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SALUS POPULI SUPREMA LEX ESTO

"The welfare of the people shall be the supreme law."



ROBIN CARNAHAN
SECRETARY OF STATE

MISSOURI
REGISTER

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IN THIS ISSUE:

EMERGENCY RULES

Department of Agriculture
 Missouri Agricultural and Small Business Development Authority2527

Department of Revenue
 Director of Revenue2528

Elected Officials
 Treasurer2528

Department of Insurance, Financial Institutions and Professional Registration
 State Board of Registration for the Healing Arts2529
 State Board of Pharmacy2531

Department of Social Services
 MO HealthNet Division2549

DISSOLUTIONS2550

SOURCE GUIDES

RULE CHANGES SINCE UPDATE2555
EMERGENCY RULES IN EFFECT2564
EXECUTIVE ORDERS2566
REGISTER INDEX2569

PROPOSED RULES

Department of Revenue
 Director of Revenue2536

Elected Officials
 Treasurer2540

Department of Insurance, Financial Institutions and Professional Registration
 State Board of Registration for the Healing Arts2540
 State Board of Pharmacy2542

ORDERS OF RULEMAKING

Department of Agriculture
 State Milk Board2546

Department of Revenue
 Director of Revenue2549

Register Filing Deadlines	Register Publication Date	Code Publication Date	Code Effective Date
August 3, 2009 August 17, 2009	September 1, 2009 September 15, 2009	September 30, 2009 September 30, 2009	October 30, 2009 October 30, 2009
September 1, 2009 September 15, 2009	October 1, 2009 October 15, 2009	October 31, 2009 October 31, 2009	November 30, 2009 November 30, 2009
October 1, 2009 October 15, 2009	November 2, 2009 November 16, 2009	November 30, 2009 November 30, 2009	December 30, 2009 December 30, 2009
November 2, 2009 November 16, 2009	December 1, 2009 December 15, 2009	December 31, 2009 December 31, 2009	January 30, 2010 January 30, 2010
December 1, 2009 December 15, 2009	January 4, 2010 January 15, 2010	January 29, 2010 January 29, 2010	February 28, 2010 February 28, 2010
January 4, 2010 January 15, 2010	February 1, 2010 February 16, 2010	February 28, 2010 February 28, 2010	March 30, 2010 March 30, 2010
February 1, 2010 February 16, 2010	March 1, 2010 March 15, 2010	March 31, 2010 March 31, 2010	April 30, 2010 April 30, 2010
March 1, 2010 March 15, 2010	April 1, 2010 April 15, 2010	April 30, 2010 April 30, 2010	May 30, 2010 May 30, 2010
April 1, 2010 April 15, 2010	May 3, 2010 May 17, 2010	May 31, 2010 May 31, 2010	June 30, 2010 June 30, 2010

Documents will be accepted for filing on all regular workdays from 8:00 a.m. until 5:00 p.m. We encourage early filings to facilitate the timely publication of the *Missouri Register*. Orders of Rulemaking appearing in the *Missouri Register* will be published in the *Code of State Regulations* and become effective as listed in the chart above. Advance notice of large volume filings will facilitate their timely publication. We reserve the right to change the schedule due to special circumstances. Please check the latest publication to verify that no changes have been made in this schedule. To review the entire year's schedule, please check out the website at <http://www.sos.mo.gov/adrules/pubsched.asp>

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HOW TO CITE RULES AND RSMo

RULES—Cite material in the *Missouri Register* by volume and page number, for example, Vol. 28, *Missouri Register*, page 27. The approved short form of citation is 28 MoReg 27.

The rules are codified in the *Code of State Regulations* in this system—

Title	Code of State Regulations	Division	Chapter	Rule
1	CSR	10-	1.	010
Department		Agency, Division	General area regulated	Specific area regulated

They are properly cited by using the full citation, i.e., 1 CSR 10-1.010.

