**

A pharmacist who holds a certificate of administration shall record the administration of a drug or vaccine in a computerized or non-computerized recordkeeping system that includes, at a minimum, the following information. The recordkeeping system may be a pharmacy's patient profile record system:

A. **For drugs and both influenza and non-influenza vaccines**

(1) The name, date of birth, gender and contact information of the patient;

(2) The name of the pharmacist holding a certificate of administration who administered the drug or vaccine;

(3) The written informed consent required by Section 2(4) of this chapter, or an electronic copy of the document;

(4) The date of administration;

(5) The street address or location of the building where the drug or vaccine was administered;

(6) The name of the drug or vaccine administered, including the dose, route of administration, expiration date, manufacturer and lot number; and

(7) In the event that epinephrine or diphenhydramine is administered pursuant to 32 M.R.S.~~A~~ §13831(3),

(a) The name of the pharmacist holding a certificate of administration who administered the drug;

(b) The date of administration;

(c) The street address or location of the building where the drug was administered; and

(d) The name of the drug administered, including the dose, route of administration, expiration date, manufacturer and lot number.

B. **For drugs and non-influenza vaccines**

(1) For drugs and vaccinations authorized by prescription, the prescription; and

(2) For drugs and vaccinations authorized by a treatment protocol or standing written order, the name of the authorized practitioner who issued the treatment protocol or standing written order and the date of issuance.

~~7. [deleted]~~

3. Operation of Drug or Vaccine Administration Clinics; One-Time Approval by Board for a Drug Administration Clinic

1. Site Suitability

A drug or vaccine administration clinic must be located in a sanitary, well-maintained, adequately-equipped space that is appropriately sized for the expected patient volume and facilitates interaction among clinic staff and patients.

2. Written Plan of Operation

The pharmacist holding a certificate of administration or pharmacy that operates a drug or vaccine administration clinic shall develop a written plan of operation prior to conducting the clinic, and shall ensure that the plan is complied with during operation. The plan may cover multiple pharmacies under common ownership, provided that each such pharmacy adheres to the plan. A drug administration clinic may not be conducted until the written plan of operation has been approved by the board pursuant to subsection 5 of this Section. The plan must, at a minimum:

A. Require that any non-health care personnel who assist at the clinic have no contact whatsoever with drugs, vaccines, needles or syringes;

B. Include a specific protocol for prevention of administration errors (e.g., administration of incorrect drug or incorrect dose to patient; administration of drug to wrong patient);

C. Include procedures for the orderly management and flow of patients through the clinic both pre- and post-administration;

D. Include a specific protocol for performing the following procedures

(1) Verification (Section 2(1));

(2) Assessment (Section 2(2));

(3) Provision of drug or vaccine information ~~statement~~ and discussion of possible adverse reactions (Section 2(3));

(4) Obtaining written informed consent (Section 2(4)); and

(5) Issuance of certificate of vaccination (Section 2(5));

E. Incorporate the protocol for observing patients following administration required by Section 1(5) of this chapter. Clinic staff shall strongly recommend that all patients remain in the immediate vicinity of the drug or vaccination site for the post-administration observation period specified in the treatment protocol. To facilitate patient compliance, the operator of the clinic shall make a comfortable sitting area available in the immediate vicinity of the administration site. The sitting area must be of adequate size and must be suitably equipped to accommodate the flow of patients for the full duration of the post-administration observation period;

F. Include a protocol for the safe storage and transportation of drugs and vaccines to ensure that the drug or vaccine remains viable until the point of administration;

G. Include procedures to ensure that an adequate number of epinephrine and diphenhydramine syringes and other emergency medical supplies will be available for use in case a patient has an adverse reaction to the drug or vaccine administered; and

H. Include a protocol for infection control. Standard precautions to minimize the risks of spreading disease during drug or vaccine administration must be in place. The protocol must include, at a minimum, the following provisions:

(1) *Handwashing*. Hands must be washed thoroughly with soap and water or cleansed with an alcohol-based waterless antiseptic between patients, before vaccine preparation or any time hands become soiled;

(2) *Gloving*. Gloves are not required to be worn when administering drugs or vaccines unless the person administering the vaccine is likely to come into contact with potentially infectious body fluids or has open lesions on the hands. It is important to remember that gloves cannot prevent needlestick injuries;

