

BASIS STATEMENT

EMERGENCY RULE

02-392 C.M.R. CHAPTER 36

LICENSURE OF OPIOID TREATMENT PROGRAMS

The Maine Board of Pharmacy (“Board”) adopts these emergency rule changes in 02-392 C.M.R. Ch. 36, Licensure of Opioid Treatment Programs (“OTPs”) pursuant to 32 M.R.S. § 13751(2)(A) and (3) and the Board’s emergency rulemaking authority under 5 M.R.S. § 8054 and in response to the Governor’s *Proclamation of State of Civil Emergency to Further Protect Public Health* (dated March 15, 2020) and the Governor’s Executive Order 19 FY 19/20, *An Order Regarding Essential Businesses and Operations* (effective March 24, 2020).

Purpose of Emergency Changes.

As permitted by 32 M.R.S. § 13751(3), under Chapter 36, Section 1 of its rules, the Board has designated OTPs to be a classification of “retail pharmacy” and thereby not subject to all the requirements applicable to retail pharmacies, but subject to some special requirements. Like all retail pharmacies, OTPs must obtain a license from the Board. Chapter 36, Section 2. Like all retail pharmacies, no OTP may operate without a pharmacist in charge (“PIC”). Chapter 36, Section 4(1). Like all retail pharmacies, the PIC of an OTP is responsible legally and professionally for all activities related to the practice of pharmacy within the licensed facility and for the facility’s compliance with the provisions of the Maine Pharmacy Act. Chapter 36, Section 4(2). Unlike other retail pharmacies, however, the PIC of an OTP is required to “be physically present at the facility to prepare drugs for delivery” “in properly labeled, patient-specific containers for delivery of such drugs to patients for consumption away from the facility.” Chapter 36, Section 4(2) and (3). In other types of retail pharmacies, the PIC is not required to be “physically present” for the preparation of all drug orders. Other licensed pharmacists besides the PIC may fulfill this function.

This emergency rule will amend Sections 4(2) and (3) of Chapter 36 to remove the requirement that the PIC be “physically present” for the preparation of all take-home doses and allow other licensed pharmacists who are authorized by the PIC to be present instead. The need for this emergency change is the on-going COVID-19 public health emergency and governmental recommendations and orders for individuals to shelter at home to mitigate the spread of this disease. In response, on March 11, 2020, the Substance Abuse and Mental Health Services Administration (“SAMHSA”) of the United States Department of Health and Human Services issued guidance that would allow states to request that a greater number of patients at OTPs be permitted to receive take-home doses as opposed to receiving single doses administered at the OTP. Maine subsequently requested and obtained permission that expanded the pool of patients eligible for take-home doses. As a result, a significantly greater number of patients is requesting take-home doses, which is significantly increasing the amount of time that PICs must be physically present at their respective OTPs for the preparation of take-home doses. The ability of these PICs to be physically present for all these preparations appears to be unsustainable

during the state of emergency. Allowing another licensed pharmacist to be physically present instead of the PIC will not compromise the ability of OTPs to safely prepare take-home doses.

Specific Changes to Chapter 36

1. The proposed changes will amend Section 4(2) to clarify that the PIC's responsibility for the preparation of take-home doses does not require him/her to personally supervise the preparation of each dose.
2. The proposed changes will amend Section 4(3) to remove the requirement that the PIC him/herself must be physically present at the OTP during the preparation of take-home doses and permit another licensed pharmacist authorized by the PIC to be present instead.

Findings of Emergency

1. The spread of the novel coronavirus disease referred to as COVID-19 has created a public health emergency.
2. COVID-19 is a highly contagious and sometimes fatal disease that has infected more than 130,000 persons and caused more than 2,000 deaths to this date in the United States.
3. On March 11, 2020, the COVID-19 outbreak was characterized as a pandemic by the World Health Organization.
4. On March 11, 2020, SAMHSA issued guidance that would permit states to request exceptions to restrictions pertaining on to the dispensing of take-home doses by OTPs of medication for opioid use disorder.
5. On March 15, 2020, Governor Janet T. Mills declared a State of Civil Emergency in Maine to respond to the spread of COVID-19.
6. On March 16, 2020, Maine's Office of Behavioral Health requested a blanket exemption from SAMHSA that would allow all stable patients from all ten of Maine's licensed OTPs to receive 28 days of take-home doses of medication for opioid use disorder, and on March 17, 2020, SAMHSA approved this request.
7. As a result of this expansion of patients eligible for take-home doses, there has been a significant influx in the number of take-home doses dispensed by Maine's OTPs.
8. On March 24, 2020, Governor Mills issued Executive Order 19 FY 19/20 *An Order Regarding Essential Businesses and Operations*, which ordered the cessation of or restrictions on the operation of non-essential businesses and imposed social distancing requirements on the activities of essential businesses and operations and strongly encouraged the use of telehealth.

