

BEFORE THE BOARD OF PHARMACY
DEPARTMENT OF LABOR AND INDUSTRY
STATE OF MONTANA

In the matter of the adoption of)
temporary emergency rule I)
pertaining to waiving the pharmacist)
to pharmacy technician ratio for)
vaccine activities and COVID-19)
testing, and temporary emergency)
rule II pertaining to allowing any)
licensed health care provider)
authorized to administer vaccines)
within their scope of practice to assist)
pharmacists in administering)
vaccines)

NOTICE OF ADOPTION OF
TEMPORARY EMERGENCY RULES

TO: All Concerned Persons

1. The Montana Board of Pharmacy (board) is adopting temporary emergency rules I and II for the following reasons:

A. On June 30, 2021, Governor Greg Gianforte rescinded Executive Order 2-2021 that had declared that a state of emergency existed in Montana due to the global outbreak of COVID-19. This action also rescinded a corresponding directive issued on March 30, 2021, to help address pharmacy staffing issues for COVID-19 vaccinations that authorized the following: waiving the pharmacist to pharmacy technician ratio for purposes of vaccine activities and allowing any licensed health care provider with authority to administer vaccines in their scope of practice to assist pharmacists in administering COVID-19 vaccines.

B. In late August 2021, pharmacy stakeholders contacted the board requesting assistance in addressing pharmacy staffing shortages and to help accommodate the increasing number of patients seeking vaccines. With overlapping vaccine activities and demands, pharmacy stakeholders requested that the board consider implementing the same provisions that had been authorized in the March 30, 2021, directive. The board considered concerns raised by the stakeholders including FDA approval of certain COVID-19 vaccines, the potential for COVID-19 booster shots, the expanded age range authorized for COVID-19 vaccines, the upcoming timeframe for administration of the seasonal influenza vaccine, and increasing requests for pharmacists to travel to facilities and employers to administer vaccines on location for patients and/or employees in determining emergency rules were necessary to address staffing shortages.

C. The federal Public Readiness and Emergency Preparedness Act (PREP Act, Public Law 109-148) authorizes pharmacists to independently order and administer authorized COVID-19 vaccines, other vaccines, and COVID-19 tests.

Pursuant to 37-7-105, MCA, pharmacists have independent authority to order and administer certain vaccines, including influenza for ages 12 and older.

D. The PREP Act also authorizes qualified pharmacy technicians who meet certain training requirements and operate under the supervision of a pharmacist, to administer authorized COVID-19, influenza, and other vaccines, and to administer COVID-19 tests. Montana law does not authorize pharmacy technicians to administer vaccines, but the restriction is preempted by PREP Act authority. By waiving the restriction of the number of pharmacy technicians that a pharmacist may supervise, in ARM 24.174.711(1), the board will reduce potential barriers for qualified pharmacy technicians to assist pharmacists in providing greater patient access to vaccines.

E. To further expand patient access to vaccines and address pharmacy staffing issues, the board recognizes provisions of the PREP Act and corresponding declaration and amendments that include preemption of any state law that would prohibit qualified health care professionals from administering COVID-19 vaccines. These changes are necessary immediately to protect the public health, safety, and welfare. Pursuant to the board's authority in 37-7-201(1)(a)(iii) and (3)(b), MCA, to regulate personnel who work in a pharmacy and to establish standards of care for patients concerning health care services that patients may expect with regard to pharmaceutical care, the board deems it necessary to allow pharmacists to utilize any health care provider licensed by this state, and qualified to administer vaccines under their scope of practice, to assist in the administration of vaccines. Such authority will further expand patient access to available vaccines and contribute to improving patient safety and public health.

F. There is reasonable necessity to immediately adopt temporary emergency rules I and II, pursuant to 2-4-303, MCA, and authorities in the PREP Act, to address the acute public health and safety issues that arise from a lack of access to COVID-19, influenza, and other vaccines, and COVID-19 testing.

2. The temporary emergency rules are effective September 14, 2021, when this rule notice is filed with the Secretary of State.

3. The board intends to implement similar provisions through the standard rulemaking process, but recognizes the need to take emergency action to address the ongoing shortages that hinder the public's ability to receive vaccines.

4. The Department of Labor and Industry (department) will make reasonable accommodations for persons with disabilities who wish to participate in the rulemaking process and need an alternative accessible format of this notice. If you require an accommodation, contact the Board of Pharmacy no later than 5:00 p.m., on October 8, 2021, to advise us of the nature of the accommodation that you need. Please contact Marcie Bough, Board of Pharmacy, 301 South Park Avenue, P.O. Box 200513, Helena, Montana 59620-0513; telephone (406) 841-2371; Montana

Relay 1 (800) 253-4091; TDD (406) 444-2978; facsimile (406) 841-2305; or dlibsdp@mt.gov (board's e-mail).

