

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

In the matter of the amendment of) NOTICE OF PUBLIC HEARING ON
ARM 24.174.503 administration of) PROPOSED AMENDMENT
vaccines by pharmacists and)
24.174.1712 prescription drug registry)
fee)

TO: All Concerned Persons

1. On November 1, 2019, at 10:00 a.m., a public hearing will be held in Basement Conference Room #B-07, 301 South Park Avenue, Helena, Montana, to consider the proposed amendment of the above-stated rules.

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 October 25, 2019, 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 dlibsdpdpha@mt.gov (board's e-mail).

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

24.174.503 ADMINISTRATION OF VACCINES BY PHARMACISTS

(1) remains the same.

(2) An immunization-certified pharmacist must have a collaborative practice agreement with a practitioner authorized to prescribe drugs to administer immunizations not listed in 37-7-105, MCA, to persons ~~48~~ seven years of age or older, as provided in the most recent guidelines by vaccine and age group published by the U.S. Centers for Disease Control and Prevention (CDC) and as determined within a collaborative practice agreement; or, in the case of a public health emergency, a directive from the State Medical Officer of the Montana Department of Public Health and Human Services.

(3) An immunization-certified pharmacist, as defined in ~~37-7-105(3)(a)~~ 37-7-101, MCA, shall:

(a) and (b) remain the same.

(4) In order to administer immunizations, with or without a collaborative practice agreement, an immunization-certified pharmacist must meet the requirements of 37-7-105, MCA, and:

(a) remains the same.

(b) have access to a current edition of the ~~United States Centers for Disease~~

Control and Prevention (CDC) CDC reference "Epidemiology and Prevention of Vaccine-Preventable Diseases";

~~(c) provide a copy of the most current vaccine information statement (VIS) to the patient or the patient's legal representative, as required by 37-7-105(2)(b), MCA;~~

(d) through (d)(iv) remain the same but are renumbered (c) through (c)(iv).

(v) disposal of used or contaminated supplies; and

~~(e) ensure that the individual immunized is assessed for contraindications to immunization, as required by 37-7-105(2)(a), MCA;~~

~~(f) report any significant adverse events to the primary care provider if one is identified by the patient, and to the Vaccine Adverse Events Reporting System (VAERS), if applicable, as required by 37-7-105(2)(c), MCA; and~~

~~(g) (d)~~ maintain the following information in the patient's medical records ~~for a period of at least seven years, as required by 37-7-105(2)(d) 37-7-105, MCA,~~ which shall be considered confidential information:

(i) the patient's name, address, allergies, and date of birth ~~of the patient;~~

~~(ii) the date of administration;~~

~~(iii) (ii)~~ the product's name, dose, manufacturer, ~~dose~~, lot number, and expiration date ~~of the vaccine;~~

~~(iv) the vaccine information statement provided;~~

~~(iii) the date of administration;~~

~~(v) (iv)~~ the site and route of administration; and

~~(vi) (v)~~ the administering pharmacist's name or identifiable initials ~~of the administering pharmacist; and the pharmacy's address.~~

~~(vii) any adverse events encountered.~~

(5) and (6) remain the same.

AUTH: 37-7-201, MCA

IMP: 37-7-101, 37-7-105, 37-7-201, MCA

REASON: The 2019 Montana Legislature enacted Chapter 463, Laws of 2019 (House Bill 231), an act revising the scope of practice for pharmacists allowed to administer vaccines pursuant to 37-7-105, MCA. The bill was signed by the Governor on May 10, 2019 and was effective July 1, 2019. The board determined it is reasonably necessary to amend this rule to implement the legislation and reflect statutory changes regarding age, collaborative practice requirements, definition of an immunizing-certified pharmacist, notification, and recordkeeping.

24.174.1712 PRESCRIPTION DRUG REGISTRY FEE (1) Every person licensed under Title 37, MCA, ~~who is authorized to prescribe or dispense controlled substances,~~ prescription drugs shall pay a fee to the board for the purpose of establishing and maintaining the prescription drug registry.

(2) remains the same.

~~(3) A licensee who is not authorized to prescribe or dispense controlled substances is not required to pay the fee.~~

(4) remains the same but is renumbered (3).

AUTH: 37-1-134, 37-7-1511, 37-7-1512, MCA

IMP: 37-1-134, 37-1-141, 37-7-1511, 37-7-1512, MCA

REASON: The 2019 Montana Legislature enacted Chapter 130, Laws of 2019 (Senate Bill 61), an act revising the Montana Prescription Drug Registry (MPDR). The bill was signed by the Governor on April 10, 2019 and will become effective October 1, 2019. The board determined it is reasonably necessary to amend this rule to reflect the bill's amendments to 37-7-1511, MCA, expanding the licensees required to pay the MPDR fee. The amendment reflects that all licensees authorized under Title 37, MCA, to prescribe or dispense prescription drugs are now required to pay the MPDR fee.

4. 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 dlibsdpha@mt.gov, and must be received no later than 5:00 p.m., November 1, 2019.

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

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 dlibsdpha@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, apply and have been fulfilled. Regarding House Bill 231, the primary bill sponsor was contacted on July 18, 2019 by e-mail. Regarding Senate Bill 61, the primary bill sponsor was contacted on July 18, 2019 and September 19, 2019 by e-mail.

8. Regarding the requirements of 2-4-111, MCA, the board has determined that the amendment of ARM 24.174.503 and 24.174.1712 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 dlibsdp@mt.gov.

9. Marcie Bough, Executive Officer, has been designated to preside over and conduct this hearing.

BOARD OF PHARMACY
TONY KING, PharmD
PRESIDENT

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

/s/ GALEN HOLLENBAUGH
Galen Hollenbaugh, Commissioner
DEPARTMENT OF LABOR AND INDUSTRY

Certified to the Secretary of State September 24, 2019.