

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

In the matter of the amendment of)
ARM 24.174.701 pharmacy technician)
registration requirements, 24.174.711)
ratio of pharmacy technicians and)
interns to supervising pharmacists, and)
24.174.712 application for approval of)
utilization plan)

NOTICE OF PUBLIC HEARING ON
PROPOSED AMENDMENT

TO: All Concerned Persons

1. On February 4, 2022, at 10:00 a.m., a public hearing will be held via remote conferencing to consider the proposed amendment of the above-stated rules. There will be no in-person hearing. Interested parties may access the remote conferencing platform in the following ways:

- a. Join Zoom Meeting, <https://mt-gov.zoom.us/j/88393888233>
Meeting ID: 883 9388 8233, Passcode: 746830
- OR-
- b. Dial by telephone, +1 406 444 9999 or +1 646 558 8656
Meeting ID: 883 9388 8233, Passcode: 746830

The hearing will begin with a brief introduction by department staff to explain the use of the videoconference and telephonic platform. All participants will be muted except when it is their time to speak.

2. The Department of Labor and Industry (department) will make reasonable accommodations for persons with disabilities who wish to participate in this public hearing or 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 January 28, 2022, 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 711; facsimile (406) 841-2305; or dlibsdpaha@mt.gov (board's e-mail).

3. GENERAL REASON: The board determined it is reasonably necessary to amend three rules regarding pharmacy staffing to remove the 1:4 pharmacist to pharmacy technician ratio, change technician utilization plan requirements, and recognize use of other health care licensees in vaccine administration.

The amendments recognize provisions implemented through the board's emergency rule, MAR Notice No. 24-174-77, effective September 14, 2021, that waived the ratio for purposes of administering COVID-19 vaccines and tests and other vaccines and allowed other health care licensees to assist pharmacists in vaccine administration if authorized within their own scopes of practice. The emergency rule implemented provisions similar to those in Governor Greg

Gianforte's March 2021 directive that expired June 30, 2021, with the end of the COVID-19 state of emergency. Because the emergency rule will expire January 11, 2022, the board determined these changes are reasonably necessary to make permanent the provisions of the directive and emergency rule as requested by pharmacy stakeholders to address pharmacy staffing shortages and accommodate the increasing number of patients seeking COVID-19 and flu vaccines.

While the board did amend the ratio in 2019 (MAR Notice No. 24-174-71) from 1:3 to 1:4 and removed pharmacy interns from counting against the ratio, the proposed amendments build on past discussions and also address ongoing requests from pharmacy stakeholders to remove the ratio as has happened in 23 other states.

The board reviewed other states' requirements for specific ratios or lack of ratios, and considered pharmacy stakeholders' input. Noting that the board has received neither patient safety nor other complaints based on the ratio waiver, the board determined it is reasonably necessary to remove the technician ratio while emphasizing pharmacist-in-charge oversight and responsibility in pharmacy staffing to ensure patient safety and compliance with technician utilization plans. Further, removing the ratio will ensure continued vaccine access while allowing pharmacists more time to focus on patient care services and better utilizing the evolving role of pharmacy technicians for other authorized duties.

The board recognizes that currently pharmacy technicians have federal, not state, authority to assist pharmacists in vaccine administration and tests per the Public Readiness and Emergency Preparedness Act (PREP Act, Public Law 109-148). The PREP Act and corresponding declarations authorize pharmacists to independently order and administer authorized COVID-19 vaccines, other vaccines, and COVID-19 tests. The PREP Act also allows interns and qualified pharmacy technicians, who meet certain training requirements and operate under pharmacist supervision, to administer COVID-19 vaccines and tests and other vaccines. For reference, the board also recognizes that Montana pharmacists have independent authority to order and administer certain vaccines without a collaborative practice agreement, pursuant to 37-7-105, MCA, and ARM 24.174.501, and can utilize interns to assist in administering vaccines.

4. The rules proposed to be amended are as follows, stricken matter interlined, new matter underlined:

24.174.701 PHARMACY TECHNICIAN REGISTRATION REQUIREMENTS

(1) through (1)(f) remain the same.