5. The text of the temporary emergency rules provides as follows:

NEW RULE I TEMPORARY EMERGENCY SUSPENSION OF PHARMACIST TO PHARMACY TECHNICIAN RATIO FOR PURPOSES OF VACCINE ACTIVITIES AND COVID-19 TESTING

(1) The terms of this temporary emergency rule expire on January 11, 2022, unless additional rulemaking is needed to continue the response to COVID-19, influenza, and other vaccine administration activities, including COVID-19 testing, to meet patient safety and public health needs.

(2) The restricted number of licensed certified pharmacy technicians and technicians-in-training that a registered pharmacist may supervise is waived with the following limitations:

(a) A registered pharmacist and pharmacy technician must be authorized to administer an authorized COVID-19 vaccine and/or influenza vaccine, in compliance with federal requirements outlined in the Public Readiness and Emergency Preparedness Act (PREP Act, Public Law 109-148) for qualified pharmacy technicians to administer authorized vaccines and COVID-19 tests.

(b) The ratio is waived solely for the purpose of administering authorized vaccines in compliance with state and federal requirements, conducting associated administrative duties and procedures, and for administering COVID-19 tests.

AUTH: 37-7-201, MCA

IMP: 37-7-101, 37-7-201, 37-7-307, 37-7-308, 37-7-309, MCA

NEW RULE II TEMPORARY EMERGENCY EXPANSION OF PERSONNEL WHO MAY WORK IN A PHARMACY OR UNDER THE SUPERVISION OF A PHARMACIST

(1) The terms of this temporary emergency rule expire on January 11, 2022, unless additional rulemaking is needed to continue the response to COVID-19, influenza, and other vaccine administration activities to meet patient safety and public health needs.

(2) The board regulates personnel who may work in a pharmacy or under the supervision of a pharmacist.

(3) The board is taking emergency action to help address pharmacy staffing shortages as an increasing number of patients are utilizing pharmacies for administration of COVID-19 vaccines, including expanded youth age ranges, and for the emerging seasonal influenza vaccine. In addition, the board is aware that facilities and employers are also requesting pharmacists come directly to their place of business to administer vaccines to employees, patients, and the community.

(4) To further expand COVID-19 and influenza vaccine access, the board is authorizing pharmacists who are qualified to prescribe, administer, and dispense authorized COVID-19, influenza, and other vaccines to use any health care provider licensed by this state, and qualified to administer vaccines under their scope of practice, to assist pharmacists in the administration of vaccines.

(5) For the purposes of this emergency rule and expanding patient access to vaccines, the board recognizes the Public Readiness and Emergency Preparedness Act (PREP Act, Public Law 109-148) and corresponding declarations and amendments that include authority for preemption of any state law that would prohibit qualified health care professionals from administering COVID-19 vaccines.

AUTH: 37-7-201, MCA

IMP: 37-7-201, MCA

REASON: In addition to the rational stated in paragraph 1, and the information provided in the federal PREP Act authorities, the board deems it necessary to adopt New Rule I as an emergency rule to temporarily waive the pharmacist to pharmacy technician ratio for purposes of vaccine administration, associated administrative activities, and for the administration of COVID-19 tests. To further expand staffing options for pharmacists, the board deems it necessary to adopt New Rule II as an emergency rule to temporarily allow any licensed health care provider who is authorized in their scope of practice to administer vaccines, to assist pharmacists in administering vaccines and in providing increased access to COVID-19 and influenza vaccines.

6. The board maintains a list of interested persons who wish to receive notices of rulemaking actions proposed by this board. Persons who wish to have their name added to the list shall make a written request that includes the name, e-mail, and mailing address of the person to receive notices and specifies that the person wishes to receive notices regarding all board administrative rulemaking proceedings or other administrative proceedings. The request must indicate whether e-mail or standard mail is preferred. Such written request may be sent or delivered to the Board of Pharmacy, 301 South Park Avenue, P.O. Box 200513, Helena, Montana 59620-0513; faxed to the office at (406) 841-2305; e-mailed to dlibsdp@mt.gov; or made by completing a request form at any rules hearing held by the agency.

7. The bill sponsor contact requirements of 2-4-302, MCA, do not apply.

BOARD OF PHARMACY
TONY KING, RPh
PRESIDENT

/s/ QUINLAN L. O'CONNOR
Quinlan L. O'Connor
Rule Reviewer

/s/ LAURIE ESAU
Laurie Esau, Commissioner
DEPARTMENT OF LABOR AND INDUSTRY

Certified to the Secretary of State September 14, 2021.