Each department of state government is assigned a title. Each agency or division within the department is assigned a division number. The agency then groups its rules into general subject matter areas called chapters and specific areas called rules. Within a rule, the first breakdown is called a section and is designated as (1). Subsection is (A) with further breakdown into paragraph 1., subparagraph A., part (I), subpart (a), item I. and subitem a.

RSMo—The most recent version of the statute containing the section number and the date.

Rules appearing under this heading are filed under the authority granted by section 536.025, RSMo 2000. An emergency rule may be adopted by an agency if the agency finds that an immediate danger to the public health, safety, or welfare, or a compelling governmental interest requires emergency action; follows procedures best calculated to assure fairness to all interested persons and parties under the circumstances; follows procedures which comply with the protections extended by the *Missouri* and the *United States Constitutions*; limits the scope of such rule to the circumstances creating an emergency and requiring emergency procedure, and at the time of or prior to the adoption of such rule files with the secretary of state the text of the rule together with the specific facts, reasons, and findings which support its conclusion that there is an immediate danger to the public health, safety, or welfare which can be met only through the adoption of such rule and its reasons for concluding that the procedure employed is fair to all interested persons and parties under the circumstances.

Rules filed as emergency rules may be effective not less than ten (10) days after filing or at such later date as may be specified in the rule and may be terminated at any time by the state agency by filing an order with the secretary of state fixing the date of such termination, which order shall be published by the secretary of state in the *Missouri Register* as soon as practicable.

All emergency rules must state the period during which they are in effect, and in no case can they be in effect more than one hundred eighty (180) calendar days or thirty (30) legislative days, whichever period is longer. Emergency rules are not renewable, although an agency may at any time adopt an identical rule under the normal rulemaking procedures.

Title 2—DEPARTMENT OF AGRICULTURE
Division 100—Missouri Agricultural and Small Business
Development Authority
Chapter 6—Single-Purpose Animal Facilities Loan
Guarantee Program

EMERGENCY AMENDMENT

2 CSR 100-6.010 Description of Operation, Definitions, Fee Structures, Applicant Requirements, and Procedures for Making and Collecting Loans and Amending the Rules for the Single-Purpose Animal Facilities Loan Guarantee Program. The authority is amending subsections (2)(H) and (3)(C), deleting subsection (3)(E) and renumbering thereafter, and amending subsection (4)(E).

PURPOSE: This emergency amendment is to expand the program in order to offer guarantees on operating loans, as well as refinancing and restructuring of agricultural debt, for qualifying operations.

EMERGENCY STATEMENT: The current lending crisis and economic conditions have caused severe financial strain for Missouri livestock producers. This emergency amendment is necessary to allow credit to flow to livestock producers who may not be able to obtain financing otherwise. This emergency amendment broadens the types of loans that can be guaranteed through the Single-Purpose Animal Facilities Loan Guarantee Program. The urgency is due to the severity of the situation facing Missouri's animal agriculture industry. The

recession, combined with H1N1 fears, has caused pork prices to drop more than twenty-five percent (25%) year over year. Milk prices paid to farmers have dropped more than fifty percent (50%). Farmers are struggling to obtain financing to keep their operation running day-to-day during this "perfect storm" of poor economic conditions, poor lending conditions, and the temporary drop in commodity prices. This emergency amendment is necessary to free up lending to these farmers. Agriculture is the single largest industry in the state of Missouri and protecting this industry is a matter of public welfare. This emergency amendment was filed October 22, 2009, becomes effective November 2, 2009, and expires April 30, 2010.

(2) Definitions. As used in this rule, the following terms shall mean:

(H) Single-purpose animal facilities loan means a **collateralized** loan to finance the acquisition, construction, improvement, [or] rehabilitation, or operation of land, buildings, facilities, equipment, machinery, and animal waste facilities used to produce poultry, hogs, beef or dairy cattle, or other animals.

(3) Criteria Relating to Participating Borrowers and Single-Purpose Animal Facilities Loan Guarantee Program.

