

**TITLE 20 – DEPARTMENT OF COMMERCE AND
INSURANCE****Division 2220 – State Board of Pharmacy
Chapter 6 – Pharmaceutical Care Standards****EMERGENCY 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.

EMERGENCY STATEMENT: Newly enacted Senate Bill 45 contains substantial revisions to section 338.010, RSMo, governing pharmacist immunization authority. Effective August 28, 2023, revised section 338.010.1(4), RSMo, removes statutory authority granting pharmacists ability to immunize Missouri patients pursuant to a protocol with a Missouri licensed physician, and enacts in lieu thereof provisions granting the Missouri Board of Pharmacy and the Missouri Board of Registration for the Healing Arts authority to promulgate joint rules to implement pharmacist immunization authority. According to provisional data from ShowMeVax, the Missouri Department of Health and Senior Services' statewide immunization registry, more than 2.4 million vaccines were reported to ShowMeVax as administered by/under pharmacy providers in 2022. This emergency amendment is needed to allow pharmacists to continue providing immunization services after August 28, 2023, including, seasonal influenza vaccines for the upcoming 2023 influenza season. Absent an emergency rule, patient access to pharmacy/pharmacist provided vaccine services would be critically eliminated or limited which will detrimentally impact the health, safety, and welfare of Missouri citizens. Rural Missouri communities where the local pharmacist/pharmacy may be the only available or accessible vaccination site/provider will be particularly detrimentally impacted by a gap/lapse in pharmacist immunization authority. Notably, other healthcare providers may not be able to procure adequate vaccine supplies to meet Missouri patient demand prior to the upcoming 2023 influenza season.

The emergency amendment is also needed to clarify the scope of pharmacist immunization authority under revised section 338.010.1(4), RSMo, for annually reformulated/updated FDA approved vaccines. Specifically, revised section 338.010.1(1), RSMo, prohibits pharmacists from administering vaccines approved by the U.S. Food and Drug Administration (FDA) after January 1, 2023. The board has received a significant number of inquiries from pharmacy providers, pharmacy associations, and hospital representatives since Senate Bill 45 was enacted, questioning if the January 1, 2023, vaccine date restriction in revised section 338.010.1(4), RSMo, prohibits pharmacist from administering vaccines initially approved by the FDA prior to January 1, 2023, that are reformulated/updated annually to match new virus strains. Licensees/Pharmacy representatives have indicated they may be forced to terminate or suspend pharmacist administration of these annually reformulated/updated vaccines without legal clarification on the scope of allowed pharmacist immunization authority. Significantly, this includes influenza vaccines for the upcoming 2023 influenza season which are historically reformulated/updated on an annual basis.

As a result, the Missouri State Board of Pharmacy finds there is an

immediate danger to the public health, safety, and/or welfare and a compelling governmental interest that requires this emergency action. Absent an emergency rule authorizing and clarifying pharmacist immunization authority under section 338.010, RSMo, patient access to pharmacy/pharmacist provided vaccine services would be critically eliminated or limited which will detrimentally impact the health, safety, and welfare of Missouri citizens. The scope of this emergency amendment is limited to the circumstances creating the emergency and complies with the protections extended in the Missouri and United States Constitutions. The Missouri State Board of Pharmacy believes this emergency rule is fair to all interested persons and parties under the circumstances. This emergency amendment was filed August 14, 2023, becomes effective August 28, 2023, and expires February 23, 2024.

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;

[8.]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] 2023. Emergency rule filed Oct. 24, 2007, effective Nov. 3, 2007, expired April 30, 2008. Original rule filed Oct. 24, 2007, effective May 30, 2008. For intervening history, please consult the Code of State Regulations. Emergency amendment filed Aug. 14, 2023, effective Aug. 28, 2023, expires Feb. 23, 2024. An emergency amendment and a proposed amendment covering this same material will be published in the Sept. 15, 2023, issue of the Missouri Register.

PUBLIC COST: This emergency amendment will not cost state agencies more than five hundred dollars (\$500) in the time the emergency is effective.

PRIVATE COST: This emergency amendment will not cost private entities more than five hundred dollars (\$500) in the time the emergency is effective.