(i) The board recognizes other Montana health care licensing boards as certifying entities for which licensees can assist the pharmacist(s) in administering vaccines, in compliance with state and federal requirements, under the supervision of a pharmacist, pursuant to the following restrictions:

(A) The health care licensee is in good standing with their licensing board and is authorized to administer vaccines under their own scope of practice. The health care licensee does not need a separate pharmacy technician license issued by the board.

(B) The pharmacist(s) is authorized to prescribe, dispense, and administer vaccines, pursuant to 37-7-105, MCA, and ARM 24.174.503, and in compliance with state and federal requirements.

(ii) The technician utilization plan must reflect use of health care licensees to assist pharmacists in administration of vaccines as authorized in (i) and their license must be conspicuously displayed at the pharmacy.

(2) remains the same.

(3) No pharmacist, ~~or intern,~~ or health care licensee whose license has been denied, revoked, or is currently suspended, or restricted for disciplinary purposes shall be eligible to be registered as a pharmacy technician.

AUTH: 37-1-131, 37-7-201, MCA

IMP: 37-1-305, 37-7-201, MCA

REASON: The board is amending this rule to recognize other Montana health care licensing boards as board-approved certifying entities and allow licensees with vaccine administration authority under their own scopes of practice to assist in vaccine administration. The board recognizes the success of pharmacists utilizing other licensees as authorized in the directive and emergency rules and notes that the assisting health care licensees will not need a separate license from the board, but the technician utilization plan must reflect such services.

24.174.711 RATIO OF PHARMACY TECHNICIANS AND INTERNS TO SUPERVISING PHARMACISTS (1) ~~A registered pharmacist in good standing may supervise the services of no more than four pharmacy technicians at any time. The 1:4 pharmacist to pharmacy technician ratio may be revised by the board at any time for good cause.~~ The ratio of pharmacy technicians to pharmacist(s) on duty is to be determined by the pharmacist-in-charge. A pharmacist intern does not count against the pharmacist to pharmacy technician ratio.

(2) ~~Registered pharmacists in good standing in the state of Montana may supervise a maximum of four registered pharmacy technicians~~ The pharmacist-in-charge will ensure that the number of pharmacy technicians on duty can be satisfactorily supervised by the pharmacist(s) on duty to ensure patient safety and a safe work environment, provided:

(a) in the professional judgment of the pharmacist on duty, the ratio and supervision of pharmacy technicians is adequate and manageable based on the technician's scope of practice, education, skill and experience, the policy and procedures of the pharmacy must allow for safe and accurate filling and labeling of prescriptions, and the ratio must be assessed with regard to the pharmacy's quality assurance program, pursuant to ARM 24.174.407;

(b) a technician utilization plan, as described in ARM 24.174.712, must include the policy and procedures and shall be reviewed annually. All affected supervising pharmacists and pharmacy technicians must be familiar with the contents and any changes made must be reported to the board; and

(c) a copy of the policy and procedures must be available for inspection by the board ~~compliance officer.~~

(3) ~~If a pharmacy desires more than four technicians to work under the~~

~~supervision, direction, and control of one pharmacist, the pharmacy shall obtain the prior written approval of the board. To apply for approval, the pharmacist in charge shall submit a pharmacy services plan to the board. The pharmacy services plan submitted shall demonstrate how the plan facilitates the provision of pharmaceutical care and shall include, but shall not be limited to the following:~~

- ~~(a) design and equipment;~~
- ~~(b) information systems;~~
- ~~(c) work flow; and~~
- ~~(d) quality assurance procedures.~~

~~(4) The board shall grant approval of a pharmacy service plan only when the board is satisfied that the provision of pharmaceutical care by the pharmacy will be enhanced by the increased use of technicians. An exception may be revoked by the board at any time for good cause.~~

~~(5) (3) No pharmacy shall modify a board-approved pharmacy service plan technician utilization plan without the prior written approval of the board.~~

~~(6) Nothing in this rule shall prevent a pharmacy from terminating a service plan upon written notification to the board.~~

AUTH: 37-7-201, MCA

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

REASON: The board is amending this rule to eliminate the 1:4 pharmacist to technician ratio. Following the amendment, patient and work environment safety will be ensured when the pharmacist-in-charge sets staffing ratios on duty, so the number of technicians (ratio) and supervision is adequate and manageable based on the technicians' scopes of practice, education, skill, and experience.

