

Title 20—DEPARTMENT OF
COMMERCE AND INSURANCE
Division 2220—State Board of Pharmacy
Chapter 6—Pharmaceutical Care Standards

PROPOSED AMENDMENT

20 CSR 2220-6.050 Administration of Vaccines [Per Protocol]. The Board of Pharmacy is amending title, purpose, adding a new section (4) and renumbering as necessary, and amending sections (1) – (8).

PURPOSE: This emergency amendment implements 2023 legislative revisions to section 338.010, RSMo, and establishes pharmacist immunization procedures under revised section 338.010.1(4), RSMo.

*PURPOSE: This rule establishes [the] procedures for pharmacists [to administer vaccines per written protocol with a physician] **administering vaccines as authorized by section 338.010.1, RSMo.***

- (1) *[A pharmacist may administer vaccines authorized by Chapter 338, RSMo, pursuant to a written protocol with a Missouri licensed physician who is actively engaged in the practice of medicine. Unless otherwise restricted by the governing protocol, vaccines may be administered at any Missouri licensed pharmacy or at any non-pharmacy location as allowed in the governing protocol.] **A Missouri licensed pharmacist may order and administer vaccines as authorized by section 338.010.1, RSMo. Pharmacists must be competent to perform the services provided and maintain ongoing/continued competency. Except as otherwise authorized by law, for purposes of section 338.010.1(4), RSMo, pharmacists may administer reformulated or updated versions of vaccines authorized by the U.S. Food and Drug Administration (FDA) after January 1, 2023, provided the initial vaccine was approved by the FDA prior to January 1, 2023.***
- (2) **For vaccines administered by protocol, [T]the authorizing physician is responsible for the oversight of, and accepts responsibility for, the vaccines administered by the pharmacist.**
- (3) Pharmacist Qualifications. Pharmacists administering vaccines *[by protocol]* as authorized by *[Chapter 338, RSMo]***section 338.010.1, RSMo**, must first file a Notification of Intent (NOI) to administer vaccines with the Missouri Board of Pharmacy **via the Board of Pharmacy's website or on a form provided by the Board of Pharmacy**. To file a NOI, a pharmacist must—
 - (D) *[Notifications of Intent must be filed on the board's website or on a form approved by the board.] **Prior to administering vaccines by a route of administration not included in the original certificate program, the pharmacist must first be trained in the techniques of that route of administration by a licensed health care practitioner who is authorized to administer medication. Documentation of the required training and training date(s) must be maintained and available to the board on request.***

- (4) **Pharmacist immunization activities must be safely and properly performed in accordance with the applicable standard of care.**
- (A) **An adequate patient or medical history must be collected as deemed necessary or appropriate to allow the pharmacist to properly assess the patient.**
 - (B) **Prior to ordering or administering a vaccine authorized by Chapter 338, RSMo, the pharmacist shall use a screening procedure based on generally accepted clinical guidelines to identify appropriate patients for immunization. The pharmacist shall refer patients with a contraindication to the patient's primary care provider or an appropriate healthcare provider, as deemed necessary or appropriate.**
 - (C) **Pharmacists ordering or administering a vaccine as authorized by section 338.010, RSMo, may create a prescription in the pharmacist's name or, if applicable, the name of the governing protocol physician. The prescription may be dispensed by a licensed pharmacy and must be maintained in the prescription records of the dispensing pharmacy as provided by the Board of Pharmacy's rules. In addition to this rule, pharmacists shall comply with all applicable provisions of Chapter 338, RSMo, and the rules of the Board of Pharmacy governing prescribing and record-keeping, including, but not limited to, 20 CSR 2220-2.018.**
 - (D) **For vaccines ordered by a pharmacist, the pharmacist must maintain a patient record of each vaccine ordered that includes:**
 - 1. **The patient's name, address, and date of birth;**
 - 2. **The name and dosage of any vaccine ordered;**
 - 3. **The name and address of the patient's primary health care provider, as provided by the patient;**
 - 4. **The identity of the ordering pharmacist;**
 - 5. **Documentation of any patient screening; and**
 - 6. **Any other pertinent medical or medication information/history.**

[(4)](5) Protocol Requirements.

- (A) **[In addition to filing a NOI, pharmacists administering vaccines under this rule must first enter] A Missouri licensed pharmacist may enter** into a written protocol with a Missouri licensed physician **to order and administer vaccines authorized by section 338.010.1(4), RSMo.** The written protocol may be valid for a time period not to exceed one (1) year. The protocol must be renewed annually and include the following:
 - 1. The identity of the participating pharmacist and physician;
 - 2. Time period of the protocol;
 - 3. Authorized vaccines;
 - 4. The patient or groups of patients authorized for vaccination;
 - 5. Allowed routes and anatomic sites of administration;
 - 6. If applicable, authorization to create a prescription for each administration under the physician's name;
 - 7. **Patient assessment or referral requirements, if applicable;**
 - 7.8. **Emergency response procedures, including, but not limited to, procedures for handling/addressing adverse reactions, anaphylactic reactions, and accidental needle sticks;**
 - 7.9. **The length of time the pharmacist must observe an individual for adverse events following an injection;**

- [9.]10. Procedures for disposing of used and contaminated supplies;
- [10.]11. Authorization to administer vaccines at a non-pharmacy location, if applicable;
- [11.]12. Record-keeping requirements and any required notification procedures; and
- [12.]13. A provision allowing termination of the protocol at any time at the request of any party.