(3) *Needlestick Injuries*. Needlestick injuries must be reported immediately to a lead person, with appropriate care and follow-up given. Safety needles or needle-free injection devices should be used if available to reduce the risk of injury;

(4) *Equipment Disposal*. Used needles may not be detached from syringes, recapped or cut before disposal. All used syringe/needle devices must be placed in puncture-proof containers to prevent accidental needlesticks and reuse. Empty or expired vaccine vials are considered medical waste and are subject to Chapter 900 of the rules of the Department of Environmental Protection, "Biomedical Waste Management Rules;" and

~~[**NOTE**: The operator of a drug administration clinic may be required to register as a biomedical waste generator with the Department of Environmental Protection.]~~

(5) *Drug or Vaccine Preparation*. Proper drug or vaccine handling and preparation is critical in maintaining the integrity of the drug or vaccine during transfer from the manufacturer's vial to the syringe and ultimately to the patient.

3. Clinic Personnel

At the conclusion of a drug or vaccine administration clinic the pharmacist holding a certificate of administration or pharmacy that conducted the clinic shall attach to the written plan of operation for that clinic a list that identifies, by name and position:

A. The lead person or persons who were responsible for operation of the clinic; and

B. All pharmacists holding a certificate of administration, pharmacy technicians, student interns, other health care personnel and non-health care personnel who staffed or assisted at the clinic.

4. Retention of Records

Records received or created by a pharmacy or pharmacist pursuant to this chapter are subject to the record retention and production requirements of Chapter 24 of the board's rules.

5. One-Time Approval of Written Plan of Operation for a Drug Administration Clinic

The written plan of operation described in subsection 2 of this Section must be submitted to the board for approval no less than 30 days prior to initial operation of a ~~vaccine~~ drug administration clinic pursuant to the plan. The duration of approval is indefinite, provided that in the event of any change to the plan, or any change in operation of a clinic that is not documented by or is inconsistent with the approved plan, the entire written plan of operation must be re-submitted to the board for approval. This section does not apply to a vaccine administration clinic.

4. Administration of Drugs and Vaccines by Pharmacy Intern

A pharmacy intern who is under the direct supervision of a pharmacist holding a certificate of administration and has obtained the drug administration training required by 32 M.R.S.~~A~~ §13832(3) may administer drugs and vaccines ~~to a person 18 years of age or older~~.

5. Scope of this Chapter

The provisions of this chapter apply to drugs and vaccines that may be administered pursuant to 32 M.R.S. § 13831.

The provisions of this chapter do not apply to prescribing, administering, or dispensing HIV prevention drugs pursuant to 32 M.R.S. 13786-E.

STATUTORY AUTHORITY: 32 M.R.S.~~A~~ §§ 13720, 13723, 13831, 13832, 13833, 13834(1), 13835

EFFECTIVE DATE:
~~October 1, 2009 – filing 2009-511 (EMERGENCY)~~
~~November 25, 2009 – filing 2009-611~~

~~AMENDED:~~
~~December 11, 2013 – filing 2013-300~~

PROPOSED

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

392 MAINE BOARD OF PHARMACY

Chapter 41: SALE OF NONPRESCRIPTION DRUGS THROUGH VENDING MACHINE OUTLETS

Summary: This chapter sets forth requirements for licensing, management and safe operation of vending machine outlets.

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1. DEFINITIONS. As used in this chapter, the following terms are defined as follows:

1. Nonprescription drugs. "Nonprescription drugs" has the same meaning as set forth in 32 M.R.S. § 13702-A(20).

2. Targeted methamphetamine precursor. "Targeted methamphetamine precursor" has the same meaning as set forth in 32 M.R.S. § 13702-A(33).

3. Vending machine. "Vending machine" means any automated mechanical device operated by a vending machine outlet licensee from which nonprescription drugs are dispensed to a consumer after payment.

4. Vending machine outlet. "Vending machine outlet" means any location licensed by the Board pursuant to 32 M.R.S. § 13751(E) to operate one or more vending machine(s) to sell non-prescription drugs.