(C) **Initial** [C]certificates of guaranty cannot be issued for a period exceeding ten (10) years. **Refinancing of loans previously guaranteed by the Single-Purpose Animal Facilities Loan Guarantee Program may extend the guaranty as approved by the Missouri Agricultural and Small Business Development Authority.**

[(E)] *Loan guarantees made under the program may not apply to refinancing of loans.*

[(F)](E) Loans made under the program may not be assigned by the lender without approval of the authority.

[(G)](F) Loans made under the program may not be extended beyond the original time established for the loan without prior approval of the authority.

[(H)](G) The authority will receive a loan participation fee of one percent (1%), with the fee being collected from the borrower by the lender and submitted to the authority at the time the loan is closed.

[(I)](H) The authority will receive a special loan guarantee fee of up to one percent (1%) per annum of the outstanding principal which shall be collected from the borrower by the lender and paid to the authority.

[(J)](I) The rate of interest to be charged to a borrower will be negotiated between the lender and the borrower, but cannot exceed the rate normally charged by the lender for similar loans.

[(K)](J) The loan amortization schedule will be negotiated between the lender and the borrower. Payments may be repaid monthly, quarterly, semi-annually, annually, or in installments that coincide with payments as they are normally received for the products being sold or delivered.

[(L)](K) Borrowers may accelerate payments, including early payoff of the loan without incurring a prepayment penalty.

(4) Procedure for Making Eligible Loans.

(E) Upon determining that all requirements for the loan guarantee are met, the authority will issue to the lender a certificate of guaranty for up to fifty percent (50%) of any loss of the loan amount on a declining principal basis, and for a period not exceeding ten (10) years, **except in the case of refinances as approved by the authority.**

AUTHORITY: sections 348.195 and 348.210, RSMo Supp. [2003] 2008. Original rule filed Feb. 15, 1995, effective July 30, 1995. Amended: Filed Sept. 15, 2003, effective March 30, 2004. Emergency amendment filed Oct. 22, 2009, effective Nov. 2, 2009, expires April 30, 2010.

**Title 12—DEPARTMENT OF REVENUE
Division 10—Director of Revenue
Chapter 41—General Tax Provisions**

EMERGENCY AMENDMENT

12 CSR 10-41.010 Annual Adjusted Rate of Interest. The department proposes to amend section (1).

PURPOSE: Under the Annual Adjusted Rate of Interest (section 32.065, RSMo), this amendment establishes the 2010 annual adjusted rate of interest to be implemented and applied on taxes remaining unpaid during calendar year 2010.

EMERGENCY STATEMENT: The director of revenue is mandated to establish, not later than October 22, an annual adjusted rate of interest based upon the adjusted prime rate charged by banks during September of that year as set by the Board of Governors of the Federal Reserve rounded to the nearest full percent. This emergency amendment is necessary to ensure public awareness and to preserve a compelling governmental interest requiring an early effective date in that the amendment informs the public of the established rate of interest to be paid on unpaid amounts of taxes for the 2010 calendar year. A proposed amendment that covers the same material is published in this issue of the *Missouri Register*. The director has limited the scope of the emergency amendment to the circumstances creating the emergency. The director has followed procedures calculated to assure fairness to all interested persons and parties and has complied with protections extended by the *Missouri and United States Constitutions*. This emergency amendment was filed October 27, 2009, becomes effective January 1, 2010, and expires June 29, 2010.

