Title 20—DEPARTMENT OF INSURANCE, FINANCIAL INSTITUTIONS AND PROFESSIONAL REGISTRATION
Division 2220—State Board of Pharmacy
Chapter 6—Pharmaceutical Care Standards

EMERGENCY AMENDMENT

20 CSR 2220-6.050 Administration of *[Influenza]* **Vaccines Per Protocol.** *The board is proposing to amend the title and original purpose statement, as well as sections (1) through (8) of this rule.*

PURPOSE: This rule is being amended to authorize pharmacists to administer vaccines outside of a pharmacy setting and to establish procedures and standards for administering said vaccines, as authorized by Chapter 338, RSMo.

PURPOSE: This rule establishes the procedures for pharmacists to administer [viral influenza vaccinations] ***vaccines*** *per written protocol with a physician.*

EMERGENCY STATEMENT: In the spring of 2009, the Centers for Disease Control (CDC) reported confirmed cases of novel influenza A (H1N1) in Mexico and the United States. The CDC's initial data suggested "the H1N1 virus has the potential for efficient, rapid spread among the countries." On April 26, 2009, the United States government declared a public health emergency and officially began to take steps to "actively and aggressively" implement the federal pandemic response plan.

By May 2009, the Department of Health and Human Services confirmed that "widespread infection was occurring in North America." As a result, the World Health Organization (WHO) declared "the first public health emergency of international concern under the revised 2005 International Health Regulations." According to the CDC, the virus continued to spread "rapidly" around the world resulting in a "substantial" number of cases of "severe disease and death" being reported in previously healthy young adults and children.

On June 11, 2009, the WHO issued a phase-6 global pandemic alert which denotes "widespread human infection." The phase-6 pandemic alert is currently in effect.

According to CDC data, the "United States continues to report the largest number of novel H1N1 cases of any country worldwide." By June 2009, all fifty (50) states reported novel H1N1 infection, including the state of Missouri. As of September 12, 2009, twenty-one (21) states reported "geographically widespread infection activity," including states immediately bordering the state of Missouri such as Arkansas, Illinois, Kansas, Kentucky, Oklahoma, and Tennessee.

According to the CDC, doctor visits for influenza-like illness are "higher than what is expected during the late summer" resulting in "very unusual" activity. In August 2009, the CDC officially released concerns "that the new H1N1 virus could result in a particular severe 2009-

2010 flu season." The CDC subsequently alerted the states and other public health officials that it was expediting drug approval reviews and was preparing for mass vaccination efforts on a nationwide level of unprecedented proportions.

Specifically, the CDC has recommended mass influenza vaccination for high-risk groups, including pregnant women, household contacts and caregivers, healthcare and emergency medical services personnel, all people from six (6) months through twenty-four (24) years of age, and persons aged twenty-five (25) through sixty-four (64) who have health conditions associated with higher risk of medical complications from influenza.

In August 2009, federal and state authorities, including the CDC and the Missouri Department of Health, solicited assistance from the Board of Pharmacy in implementing necessary immunization procedures/regulations to accommodate a massive immunization initiative for the 2009-2010 flu season. Both federal and state authorities anticipate the immediate need for widespread immunization activities by pharmacists and other healthcare professionals in a variety of locations, including schools, individual residences, senior centers, and other declared public areas. In Missouri, pharmacists are often the most accessible health care provider, especially in medically underserved rural areas of the state. In fact, as of September 22, 2009, the board has received reports that local Missouri public health agencies have initiated searches for volunteers with a medical background able to administer immunizations outside of a pharmacy.

Under the current rule, however, pharmacists are prohibited from immunizing or providing related immunization services outside of a licensed pharmacy. During the First Regular Session of the Ninety-fifth General Assembly, Senate Bill 296 was passed, which authorized the administration of vaccines by a pharmacist outside of a pharmacy setting.

This emergency amendment is necessary to preserve a compelling governmental interest in ensuring the availability of immunization services during this global pandemic by authorizing administration of immunizations by a pharmacist outside of the pharmacy setting and by establishing related record-keeping requirements. The amendment is also needed to prevent immediate danger to the public health, safety, and/or welfare that may result from H1N1 and inadequate or insufficient immunization availability. Notably, nearly one thousand five hundred to three thousand (1,500 to 3,000) Missouri deaths are reported each year due to influenza and/or related pneumonias. An early effective date of the amendment is necessary to allow the State Board of Pharmacy and the State Board of Registration for the Healing Arts to establish procedures for providing immunizations outside of a pharmacy setting prior to the 2009-2010 influenza season.

