DISCUSSION DRAFT ONLY – Does not represent the opinion of the Administration or the Department
(Board Discussion Draft 05.31.2022)

REFERENCE INFORMATION FOR THE BOARD FROM THE 130TH LEGISLATIVE SESSION

32 MRSA § 13835, sub-§1: Administration of drugs by intramuscular or subcutaneous injection – (Public Law Chapter 271 (L.D. 1293)
http://www.mainelegislature.org/legis/bills/getPDF.asp?paper=SP0413&item=3&snum=130

NOTE – The first two sentences related to vaccine administration clinics were later repealed by Public Law Chapter 289 (L.D. 4) L.D. 1293 was passed related to administration of drugs by intramuscular or subcutaneous injections. The new law now reads:

§13835. Rules

The board, after consultation with the Maine Center for Disease Control and Prevention and the Board of Licensure in Medicine, shall adopt rules to implement this subchapter. The rules must include, at a minimum: [PL 2009, c. 308, §3 (NEW).]

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 the plan of operation for any vaccine administration clinics to be operated by a pharmacist or pharmacy. *Criteria for the administration of drugs by intramuscular or subcutaneous injection* inside, outside or off the premises of a retail pharmacy, rural health clinic or free clinic licensed under section 13751 and must *require one-time board approval of the plan for the administration of drugs by intramuscular or subcutaneous injection* by a pharmacist or pharmacy and may not require board approval for each administration;
[PL 2021, c. 271, §4 (AMD); PL 2021, c. 289, §14 (AMD).]

32 MRSA § 13786-E, Section 3 – Rulemaking related to access to HIV Prevention Medications – (Public Law Chapter 265 (L.D. 1115)
http://www.mainelegislature.org/legis/bills/getPDF.asp?paper=SP0378&item=4&snum=130

(NOTE – § 13786-E, Section 3 on rulemaking reads "Rules; protocols. The board by rule shall establish standards for authorizing pharmacists to prescribe, dispense and administer HIV prevention drugs in accordance with subsection 2, including adequate training requirements and protocols for when there is no prescription drug order, standing order or collaborative practice agreement…")

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

392 MAINE BOARD OF PHARMACY

Chapter 4-A: ADMINISTRATION OF DRUGS AND, ~~AND~~ VACCINES ~~AND OTHER FDA INJECTABLE DRUGS,~~ AND OPERATION OF DRUG AND VACCINE ADMINISTRATION CLINICS

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 drugs~~ 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 M.R.S. § 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;

(Board discussion – (BH) - Since the new law allows administration but not prescribing, i.e. the practitioner will have to issue either a patient specific prescription, be part of the Standing Order or CPA, would we still need to notify the practitioner? For example, the practitioner issues a patient specific prescription for Testosterone Cypionate to be injected weekly / monthly and a pharmacy administers all of these doses, is reporting to the practitioner on the

administration required or necessary? Currently, a patient would administer themselves at home and certainly don't talk to the doctor each time.
Or, is there value in having the requirement for accountability/ documentation for the patient, the pharmacist, and the prescriber/primary care provider.

Commented [NJ1]: I recommend retaining the notification requirement, even though it makes little sense where there is a prescription. Section 13831(5)(A) requires notification under Section 13833(3).

B. 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 Events 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.~~

(NOTE for Board Discussion: Reference 32 MRS § 13833 addresses the treatment protocol kept by the pharmacy, this section is not necessary.)

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 MRSA §13831(2); and
- The applicable treatment protocol issued pursuant to 32 MRSA §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 MRSA §13832(3) may administer drugs and vaccines to a person 18 years of age or older.

STATUTORY AUTHORITY: 32 MRSA §§ 13720, 13723, 13831, 13832, 13833, 13834(1), 13835

EFFECTIVE DATE:
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AMENDED:
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