(1) Pursuant to section 32.065, RSMo, the director of revenue upon official notice of the average predominant prime rate quoted by commercial banks to large businesses, as determined and reported by the Board of Governors of the Federal Reserve System in the Federal Reserve Statistical Release H.15(519) for the month of September of each year has set by administrative order the annual adjusted rate of interest to be paid on unpaid amounts of taxes during the succeeding calendar year as follows:

Calendar Year	Rate of Interest on Unpaid Amounts of Taxes
1995	12%
1996	9%
1997	8%
1998	9%
1999	8%
2000	8%
2001	10%
2002	6%
2003	5%
2004	4%
2005	5%
2006	7%
2007	8%
2008	8%
2009	5%
2010	3%

AUTHORITY: section 32.065, RSMo 2000. Emergency rule filed Oct. 13, 1982, effective Oct. 23, 1982, expired Feb. 19, 1983. Original rule filed Nov. 5, 1982, effective Feb. 11, 1983. For intervening history, please consult the *Code of State Regulations*. Emergency amendment filed Oct. 27, 2009, effective Jan. 1, 2010, expires June 29, 2010. A proposed amendment covering this same material is published in this issue of the *Missouri Register*.

**Title 15—ELECTED OFFICIALS
Division 50—Treasurer
Chapter 2—Linked Deposit Program**

EMERGENCY AMENDMENT

15 CSR 50-2.050 Interest Rate on Linked Deposit Loans [and Loan Categories]. The state treasurer’s office is amending sections (1), (2), (3), and (4) and deleting sections (5) and (6).

PURPOSE: This amendment informs the public of changes to the procedure to be used to set the interest rate under the Linked Deposit Program.

PURPOSE: This rule establishes the procedure to be used to set the interest rate [on loan categories] under the Linked Deposit Program and the maximum interest rate on loans in [those categories] this program.

EMERGENCY STATEMENT: This emergency amendment informs the public of changes to the procedure to be used to set the interest rate under the Linked Deposit Program. This emergency amendment is necessary to preserve the compelling governmental interest of avoiding any confusion by lending institutions and their consumers about the correct procedure to set the interest rate for linked deposit loans. Without amending the rule through the emergency process, lending institutions may not know how to calculate the interest rate for the two (2) new loan programs created by HB 883. HB 883 was truly agreed and finally passed in May 2009 and signed into law by Governor Nixon on June 29, 2009. It had an effective date of August 28, 2009. HB 883 created two (2) new linked deposit loan programs, eligible alternative energy consumer and eligible governmental entity. The current rule does not include a process for setting the interest rate for the new loan programs. An incorrect interest rate could harm consumers if it is set at the wrong rate. Further, lending institutions may be burdened by administrative tasks when they set the interest rate at the incorrect level and have to go back and correct the interest rate to the appropriate level. As a result, the state treasurer’s office finds the amendment is necessary to preserve a compelling governmental interest, which requires 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 amendment is limited to the circumstances creating the emergency and complies with the protections extended in the *Missouri and United States Constitutions*. The state treasurer’s office believes this emergency amendment is fair to all interested parties under the circumstances. This emergency amendment was filed Oct. 28, 2009, becomes effective Nov. 7, 2009, and expires May 5, 2010.

(1) [The interest rate on loan categories under the Linked Deposit Program shall be equal to the prime rate, as published in the *Wall Street Journal*, on the first business day of any given week, plus one and a half percent (1.50%). This rate shall apply to the following linked deposit loan categories: Agri-Business, Beginning Farmer (if loan is less than one hundred thousand dollars (\$100,000)), Farming Operation, Livestock Operation, Marketing Operation, Small Business, Student Borrower, and Water Supply System.] For all linked deposit loan applications, the lending institution shall certify the interest rate on the loan to be made to the applicant based on the lending institution’s assessment of the applicant’s credit risks and profile and other relevant factors as determined by the lending institution. Upon acceptance of the linked deposit application by the Office of the State Treasurer and acceptance of the linked deposit to be placed with the lending institution, the interest rate on the loan shall be no greater than seventy percent (70%) of the above rate certified by the lending institution. The loan rate must be approved by the Office of the State Treasurer,

and, upon placement of the linked deposit, the loan rate shall remain fixed for the period agreed to by the lending institution and the Office of the State Treasurer, not to exceed a period of five (5) years and subject to adjustment under the terms and conditions described in section (4).

(2) The treasurer's office will advise [financial] lending institutions of the applicable category loan rate upon request and at the time a deposit offer is made under the program.