To align with the elimination of the ratio and the inclusion of a pharmacy's staffing ratio in the technician utilization plans, the board will no longer need to approve ratio variances. The board is striking (6) as unnecessary since all utilization plan changes, including termination must be board approved per (3).

24.174.712 APPLICATION FOR APPROVAL OF UTILIZATION PLAN (1) A ~~registered pharmacist in good standing in the state of Montana~~ The pharmacist-in-charge may apply to the board for ~~permission~~ approval to use the services of a pharmacy technician, including the use of authorized health care licensees, as described in ARM 24.174.701(1)(f), to assist pharmacists in the administration of vaccines, in compliance with state and federal requirements, by submitting to the board:

- (a) remains the same.
- (b) a summary of the technician utilization plan, to include information showing compliance with all requirements set forth in these rules, plus all other requirements of 37-7-307, 37-7-308, and 37-7-309, MCA, and this chapter;
- (c) the appropriate fee for initial approval of the technician utilization plan;
- (d) any changes in the technician utilization plan, including technician training and use of other health care licensees for administration of vaccines, as described in ARM 24.174.701(1)(f), must be resubmitted to the board for approval before implementation of the changes by the supervising pharmacist.

(2) Any number of registered pharmacists employed in the same pharmacy may sign as supervising pharmacist of a pharmacy technician on a single technician utilization plan submitted for approval to the board by that pharmacy.

(3) A ~~registered pharmacist in good standing in the state of Montana~~ pharmacist-in-charge may apply to the board to designate that pharmacy as a technician training site for a board-approved academic program curriculum. If the pharmacy training site does not have an approved technician utilization plan in place, the pharmacy may substitute an academic program training plan, assessment criteria and periodic contact plan for board approval, for the purpose of providing on-the-job experience for technician trainees.

(4) A technician utilization plan must be available for inspection by the board.

AUTH: 37-7-201, MCA

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

REASON: The board is amending the technician utilization plan requirements to reflect removal of the ratio and inclusion of other health care licensees for vaccine administration. With the shift of additional responsibility to the pharmacist-in-charge regarding ratio, the board determined it is reasonably necessary for the pharmacist-in-charge to also be the single point of communication for submitting and updating technician utilization plans.

5. Concerned persons may present their data, views, or arguments either orally or in writing at the hearing. Written data, views, or arguments may also be submitted to the Board of Pharmacy, 301 South Park Avenue, P.O. Box 200513, Helena, Montana 59620-0513, by facsimile to (406) 841-2305, or e-mail to dlibsdpba@mt.gov, and must be received no later than 5:00 p.m., February 11, 2022.

6. An electronic copy of this notice of public hearing is available at www.pharmacy.mt.gov (department and board's website). Although the department strives to keep its websites accessible at all times, concerned persons should be aware that websites may be unavailable during some periods, due to system maintenance or technical problems, and that technical difficulties in accessing a website do not excuse late submission of comments.

7. 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 dlibsdpba@mt.gov; or made by completing a request form at any rules hearing held by the agency.

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

9. Regarding the requirements of 2-4-111, MCA, the board has determined that the amendment of ARM 24.174.701, 24.174.711, and 24.174.712 will not significantly and directly impact small businesses.

Documentation of the board's above-stated determination is available upon request to the Board of Pharmacy, 301 South Park Avenue, P.O. Box 200513, Helena, Montana 59620-0513; telephone (406) 841-2371; facsimile (406) 841-2305; or to dlibspha@mt.gov.

10. Department staff has been designated to preside over and conduct this hearing.

BOARD OF PHARMACY
TONY KING, RPh
PRESIDENT

/s/ DARCEE L. MOE
Darcee L. Moe
Rule Reviewer

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

Certified to the Secretary of State January 4, 2022.