2. LICENSURE.

1. License Required. Only vending machine outlets may operate one or more vending machine(s) in accordance with the terms and conditions set forth in this chapter. A vending machine outlet is solely responsible for all vending machines the licensee operates.

2. Limited Authorization. A vending machine outlet license only authorizes operation of vending machines for one (1) physical location where one or more vending machines are located. Any person desiring to operate a vending machine outlet shall obtain from the board a vending machine outlet license for each physical location where one or more vending machines outlets are located.

3. Non-transferrable. A vending machine outlet license issued under this section is not transferable.

4. Application.

PROPOSED

A. A person seeking a vending machine outlet license shall submit an application on a form provided by the Board and pay any fees as set forth in Chapter 10 of the rules of the Office of Professional and Occupational Regulation.

B. Any application shall include a detailed description, photograph(s) and drawing(s) of the intended location of each vending machine within the physical setting, as well as photograph(s) and drawings of the vending machine(s). Each vending machine shall be assigned a specific physical placement and orientation within a physical location that is:

1. weather-tight;
2. well-ventilated;
3. in a moisture-controlled environment;
4. well-lighted; and
5. protected from direct sunlight.

3. VENDING MACHINE REQUIREMENTS

1. **Nonprescription Drugs Only; Limits.** Only nonprescription drugs may be sold or dispensed from a vending machine. Any single vending machine may sell or dispense no more than twelve (12) different nonprescription drugs.

2. **No Targeted Methamphetamine Precursors.** Under no circumstance may targeted methamphetamine precursors be sold from any vending machine.

3. **Compliance with Manufacturer Recommendations**. Nonprescription drugs dispensed by a vending machine shall be:

A. Stored in accordance with manufacturer recommendations, including those that require a stable temperature;

B. Sold only in the manufacturer's clearly labeled, original, unbroken, tamper-proof and expiration-dated packaging; and

C. No older than the manufacturer's expiration date.

4. **Machine Labeling**.

1. Each vending machine outlet must have an obvious and legible statement or label on each machine that:

A. Identifies the owner of the machine, and, if different, the vending machine outlet licensee;

B. Identifies the vending machine's serial number;

C. Lists the Vending Machine License number issued by the Maine Board of Pharmacy and the license expiration date;

D. Provides a toll-free telephone number at which the consumer may contact the owner of the machine, and, if different, the vending machine outlet licensee;

E. Provides contact information for the Northern New England Poison Center; and

E. Advises the consumer to check the expiration date of the product before using the product.

4. Expired Nonprescription Drugs

Under no circumstance may expired nonprescription drugs be sold or dispensed from a vending machine. It is the sole responsibility of each vending machine outlet licensee to ensure products are in date and that expired drugs are promptly removed upon expiration.

4. PROCEDURE FOR RELOCATING OR RETIRING A VENDING MACHINE

Before relocating or retiring any vending machine outlet previously covered by a vending machine outlet license, the vending machine outlet licensee shall notify the Board in writing of that relocation or retirement. The notice shall include the following: license number; vending machine's serial number; action planned (relocation or retirement); if relocating, provide all information required above in subsection (2)(4)(B) for the new location; and if retiring a vending machine, the manner of disposition of the nonprescription drug contents of the vending machine.

5. INSPECTION

Each vending machine outlet is subject to inspection by a Board designee. The vending machine outlet licensee or its agent shall provide access to the contents of the vending machine immediately upon request from the Board's designee.

STATUTORY AUTHORITY: 32 M.R.S.A. §§ 13751, 13792(2)

EFFECTIVE DATE:

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

392 MAINE BOARD OF PHARMACY

Chapter 42: COMPOUNDING DRUGS FOR VETERINARIAN OFFICE USE

Summary: This chapter establishes the terms and conditions for compounding drugs for veterinarian office use pursuant to 32 M.R.S. § 13722(1)(B-2). This chapter was developed in consultation with the Maine State Board of Veterinary Medicine, in accordance with P.L. 2021, ch. 289, Sec. 15.

1. Definitions.

1. **Compounding drugs for veterinarian office use.** "Compounding drugs for veterinarian office use" means the compounding of nonpatient-specific drugs for veterinarian office use according to the terms and conditions described in this chapter.