(3) The treasurer's office will [monitor interest rate markets and adjust the interest rates for each respective loan category upon changes in the prime lending rate] advise lending institutions of the deposit rate and loan rate at the time a deposit offer is made under the program.

(4) [The interest rate on the linked deposit loan made to a borrower in any of the categories listed in section (1) above, shall be no greater than seventy-five percent (75%) of the interest rate established in section (1) above.] Upon placement of a [loan] linked deposit, the interest rate for the loan shall remain fixed for [a period of one (1) year] the term; except, if it so provides in the loan agreement, the lending [financial] institution may increase the interest rate on the loan, up to the category rate established by the treasurer, if the treasurer determines that the borrower has not complied with the law relating to the Linked Deposit Program and, as a result, the treasurer has received the full market interest rate on the deposit from the [financial] lending institution.

[15] In a linked deposit loan application made for a Job Enhancement Business and Beginning Farmer (if loan is one hundred thousand dollars (\$100,000) or more), the lending financial institution shall certify the present market borrowing rate applicable on a one (1) year fixed rate loan to the borrower. The lending financial institution shall also certify the interest rate on the loan to be made to the borrowing Job Enhancement Business under the Linked Deposit Program, but the interest rate on the loan shall be no greater than seventy percent (70%) of the certified market rate. The loan rate must be approved by the state treasurer and, upon placement of the linked deposit, the loan rate shall remain fixed for a period of one (1) year, subject to adjustment under the terms and conditions described in section (4), above.

(6) In a linked deposit loan application made for a residential property developer or a residential property owner, the lending financial institution shall certify the present market borrowing rate applicable on a three (3) year fixed rate loan to that borrower. The lending financial institution shall also certify the interest rate on the loan to be made to the residential property developer or residential property owner under the Linked Deposit Program, but the interest rate on the loan shall be no greater than seventy-five percent (75%) of the certified market rate for a loan up to one hundred thousand dollars (\$100,000), nor greater than seventy percent (70%) of the certified market rate for a loan of one hundred thousand dollars (\$100,000) or more. The loan rate must be approved by the state treasurer and, upon placement of the linked deposit, the loan rate shall remain fixed for a period of up to three (3) years, subject to adjustment under the terms and conditions described in section (4), above.]

AUTHORITY: sections 30.260 and 30.760, RSMo [2000] Supp. 2008. Emergency rule filed March 7, 1986, effective March 27, 1986, expired July 14, 1986. Original rule filed June 26, 1986, effective Oct. 15, 1986. For intervening history, please consult the Code of State Regulations. Emergency amendment filed Oct. 28, 2009,

effective Nov. 7, 2009, expires May 5, 2010. A proposed amendment covering this same material is published in this issue of the Missouri Register.

**Title 20—DEPARTMENT OF INSURANCE,
FINANCIAL INSTITUTIONS AND PROFESSIONAL
REGISTRATION
Division 2150—State Board of Registration for the
Healing Arts
Chapter 5—General Rules
EMERGENCY AMENDMENT**

20 CSR 2150-5.025 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 amendment 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 amendment is fair to all interested persons and parties under the circumstances. This emergency amendment was filed October 22, 2009, becomes effective November 1, 2009, and expires April 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:

(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)](5) 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 addresses 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 [r]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 334.125, RSMo 2000 and sections 338.010I, RSMo Supp. 2007] and 338.220, as amended by Senate Bill 296, Ninety-fifth 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 amendment filed Oct. 22, 2009, effective Nov. 1, 2009, expires April 29, 2010. A proposed amendment covering this same material is published in this issue of the Missouri Register.

**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 amendment 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 amendment is fair to all interested persons and parties under the circumstances. This emergency amendment was filed October 22, 2009, becomes effective November 1, 2009, and expires April 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:

- (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)](5) 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 addresses 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 notifica-

tion 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: sections 338.010, [RSMo Supp. 2007 and section] 338.140, [RSMo 2000] and 338.220, as amended by Senate Bill 296, Ninety-fifth 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 amendment filed Oct. 22, 2009, effective Nov. 1, 2009, expires April 29, 2010. A proposed amendment covering this same material is published in this issue of the Missouri Register.