(D) Within seventy-two (72) hours after a vaccine is administered, a prescription must be created in the ordering pharmacist's name for any vaccine dispensed. For vaccines provided pursuant to an immunization protocol with a Missouri licensed physician, the prescription must be obtained from the authorizing protocol physician for any vaccine dispensed or a prescription must be created in the protocol physician's name documenting the dispensing within seventy-two (72) hours as authorized by protocol.

[(5)](6) Record keeping.

(A) The pharmacist shall ensure a record is maintained for each vaccine administered *[by protocol]* pursuant to **section 338.010.1(4), RSMo**, that includes:

1. The patient's name, address, and date of birth;
2. The date, route, and anatomic site of the administration;
3. The vaccine's name, dose, manufacturer, lot number, and expiration date;
4. The name and address of the patient's primary health care provider, as provided by the patient;
5. The identity of the administering pharmacist or, if applicable, the identity of the administering intern pharmacist or qualified pharmacy technician and supervising pharmacist; *[and]*

6. Documentation of patient screening, if applicable;

[6.]7. The nature of any adverse reaction and who was notified, if applicable*[,]*; **and**

8. Any other pertinent medical or medication information/history.

(B) *[Within seventy-two (72) hours after a vaccine is administered, a prescription must be obtained from the authorizing physician for the drug dispensed or a prescription must be created in the physician's name documenting the dispensing as authorized by protocol.]* Notwithstanding any other provision of this rule, prescription records must be maintained as provided by Chapter 338, RSMo, and the rules of the board.

(C) The records required by this rule must be securely and confidentially maintained as follows:

1. If the vaccine is administered on behalf of a pharmacy, both the pharmacy and the *[administering]* pharmacist shall ensure the records required by subsection **[(5)](6)(A)** are promptly delivered to and maintained at the pharmacy separate from the pharmacy's prescription files;
2. If the vaccine is not being administered on behalf of a pharmacy, all records shall be maintained securely and confidentially by the *[administering]* pharmacist at an address *[that shall be]* identified in **advance by the pharmacist or, if applicable, identified in** the protocol *[prior to administering the vaccine]*;
3. Prescription records must be maintained as required by Chapter 338, RSMo, and the rules of the board; and
4. Records required by this rule must be maintained for two (2) years and made available for inspecting and copying by the State Board of Pharmacy or the State Board of Registration for the Healing Arts and/or their authorized representatives. Records

maintained at a pharmacy must be produced during an inspection by the board and/or their authorized representatives. Records not maintained at a pharmacy must be produced within three (3) business days after a request from the State Board of Pharmacy, the Board of Registration for the Healing Arts and/or their authorized representative. Failure to maintain or produce records as provided by this rule shall constitute grounds for discipline.

~~[(6)]~~(7) Notification of Immunizations. Pharmacists immunizing ~~[by protocol]~~pursuant to **section 338.010.1(4), RSMo**, must—

(B) Notify the protocol physician as required by the governing protocol, **if applicable**;

(E) Unless otherwise provided by ~~[the]~~a governing protocol, notification may be made via a common electronic medication record that is accessible to and shared by both the physician and pharmacist. Proof of notification must be maintained in the pharmacist's records as provided in subsection ~~[(5)]~~(6)(B) of this rule.

~~[(7)]~~(8) Notification of Intent Renewal. A Notification of Intent (NOI) to immunize ~~[by protocol]~~as authorized by **section 338.010.1(4), RSMo**, must be renewed biennially with the immunizing pharmacist's Missouri pharmacist license. To renew a NOI, pharmacists must—

~~[(8)]~~(9) A qualified pharmacy technician immunizing pursuant to this rule must be supervised by a Missouri-licensed pharmacist who is authorized to immunize ~~[by protocol]~~pursuant to **section 338.010, RSMo**, and who is physically present on-site when the vaccine is administered.

AUTHORITY: sections [338.010,] 338.140, and 338.220, RSMo Supp. [2020] 2022 and section 338.010, Senate Bill 45, 102nd General Assembly. Emergency rule filed Oct. 24, 2007, effective Nov. 3, 2007, expired April 30, 2008. Original rule filed Oct. 24, 2007, effective May 30, 2008. Emergency amendment filed Oct. 22, 2009, effective Nov. 1, 2009, expired April 29, 2010. Amended: Filed Oct. 22, 2009, effective June 30, 2010. For intervening history, please consult the Code of State Regulations. Amended: Filed August 14, 2023.*

PUBLIC COST: This proposed amendment will not cost state agencies or political subdivisions more than five hundred dollars (\$500) in the aggregate.

PRIVATE COST: This proposed amendment will not cost private entities more than five hundred dollars (\$500) in the aggregate.

*NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with the Missouri Board of Pharmacy, PO Box 625, 3605 Missouri Boulevard, Jefferson City, MO 65102, by facsimile at (573) 526-3464, or via email at pharmacy@pr.mo.gov. To be considered, comments must be received within thirty (30) days after publication of this rule in the **Missouri Register**. No public hearing is scheduled.*