2. **Nonfood-producing animal.** "Nonfood-producing animal" means any domesticated animal including canine, feline, fowl, bird, fish, or reptile, except those animals intended for consumption or whose products are intended for consumption by humans or other animals.

2. Pharmacy Requirements and Specifications. The pharmacy compounding drugs for veterinarian office use shall comply with USP or Current Good Manufacturing Practices and all applicable controlled substance laws and regulations.

3. General Requirements for Compounding Drugs for Veterinarian Office Use; Content of Orders.

1. **Required Information in Order**

Orders for a compounded drug for veterinarian office use shall contain, at a minimum, the following information:

A. Name, address and telephone number of the licensed veterinarian;

B. An acknowledgment, signed by the licensed veterinarian submitting the order, stating the veterinarian understands that the compounded drug is being provided for veterinarian office use and:

i. will only be dispensed or administered to nonfood-producing animals that are patients of the veterinarian with a valid veterinarian-client-patient relationship;

ii. will only be dispensed or administered for the treatment of emergency conditions or urgent situations, when, as determined by the prescribing veterinarian, urgent treatment is needed to avoid animal suffering or death and there is no timely access to a

compounding pharmacy to compound and dispense the drug under a patient-specific prescription;

iii. the quantity dispensed by a prescribing veterinarian will not exceed a 120-hour supply; and

iv. the prescribing veterinarian will provide instructions to owners to contact the prescribing veterinarian immediately if a compounded preparation has caused an adverse event or the owner suspects a defective drug product, and the veterinarian will report this information to the compounding pharmacy and the FDA Center for Veterinary Medicine.

For the purposes of this subsection, a signature may either be original or electronic.

2. **Verification**

The pharmacist who receives an order for compounded drugs for veterinarian office use shall record the order and verify the identity of the licensed veterinarian, and, if applicable, the identity and authority of the veterinarian's agent.

4. Labeling requirements. Compounding drugs for veterinarian office use shall be labeled in a conspicuous and legible manner, as appropriate for the size and attributes of the container.

The label shall include:

1. Pharmacy name, address, and telephone number;
2. Date of distribution;
3. Name, address, and telephone number of the licensed veterinarian who placed the order;
4. The name and strength of the compounded preparation or a list of the active ingredients and the strength of the active ingredients in the compounded preparation;
5. The quantity of compounded preparations;
6. Cautionary statements if appropriate for the drug;
7. An appropriate beyond-use date as determined by the pharmacist in compliance with United States Pharmacopeia and the National Formulary (USP-NF) standards for pharmacy compounding; and,
8. Text reprinted as follows:

Notice: Compounded Preparation For Veterinarian Office Use Only. Intended only for dispensing and administration for nonfood-producing animals for the treatment of emergency conditions or urgent situations, when, as determined by the prescribing veterinarian, timely access to a compounding pharmacy is not available. Intended for dispensing or administration in a quantity not to exceed a 120-hour supply.

Please contact the FDA Center for Veterinary Medicine immediately if a compounded preparation has caused an adverse event or if there is a suspected defective drug product involving these compounded preparations.

5. Record-keeping requirements.

The pharmacy compounding a drug pursuant to this chapter shall comply with all other laws and rules of the board concerning record-keeping. Any pharmacy compounding a drug pursuant to this chapter shall maintain an activity records of the distribution of the compounded drug to the veterinarian and have the ability to retrieve compounding and distribution records by both preparation and by specific veterinarian, if requested by the board or its agent.

The board or its authorized agent may inspect and make copies of any and all records of shipment, purchase, compounding record activities, quality control, and sale of these items provided, however, that such inspection shall not extend to financial data or pricing data.

6. Defective Drug Products and Adverse Events

If a pharmacist learns of an adverse event or a suspected defective drug product involving compounded preparations the pharmacy prepared, it shall without delay report this information to the board and any and all licensed veterinarians to whom, according to the pharmacy's records, the compounded preparation was provided. The pharmacist should also notify the FDA of any adverse event or product defect associated with the use of the drug within fifteen (15) days.

STATUTORY AUTHORITY:

32 M.R.S. §§ 13720, 13723, 13722(1)(B-2)

EFFECTIVE DATE:

PROPOSED