9. The escalating COVID-19 public health emergency is likely to continue and necessitate that Maine residents curtail their movement and social interaction in order to mitigate the transmission of COVID-19.
10. During the state of emergency, patients of OTPs seeking to comply with federal and state recommendations to shelter at home in order to slow the spread of COVID-19 may not be able to venture to OTPs to receive daily administration of medication for opioid use disorder and will continue to require take-home dosing.
11. PICs of OTPs, who under the current Chapter 36 are required to be “physically present” during the preparation of all take-home doses, are finding it increasingly difficult to comply with the requirement to be physically present for the preparation of all take-home doses.
12. The requirement for the PIC of an OTP to be physically present during the preparation of all take-home doses may lead to pharmacist fatigue and error and/or patients unable to receive medication or forced to leave their homes at a frequency inconsistent with recommendations to shelter at home.
13. No public or patient safety will be compromised by allowing a licensed pharmacist other than the PIC to be present for the preparation of take-home doses at an OTP.
14. Based on the above findings, the Board concludes that an emergency exists requiring the adoption of this emergency rule. Continuing to require that the PIC him/herself be physically present at the OTP for the preparation of take-home doses as opposed to another licensed pharmacist authorized by the PIC poses an immediate threat to the public health and safety and necessitates that the Board adopt these emergency changes to Chapter 36 to avoid this threat.

This emergency rule will take effect immediately upon adoption and will be in effect for ninety days. 5 M.R.S. § 8054. To avoid any lapse in policy, the Board is concurrently engaging in the routine technical rulemaking process.

STATUTORY AUTHORITY

32 M.R.S. § 13751(2)(A) and (3); 5 M.R.S. § 8054

EFFECTIVE DATE

April, ____, 2020

DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

392 MAINE BOARD OF PHARMACY

Chapter 36: LICENSURE OF OPIOID TREATMENT PROGRAMS

Summary: This chapter provides for the licensure of opioid treatment programs.

1. Authority

An opioid treatment program is a classification of retail pharmacy regulated by the board pursuant to 32 MRSA §13751(2)(A) and §13751(3).

2. License Required; Coordination With State and Federal Regulatory Requirements

An opioid treatment program must obtain a license from the board. This chapter applies to opioid treatment programs that are—

- Certified or provisionally certified by the U.S. Department of Health and Human Services, Substance Abuse and Mental Health Services Administration pursuant to 42 CFR Part 8; and
- Licensed by the Maine Department of Health and Human Services, Division of Licensing and Regulatory Services pursuant to 14-118 CMR Chapter 5, Section 19.8.

An opioid treatment program licensed by the board pursuant to this chapter must furnish copies of its federal DHHS certification, DEA number and state DHHS license to the board prior to opening for operation.

Maintenance of federal DHHS certification and state DHHS licensure as set forth above is an ongoing requirement of licensure by the board. Any loss or lapse of federal DHHS certification or state DHHS licensure may result in disciplinary action by the board.

3. Licensure

1. Application; Fees

An application for licensure as an opioid treatment program must be filed on forms provided by the board. The application must be accompanied by the application and license fees required by Chapter 10, Section 5(27) of the rules of the Department of Professional and Financial Regulation, Office of Professional and Occupational Regulation, entitled “Establishment of License Fees.” Incomplete applications will not be accepted and will be returned to the applicant. The applicant shall provide the following information:

- A. The name, address, telephone number and email address of the person responsible for submission of the application;
- B. The name, physical address, contact address, telephone number, email address and world wide web address of the opioid treatment program;
- C. All trade or business names used or to be used by the opioid treatment program;
- D. The names of the owner of the opioid treatment program, including:
 - (1) If a partnership, the name, contact address, telephone number and employer identification number of the partnership, and the name and contact address of each partner;
 - (2) If a business corporation, the name, contact address, telephone number and employer identification number of the corporation; the name of the parent company, if any; the name, contact address and title of each corporate officer and director; the name and contact address of each shareholder owning 10% or more of the voting stock of the corporation, including over-the-counter stock, unless the company is traded on a major stock exchange and not over-the-counter; a certificate of existence from the corporation's state of organization and, for corporations not organized under Maine law, a certificate of authority from the Maine Secretary of State;
 - (3) If a nonprofit corporation, the name, contact address, telephone number and employer identification number of the corporation; the name of the parent company, if any; the name, contact address and title of each corporate officer and director; the name and contact address of each voting member; a certificate of existence from the corporation's state of organization and, for corporations not organized under Maine law, a certificate of authority from the Maine Secretary of State;
 - (4) If a limited liability company, the name, contact address, employer identification number, telephone number, fax number and email address of the limited liability company; the names and mailing addresses of each member and manager; a certificate of existence from the Maine Secretary of State or, for limited liability companies not organized under Maine law, a certificate of authority or certificate of qualification from the Maine Secretary of State; and the name of the member or manager who will be representing the applicant in matters before the board.
 - (1) If a sole proprietorship, the name, contact address, telephone number and social security number of the sole proprietor and the name of the business entity;

- E. A scaled drawing and floor plan of the opioid treatment program which details the usage of each area, including the waiting area, consultation area, dispensing area and drug storage area;
- F. Confirmation that the following equipment is available on site:
 - (1) An automated data processing system;
 - (2) Containers which meet official compendia standards, available with closures that meet Federal Poison Prevention Packaging Act of 1970 requirements, as well as regular closures;
 - (3) Prescription labels imprinted or computer-generated with the name, address, and telephone number of the opioid treatment program that do not contain any symbol or background logo that interferes with the reading and interpretation of any information written by the pharmacist on the label;
 - (4) Auxiliary labels;
 - (5) Sufficient equipment to maintain the scope of practice;
- G. Demonstration of compliance with the barrier, alarm and security camera requirements of Chapter 13, Section 6 of the board's rules;
- H. The name and license number of the pharmacist in charge of the opioid treatment program;
- I. Upon request of the board, all plumbing permits, electrical permits, certificates of occupancy and other documents necessary to show full compliance with all federal, state and local laws and rules; and
- J. Such other information as the board may require.

2. Additional Qualifications

The board will consider the following additional factors in determining the applicant's eligibility for licensure as an opioid treatment program:

- A. The applicant's past experience in the dispensing or compounding of prescription drugs;
- B. The furnishing by the applicant of false or fraudulent material in any application made in connection with the dispensing or compounding of prescription drugs;
- C. Suspension, revocation or other disciplinary action taken by a federal, state or local governmental body with respect to any type of pharmacy license currently or previously held by the applicant;

- D. Issuance of a citation, warning letter or untitled letter to the applicant by the FDA, or similar action taken by another governmental body; and
- E. Compliance with the requirements to maintain and/or to make available to the board or to federal, state or local law enforcement officials those records required to be maintained by pharmacies.

1. **Processing of Application**

- A. The board shall review the application for compliance with the pharmacy law and rules and shall issue a license upon a determination that operation of the opioid treatment program will be in the best interest of the public health and welfare.
- B. Following review of the application the board may approve the application, preliminarily deny the application, approve the application with conditions, direct the applicant to resubmit the application with specific modifications, request further information from the applicant, or investigate any of the information contained in the application. A denial shall identify the specific deficiencies in the application that resulted in the denial.

2. **Response by Applicant to Adverse Board Action**

No later than 30 days following receipt of written notice from the board, or within such longer or shorter time as the board may specify, an applicant may, as the case may be-

- A. Submit an application with modifications requested by the board;
- B. Furnish additional information requested by the board;
- C. Make site modifications requested by the board;
- D. Request a hearing to contest a preliminary denial; or
- E. Request a hearing to contest a condition imposed by the board.

Failure of the applicant to act within the applicable time period shall result in the automatic denial of the application without need of further action by the board or, in the case of applications conditionally approved, finality of the conditions.

3. **Separate License for Each Facility**

The owner of an opiate treatment program must file a separate application for each facility that dispenses or administers opioids.

4. **License Term; Renewal**

All opioid treatment program licenses expire annually on December 31. A licensee may renew the license by completing the renewal application form provided by the

board and remitting the license fee required by Chapter 10, Section 5(27) of the rules of the Department of Professional and Financial Regulation, Office of Professional and Occupational Regulation, entitled “Establishment of License Fees.”