As a result, the State Board of Pharmacy and the State Board of Registration for the Healing Arts jointly find that there is an immediate danger to the public health, safety, and/or welfare and a compelling governmental interest that require this emergency action. A proposed amendment, which covers the same material, is published in this issue of the ***Missouri Register****. The scope of this emergency rule is limited to the circumstances creating the emergency and*

*complies with the protections extended in the **Missouri** and **United States Constitutions.** The State Board of Pharmacy and the State Board of Registration for the Healing Arts believe this emergency rule is fair to all interested persons and parties under the circumstances. This emergency rule was filed Oct. 22, 2009, effective Nov. 1, 2009 and expires Apr. 29, 2010.*

[(1) A pharmacist may administer viral influenza vaccinations:

(A) To persons twelve (12) years of age or older; and

(B) Pursuant to a written protocol authorized by a physician licensed pursuant to Chapter 334, RSMo, who is actively engaged in the practice of medicine in the state of Missouri.]

(1) A pharmacist may administer vaccines authorized by Chapter 338, RSMo, pursuant to a written protocol authorized by a physician licensed pursuant to Chapter 334, RSMo, who is actively engaged in the practice of medicine.

(A) A pharmacist shall administer vaccines in accordance with treatment guidelines established by the Centers for Disease Control (CDC) and in accordance with manufacturer's guidelines, provided that a pharmacist shall not administer vaccines to persons under twelve (12) years of age.

(B) A pharmacist shall comply with all state and federal laws and regulations pertaining to Vaccine Information Statements and informed consent requirements.

(2) A pharmacist may not delegate the administration of *[viral influenza vaccinations]* **vaccines** to another person, except to a pharmacist intern who has met **the** qualifications under subsections (4)(B), (C), and (D) and is working under the direct supervision of a pharmacist qualified to administer *[viral influenza vaccinations]* **vaccines**.

(3) The authorizing physician is responsible for the oversight of, and accepts responsibility for, the *[viral influenza vaccinations]* **vaccines** administered by the pharmacist.

(4) Pharmacist Qualifications*[—]***.**A pharmacist who is administering *[viral influenza vaccinations]* **a vaccine authorized by Chapter 338, RSMo,** must:

(A) Hold a current, unrestricted license to practice pharmacy in this state;

(B) Hold a current *[provider level]* cardiopulmonary resuscitation (CPR) certification issued by the American Heart Association or the American Red Cross *[or equivalent]*;

(C) Successfully complete a certificate program in the administration of *[viral influenza vaccinations]* **vaccines** accredited by the Accreditation Council for Pharmacy Education (ACPE) *[or a similar health authority or professional body approved by the state board of pharmacy]*;

(E) Complete a minimum of two (2) hours (0.2 CEU) of continuing education **as defined** per **calendar** year related to administration of *[viral influenza vaccinations]* **vaccines**. A pharmacist may use the continuing education hours required in this subsection as part of the total continuing education hours required for pharmacist license renewal;

(F) Provide documentation of subsections (A), (B), (C), and (E) of this section to the authorizing physician(s) prior to entering into a protocol or administering *[viral influenza vaccinations]* **vaccines**; and

(G) On a yearly basis prior to administering *[viral influenza vaccinations]* **vaccines**, establish a new protocol with the authorizing physician and notify the State Board of Pharmacy of their qualifications to do so. This notification shall include the types of drugs being administered and a statement that the pharmacist meets the requirements of subsections (A), (B), (C), (E), and (F) of this section.

(5) *[General requirements.*

(A) A pharmacist shall administer viral influenza vaccinations in accordance with treatment guidelines established by the Centers for Disease Control and Prevention (CDC) or in accordance with manufacturer's guidelines.

(B) A pharmacist shall comply with all state and federal laws and regulations pertaining to Vaccine Information Statements and informed consent requirements.

(6)] Administration by Written Protocol with a Missouri Licensed Physician.

(A) A pharmacist may enter into a written protocol with a physician for the administration of *[viral influenza vaccinations]* **vaccines authorized by Chapter 338, RSMo, provided that a pharmacist shall be prohibited from administering vaccines** to patients **under** twelve (12) years of age *[or older]*. The physician must be no further than fifty (50) miles by road, using the most direct route available, from the pharmacist who is administering the *[viral influenza vaccinations]* **vaccine**. The written protocol may be valid for a time period not to exceed one (1) year. The protocol must include the following:

1. The identity of the participating pharmacist and physician, including signatures;
2. Time period of the protocol;
3. The identification of the *[viral influenza vaccination]* **vaccines** which may be administered;
4. The identity of the patient or groups of patients to receive the authorized *[viral influenza vaccination]* **vaccine(s)**;
5. The identity of the authorized routes and anatomic sites of administration allowed;
6. A provision to create a prescription for each administration under the authorizing physician's name;
7. A provision establishing a course of action the pharmacist shall follow to address emergency situations including, but not limited to, adverse reactions, anaphylactic reactions, and accidental needle sticks;
8. A provision establishing a length of time the pharmacist shall observe an individual for adverse events following an injection;
9. A provision establishing the disposal of used and contaminated supplies;
10. The street address**es** of the pharmacy **or other locations** at which the pharmacist may administer the authorized *[viral influenza vaccination]* **vaccine**;
11. Record-keeping requirements and procedures for notification of administration; and
12. A provision that allows for termination of the protocol at the request of any party to it at any time.

(B) The protocol**, and any subsequent amendments or alterations,** shall be signed and dated by the pharmacist and authorizing physician prior to its implementation, signifying

that both are aware of its content and agree to follow the terms of the protocol. The authorizing physician and pharmacist shall each maintain a copy of the protocol from the beginning of implementation to a minimum of eight (8) years after termination of the protocol.

*[(7)]***(6)** Record Keeping.

(A) A pharmacist *[who administers a viral influenza vaccination]* **administering vaccines pursuant to this rule** shall maintain *[the following records regarding]* **a record of** each administration*[. These records must be separate from the prescription files of a pharmacy and include]* **which shall include**:

1. The name, address, and date of birth of the patient;
2. The date, route, and anatomic site of the administration;
3. The name, dose, manufacturer, lot number, and expiration date of the *[vaccination]* **vaccine**;
4. The name and address of the patient's primary health care provider, as identified by the patient;
5. The name or identifiable initials of the administering pharmacist; and
6. The nature of an adverse reaction and who was notified, if applicable.

[(B) All administrations of viral influenza vaccinations must have a prescription as authorized by protocol on file within seventy-two (72) hours after administration at a pharmacy documenting the dispensing of the drug.

(C) All records required by this regulation shall be kept by the pharmacist and be available for two (2) years from the date of such record, for inspecting and copying by the authorizing physician, the State Board of Pharmacy or the State Board of Registration for the Healing Arts and/or their authorized representatives.]

(B) If the vaccine was administered on behalf of a pharmacy, the pharmacist shall ensure the records required by subsection (6)(A) of this rule are promptly delivered to the pharmacy.

(C) Within seventy-two hours (72) hours after administration of a vaccine, the administering pharmacist shall obtain a prescription from the authorizing physician for the drug dispensed or shall create a prescription, as authorized by protocol documenting the dispensing of the drug. Notwithstanding any other provision of this rule, prescription records shall be maintained as provided by Chapter 338, RSMo, and the rules of the board.

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

1. If the vaccine is administered on behalf of a pharmacy, both the pharmacy and the administering pharmacist shall ensure that all records required by this rule are maintained at the pharmacy separate from the prescription files of the pharmacy. 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 the protocol prior to administering the vaccine; and

2. **Records shall be maintained for two (2) years from the date of such record and shall be 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 shall be produced within three (3) business days after a request from the State Board of Pharmacy and/or its authorized representative. Failure to maintain or produce records as provided by this rule shall constitute grounds for discipline.**

*[(8)]***(7)** Notification Requirement.

(A) A pharmacist administering *[viral influenza vaccinations]* **vaccines authorized by Chapter 338, RSMo,** shall notify the authorizing physician within seventy-two (72) hours after administration of the following:
1. The identity of the patient;
2. The identity of the *[viral influenza vaccination]* **vaccine(s)** administered;
3. The route of administration;
4. The anatomic site of the administration;
5. The dose administered; and
6. The date of administration.

(B) The pharmacist shall provide a written report to the patient's primary health care provider, if different than the authorizing physician, containing the documentation required in subsection (A) of this section within fourteen (14) days of the administration.

(C) In the event of any adverse event or reaction experienced by the patient pursuant to a written protocol, the pharmacist shall notify the patient's primary health care provider and authorizing physician, if different, within twenty-four (24) hours after learning of the adverse event or reaction.

(D) A pharmacist administering *[viral influenza vaccinations]* **vaccine(s)** shall report the administration to all entities as required by state or federal law.

(E) Documentation that notifications required by this rule have been sent must be maintained as provided in section (6) of this rule.

*AUTHORITY: section**s** 338.010, [RSMo Supp. 2007 and section] 338.140, [RSMo 2000]**and 338.220, as amended by Senate Bill 296, 95th General Assembly, First Regular Session (2009)**.* 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 rule filed Oct. 22, 2009, effective Nov. 1, 2009 and expires Apr. 29, 2010.*