

**Annual List of Rulemaking Activity**  
**Rules Adopted January 1, 2020 to December 31, 2020**  
*Prepared by the Secretary of State pursuant to 5 MRS §8053-A sub-§5*

**Agency name:** Department of Professional and Financial Regulation,  
**Maine Board of Pharmacy**

**Umbrella-Unit:** **02-392**

**Statutory authority:** 32 MRS §§ 13720, 13721(1)(E), 13723, 13751, 13758, 13759

**Chapter number/title:** **Ch. 12**, Licensure of Manufacturers and Wholesalers

**Filing numbers:** **2020-114**

**Effective date:** 6/6/2020

**Type of rules:** Major Substantive

**Emergency rules:** No

**Principal reason or purpose for rules:**

*(See Basis Statement)*

**Basis statement:**

2017 Public Law ch. 267, 32 MRS §13759, “An Act to Prohibit Certain Gifts to Health Care Practitioners”, directs the Maine Board of Pharmacy to establish definitions by rule for modest meals and refreshments, and reasonable honoraria. This rule sets standards on exceptions to the general prohibition against manufacturers and wholesalers making gifts to practitioners.

**Fiscal impact of rules:**

None.

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**Agency name:** Department of Professional and Financial Regulation,  
**Maine Board of Pharmacy**

**Umbrella-Unit:** **02-392**

**Statutory authority:** 32 MRS §§ 13751(2)(A), 3; 5 MRS §8054

**Chapter number/title:** **Ch. 36**, Licensure of Opioid Treatment Programs

**Filing numbers:** **2020-089**

**Effective date:** 4/4/2020

**Type of rules:** Routine Technical

**Emergency rules:** Yes

**Principal reason or purpose for rules:**  
*(See Basis Statement)*

**Basis statement:**

The Maine Board of Pharmacy (“Board”) adopts these emergency rule changes in 02-392 CMR 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 MRS §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 MRS §13751(3), under ch. 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. Ch. 36 section 2. Like all retail pharmacies, no OTP may operate without a pharmacist in charge (“PIC”). Ch. 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*. Ch. 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.” Ch. 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 ch. 36 to remove the requirement that 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

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licensed pharmacist to be physically present instead of the PIC will not compromise the ability of OTPs to safely prepare take-home doses. During any state of civil emergency declared by the Governor related to the COVID-19 virus, no pharmacist will be required to be physically present to prepare drugs for delivery, provided that such drugs are prepared by either an advanced practice registered nurse, a registered professional nurse, or a licensed practical nurse who is: 1) licensed by the State Board of Nursing; 2) licensed by the board as a pharmacy technician; and 3) explicitly designated by the pharmacist in charge to prepare drugs in the absence of a pharmacist.

**Fiscal impact of rules:**

None.

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**Maine Board of Pharmacy**  
**Umbrella-Unit:** **02-392**  
**Statutory authority:** 32 MRS §§ 13751(2)(A), 3  
**Chapter number/title:** **Ch. 36**, Licensure of Opioid Treatment Programs  
**Filing numbers:** **2020-148**  
**Effective date:** 7/7/2020  
**Type of rules:** Routine Technical  
**Emergency rules:** No

**Principal reason or purpose for rules:**  
*(See Basis Statement)*

**Basis statement:**

The principal purpose is to make permanent the emergency rule adopted by the Maine Board of Pharmacy (“Board”) on April 4, 2010. The emergency rule changes in 02-392 CMR ch. 36, *Licensure of Opioid Treatment Programs* (“OTPs”) pursuant to 32 MRS §13751(2)(A) and (3) and the Board’s emergency rulemaking authority under 5 MRS §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).

The emergency rule amended Sections 4(2) and (3) of ch. 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. This rule was scheduled to terminate on July 3, 2020 and the Board is now making this rule permanent and expanding it to any state of civil emergency proclamation and not just the on-going COVID-19 public health 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. During any state of civil emergency declared by the Governor, no pharmacist will be required to be physically present to prepare drugs for delivery, provided that such drugs are prepared by either an advanced practice registered nurse, a registered professional nurse, or a licensed practical nurse who is: 1) licensed by the State Board of Nursing; 2) licensed by the board as a pharmacy technician; and 3) explicitly designated by the pharmacist in charge to prepare drugs in the absence of a pharmacist.

Subject to consideration for this rule was the 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.

The initial Notice of Proposed Rulemaking was published on May 27, 2020. The Board held a hearing on June 16, 2020, at which one verbal comment was made in general favor of the proposed rule with a recommended modification. The public comment period ended on June 26, 2020, at 5:00 p.m.

**Fiscal impact of rules:**  
None.