5. Change of Ownership, Location or Application Information

Upon a change of ownership, the opioid treatment program must file a new application with the board no less than 7 days prior to the change. Upon a change of location, the opioid treatment program must file a new application with the board no less than 7 days prior to the change. The licensee shall notify the board of any other change in the information provided on its application within 10 days after the change.

6. Notice of Termination of Employment of Pharmacist For Drug-Related Reasons or Theft

An opioid treatment program shall notify the board of the termination of employment of a pharmacist for drug-related reasons or theft as required by Chapter 30, Section 1(26) of the board’s rules.

7. Alteration of Dispensing Area

An opiate treatment program may not alter the physical dimensions of the dispensing area or add or change the doors, windows or other means of access to the dispensing area prior to receiving approval from the board. The opiate treatment program must provide a scaled drawing of the proposed alteration at the time it requests approval.

[NOTE: Cosmetic changes (e.g., carpet replacement) and changes that are non-structural in nature (e.g., relocation of shelving) do not require board approval.]

4. Pharmacist in Charge

1. Generally

Dispensing of opioids and other prescription drugs must be conducted under the indirect supervision of a licensed pharmacist who has registered with the board as the pharmacist in charge of the opioid treatment program. No opioid treatment program may operate without a pharmacist in charge.

2. Responsibilities

The pharmacist in charge is responsible legally and professionally for all activities related to the practice of pharmacy within the opioid treatment program for which the licensee is registered as pharmacist in charge, and for the opioid treatment program’s compliance with the provisions of the Maine Pharmacy Act, the rules of the board, and the federal and state laws and rules specified in Chapter 29, Section 1 of the board’s rules.

The pharmacist in charge is responsible for **ensuring that preparing** doses of opiate agonist treatment medications **are prepared** in properly labeled, patient-specific containers for delivery of such drugs to patients for consumption away from the facility. The responsibilities of the pharmacist in charge also include, but are not limited to:

- A. The opioid treatment program's procedures for the procurement, storage, compounding and dispensing of drugs;
- B. The recordkeeping systems required in the practice of pharmacy for the purchase, possession, storage and repackaging of drugs; and
- C. Ensuring that the dispensing area is operating in conformance with good pharmaceutical practices.

3. **Presence **of Pharmacist** at Opioid Treatment Center**

The pharmacist in charge of an opioid treatment program **or another licensed pharmacist authorized by the pharmacist in charge** shall be physically present at the facility to prepare drugs for delivery as described in subsection 2 above. **The A** pharmacist **in charge** need not be present when drugs are delivered to patients. As set forth in Chapter 13, Section 3(4) of the board's rules, a pharmacist's application to serve as pharmacist in charge of an opioid treatment program and one other type of non-opioid pharmacy, or two opioid treatment programs and no other non-opioid pharmacy, will be approved automatically, subject to disciplinary review.

4. **Patient Counseling**

A pharmacist **in charge** may comply with the requirement of patient counseling set forth in 32 MRSA §13784 by ensuring that written directions for use and other information relating to proper utilization of the medication prescribed are included with each new prescription delivered by the opioid treatment program. The written information must include a telephone number at which the pharmacist in charge may be contacted by patients.

5. **Operational Requirements**

1. **Security**

The opioid treatment program must comply at all times with the alarm and security camera requirements of Chapter 13, Section 6 of the board's rules.

2. **Cleanliness and Sanitation**

- A. The opioid treatment program must at all times be operated in a clean and sanitary manner in compliance with all federal, state and local health laws. The program must:

- (1) Keep walls, ceilings, windows and floors clean and in good repair;

- (2) Have a sufficient number of waste receptacles in the dispensing and drug storage areas;
 - (3) Keep equipment clean and stored in an orderly manner; and
 - (4) Have adequate restroom facilities for employees and patients.
- B. All areas where drugs are dispensed or stored must be well-lighted, dry, and well-ventilated. The drug storage area must be maintained at temperatures which will ensure the integrity of the drugs prior to their dispensing as stipulated by the USP or the manufacturer's or distributor's labeling unless otherwise indicated by the board.
- C. Animals may not be kept or allowed in the dispensing or drug storage area. This provision does not apply to service animals accompanying disabled persons.

STATUTORY AUTHORITY: 32 MRSA §§ 13720, 13721(1)(E), 13722(1)(B), 13723, 13751(3),
13752, 13752-A, 13753(1)(D)

EFFECTIVE DATE:

December 11, 2013 – filing 2013-316