**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 rule 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 rule 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 rule 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 October 23, 2009, becomes effective November 2, 2009, and expires April 30, 2010.

(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, Ninety-fifth General Assembly, First Regular Session 2009. Emergency rule filed Oct. 23, 2009, effective Nov. 2, 2009, expires April 30, 2010. A proposed rule covering this same material is published in this issue of the Missouri Register.

Under this heading will appear the text of proposed rules and changes. The notice of proposed rulemaking is required to contain an explanation of any new rule or any change in an existing rule and the reasons therefor. This is set out in the Purpose section with each rule. Also required is a citation to the legal authority to make rules. This appears following the text of the rule, after the word "Authority."

Entirely new rules are printed without any special symbolology under the heading of the proposed rule. If an existing rule is to be amended or rescinded, it will have a heading of proposed amendment or proposed rescission. Rules which are proposed to be amended will have new matter printed in boldface type and matter to be deleted placed in brackets.

An important function of the *Missouri Register* is to solicit and encourage public participation in the rulemaking process. The law provides that for every proposed rule, amendment, or rescission there must be a notice that anyone may comment on the proposed action. This comment may take different forms.

If an agency is required by statute to hold a public hearing before making any new rules, then a Notice of Public Hearing will appear following the text of the rule. Hearing dates must be at least thirty (30) days after publication of the notice in the *Missouri Register*. If no hearing is planned or required, the agency must give a Notice to Submit Comments. This allows anyone to file statements in support of or in opposition to the proposed action with the agency within a specified time, no less than thirty (30) days after publication of the notice in the *Missouri Register*.

An agency may hold a public hearing on a rule even though not required by law to hold one. If an agency allows comments to be received following the hearing date, the close of comments date will be used as the beginning day in the ninety (90)-day-count necessary for the filing of the order of rulemaking.

If an agency decides to hold a public hearing after planning not to, it must withdraw the earlier notice and file a new notice of proposed rulemaking and schedule a hearing for a date not less than thirty (30) days from the date of publication of the new notice.

Reserve Statistical Release H.15(519) for the month of September of each year has set by administrative order the annual adjusted rate of interest to be paid on unpaid amounts of taxes during the succeeding calendar year as follows:

Calendar Year	Rate of Interest on Unpaid Amounts of Taxes
1995	12%
1996	9%
1997	8%
1998	9%
1999	8%
2000	8%
2001	10%
2002	6%
2003	5%
2004	4%
2005	5%
2006	7%
2007	8%
2008	8%
2009	5%
2010	3%

AUTHORITY: section 32.065, RSMo 2000. Emergency rule filed Oct. 13, 1982, effective Oct. 23, 1982, expired Feb. 19, 1983. Original rule filed Nov. 5, 1982, effective Feb. 11, 1983. For intervening history, please consult the Code of State Regulations. Emergency amendment filed Oct. 27, 2009, effective Jan. 1, 2010, expires June 29, 2010. Amended: Filed Oct. 27, 2009.

PUBLIC COST: This proposed amendment will cost state agencies or political subdivisions more than five hundred dollars (\$500) in the aggregate. This proposed amendment will result in a decrease in the interest rate charged on delinquent taxes. The precise dollar impact on public entities is unknown; however, for interest accrued on tax amounts owed as of or after the effective date of the rule, the cost to the public entities will be two dollars (\$2) per year for every one hundred dollars (\$100) of tax owed.

PRIVATE COST: This proposed amendment will not cost private entities more than five hundred dollars (\$500) in the aggregate. This proposed amendment will result in a decrease in the interest rate charged on delinquent taxes. The actual number of affected taxpayers is unknown. Because the future amount of past due taxes is unknown, the precise dollar impact on private entities is unknown; however, for interest accrued on tax amounts owed as of or after the effective date of the rule, the savings to the private entity will be two dollars (\$2) per year for every one hundred dollars (\$100) of tax owed.

