

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

EMERGENCY RULE

20 CSR 2220-6.055 Non-Dispensing Activities

PURPOSE: This rule establishes procedures and requirements for the performance of non-dispensing activities outside of a pharmacy.

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 and Senior Services, solicited assistance from the State 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.

As a result, the board has simultaneously filed a proposed emergency amendment to the current 20 CSR 2220-6.050 to authorize the administration of vaccines by a pharmacist outside of a pharmacy setting. However, to properly provide immunization services, a pharmacist would be required under current federal, state, and medical guidelines to perform a variety of non-dispensing activities within the practice of pharmacy to properly assess a patient's suitability for vaccination. These activities include, but are not limited to, obtaining patient information, reviewing patient records, patient assessment/evaluation, and consultation with other health care professionals. Under current law, the non-dispensing activities identified in the proposed emergency rule constitute the practice of pharmacy when conducted by a licensed pharmacist and can only be performed within a licensed pharmacy.

During the First Regular Session of the Ninety-fifth General Assembly, Senate Bill 296 was passed, which specifically allows a pharmacist to perform "non-dispensing" activities outside of a licensed pharmacy, as provided by the rules of the board. In the absence of an immediate rule, a Missouri pharmacist would be essentially prohibited from vaccinating outside of a pharmacy setting if the pharmacist is not allowed to perform the necessary non-dispensing activities required for proper vaccination outside of the pharmacy.

As a result and in light of the current pandemic, this emergency amendment is necessary to preserve a compelling governmental interest in ensuring the availability of immunization services during this global pandemic by authorizing non-dispensing activities outside of a 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 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 finds 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 rule, 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 believes this emergency rule is fair to all interested persons and parties under the circumstances. This emergency rule was filed Oct. 23, 2009, effective Nov. 2, 2009 and expires Apr. 30, 2009.*

- (1) Pursuant to section 338.220, RSMo, a pharmacist may perform the following non-dispensing activities outside of a licensed pharmacy:
 - (A) Patient counseling/education, as authorized by Missouri law, provided the pharmacist shall be obligated to comply with 20 CSR 2220-2.190, when applicable;
 - (B) Obtain patient history/information;
 - (C) Review patient records/medical histories;
 - (D) Patient assessment/evaluation, as authorized by Missouri law;
 - (E) Billing and insurance claim submissions/review;
 - (F) Drug utilization review;
 - (G) Assess health plan and medication eligibility/coverage;
 - (H) Pharmacy compliance audits/evaluations;
 - (I) Administer drugs, vaccines, or biologicals, as authorized by law and the rules of the board;
 - (J) Peer review/peer consultations;
 - (K) Review, select, and develop formularies or plan/practice guidelines;
 - (L) Review compliance with benefit guidelines;
 - (M) Manage inventory, including purchasing and ordering;
 - (N) Manage/review information systems;
 - (O) Patient medication review;
 - (P) Consultation with other health care professionals;
 - (Q) Patient referrals;
 - (R) Prescription order entry/review, provided that a pharmacist shall only be authorized to accept a prescription on the premises of a Missouri licensed pharmacy, as required by section 383.095.5, RSMo; and
 - (S) Medication therapy management, pursuant to and as authorized by Chapter 338, RSMo, and the rules of the board.
- (2) Confidentiality. A pharmacist performing non-dispensing activities pursuant to this rule shall comply with all applicable state and federal confidentiality laws and regulations and shall provide sufficient storage and security for confidential documents and electronic data processing hardware. In addition, data processing systems must utilize sufficient security software to ensure confidentiality and prevent unauthorized access. Any breach in the security or confidentiality of the data processing systems or confidential documents shall be documented and reported to the board in writing within seven (7) days of the breach.

- (3) Notwithstanding any other provision of this rule, a pharmacist shall not meet with patients in the pharmacist's residence or living quarters.
- (4) A pharmacist performing non-dispensing activities pursuant to this rule shall ensure compliance with Chapter 338, RSMo, and the rules of the board at all times. Nothing in this rule shall be construed to eliminate or otherwise exempt any pharmacist from the record-keeping, confidentiality, or security requirements otherwise imposed by Chapter 338, RSMo, or the rules of the board. Violations of this section shall constitute grounds for discipline.
- (5) This rule shall not be construed to authorize a pharmacist to conduct the unauthorized practice of medicine or to conduct any activity for which a license is required pursuant to Chapters 330, 331, 332, 334, or 337, RSMo.
- (6) A pharmacy permit shall be required for performing non-dispensing activities if the pharmacist is using a pharmacy technician to assist in the practice of pharmacy at the location where non-dispensing activities are being performed, provided that a pharmacy permit shall not be required for sites used solely by the pharmacist for administering vaccines as authorized by Chapter 338, RSMo, and the rules of the board. Pharmacy technicians shall only be authorized to work under the direct supervision of a pharmacist as provided by section 338.013, RSMo, and 20 CSR 2220-2.700.

AUTHORITY: Sections 338.010, 338.140 and 338.220, RSMo, as amended by Senate Bill 296, 95th General Assembly, First Regular Session (2009). Emergency rule filed Oct. 23, 2009, effective Nov. 2, 2009 and expires Apr. 30, 2009.