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with the Missouri Department of Revenue, Legal Services Division, PO Box 475, Jefferson City, MO 65105-0475. To be considered, comments must be received within thirty (30) days after publication of this notice in the Missouri Register. No public hearing is scheduled.

Proposed Amendment Text Reminder:

Boldface text indicates new matter.

[Bracketed text indicates matter being deleted.]

**Title 12—DEPARTMENT OF REVENUE
Division 10—Director of Revenue
Chapter 41—General Tax Provision**

PROPOSED AMENDMENT

12 CSR 10-41.010 Annual Adjusted Rate of Interest. The department proposes to amend section (1).

PURPOSE: Under the Annual Adjusted Rate of Interest (section 32.065, RSMo), this amendment establishes the 2010 annual adjusted rate of interest to be implemented and applied on taxes remaining unpaid during calendar year 2010.

(1) Pursuant to section 32.065, RSMo, the director of revenue upon official notice of the average predominant prime rate quoted by commercial banks to large businesses, as determined and reported by the Board of Governor's of the Federal Reserve System in the Federal

**FISCAL NOTE
 PUBLIC COST**

I. RULE NUMBER

Rule Number and Name:	12 CSR 10-41.010 Annual Adjusted Rate of Interest
Type of Rulemaking:	Proposed Amendment

II. SUMMARY OF FISCAL IMPACT

Affected Agency or Political Subdivision	Estimated Cost of Compliance in the Aggregate
Counties	There are no expenditures required by this regulation. Because the amount of interest collected on past due amounts of taxes will decrease, the aggregate impact on public entities will be more than \$500. The future amount past due taxes is unknown, however, the gross amount of delinquent taxes as of June 30, 2009, was \$899,996,302. The decreased interest on that amount as a result of the proposed amendment would be \$17,999,926.04. The precise dollar impact on public entities is also unknown, however, for interest accrued on tax amounts owed as of or after the effective date of this rule, the cost to the public entities will be \$2 per year for every \$100 of tax owed.
Cities	
Special Taxing Districts	

III. WORKSHEET

The proposed amendment adjusts the rate of interest for 2010 at 3%, down from 5% in 2009.

IV. ASSUMPTIONS

Under Section 32.065, RSMo, the director of revenue is mandated to establish an annual adjusted rate of interest based upon the adjusted prime rate charged by banks during September of that year as set by the Board of Governors of the Federal Reserve rounded to the nearest full percent.

**FISCAL NOTE
PRIVATE COST**

I. RULE NUMBER

Rule Number and Name:	12 CSR 10-41.010 Annual Adjusted Rate of Interest
Type of Rulemaking:	Proposed Amendment

II. SUMMARY OF FISCAL IMPACT

Estimate of the number of entities by class which would likely be affected by adoption of the proposed rule	Classification by types of the business entities which would likely be affected:	Estimate in the aggregate as to the cost of compliance with the rule by the affected entities:
Any taxpayer with past due tax amounts.	Any taxpayer with past due tax amounts.	Because the amount of interest collected on past due amounts of taxes will be at a decreased rate, the aggregate impact on private entities will be less than \$500. The future amount of past due taxes is unknown, however, the gross amount of delinquent taxes as of June 30, 2009 was \$899,996,302. The decreased interest on that amount as a result of the proposed amendment would be \$17,999,926.04. The precise dollar impact on private entities is also unknown, however, for interest accrued on tax amounts owed as of or after the effective date of this rule, the savings will be \$2 per year for every \$100 of tax owed.

III. WORKSHEET

The future amount of past due taxes is unknown. The gross amount of delinquent taxes as of June 30, 2009, was \$899,996,302. The 2% interest decrease on that amount as a result of the proposed amendment would be \$17,999,926.04.

Following is a comparison for the savings to a taxpayer with a past due amount of \$100:

	Current Rule – 5%	Proposed Amendment – 3%
Past due tax amount	\$100.00	\$100.00
Interest amount	5.00	3.00
Total Amount Due	\$105.00	\$103.00

IV. ASSUMPTIONS

Under Section 32.065, RSMo, the director of revenue is mandated to establish an annual adjusted rate of interest based upon the adjusted prime rate charged by banks during September of that year as set by the Board of Governors of the Federal Reserve rounded to the nearest full percent. Because the future amount of past due taxes is unknown, the precise dollar impact on private entities is also unknown. However, for interest accrued on tax amounts owed as of or after the effective date of this rule, the savings to the private entity will be \$2 per year for every \$100 of tax owed.

**Title 15—ELECTED OFFICIALS
Division 50—Treasurer
Chapter 2—Linked Deposit Program**

PROPOSED AMENDMENT

15 CSR 50-2.050 Interest Rate on Linked Deposit Loans [and Loan Categories]. The state treasurer's office is amending sections (1), (2), (3), and (4) and deleting sections (5) and (6).

PURPOSE: This amendment informs the public of changes to the procedure to be used to set the interest rate under the Linked Deposit Program.

PURPOSE: This rule establishes the procedure to be used to set the interest rate [on loan categories] under the Linked Deposit Program and the maximum interest rate on loans in [those categories] this program.

(1) [The interest rate on loan categories under the Linked Deposit Program shall be equal to the prime rate, as published in the Wall Street Journal, on the first business day of any given week, plus one and a half percent (1.50%). This rate shall apply to the following linked deposit loan categories: Agri-Business, Beginning Farmer (if loan is less than one hundred thousand dollars (\$100,000)), Farming Operation, Livestock Operation, Marketing Operation, Small Business, Student Borrower, and Water Supply System.] For all linked deposit loan applications, the lending institution shall certify the interest rate on the loan to be made to the applicant based on the lending institution's assessment of the applicant's credit risks and profile and other relevant factors as determined by the lending institution. Upon acceptance of the linked deposit application by the Office of the State Treasurer and acceptance of the linked deposit to be placed with the lending institution, the interest rate on the loan shall be no greater than seventy percent (70%) of the above rate certified by the lending institution. The loan rate must be approved by the Office of the State Treasurer, and, upon placement of the linked deposit, the loan rate shall remain fixed for the period agreed to by the lending institution and the Office of the State Treasurer, not to exceed a period of five (5) years and subject to adjustment under the terms and conditions described in section (4).

(2) The treasurer's office will advise [financial] lending institutions of the applicable category loan rate upon request and at the time a deposit offer is made under the program.

(3) The treasurer's office will [monitor interest rate markets and adjust the interest rates for each respective loan category upon changes in the prime lending rate] advise lending institutions of the deposit rate and loan rate at the time a deposit offer is made under the program.

(4) [The interest rate on the linked deposit loan made to a borrower in any of the categories listed in section (1) above, shall be no greater than seventy-five percent (75%) of the interest rate established in section (1) above.] Upon placement of a [loan] linked deposit, the interest rate for the loan shall remain fixed for [a period of one (1) year] the term; except, if it so provides in the loan agreement, the lending [financial] institution may increase the interest rate on the loan, up to the category rate established by the treasurer, if the treasurer determines that the borrower has not complied with the law relating to the Linked Deposit Program and, as a result, the treasurer has received the full market interest rate on the deposit from the [financial] lending institution.

[[5] In a linked deposit loan application made for a Job Enhancement Business and Beginning Farmer (if loan is one

hundred thousand dollars (\$100,000) or more), the lending financial institution shall certify the present market borrowing rate applicable on a one (1) year fixed rate loan to the borrower. The lending financial institution shall also certify the interest rate on the loan to be made to the borrowing Job Enhancement Business under the Linked Deposit Program, but the interest rate on the loan shall be no greater than seventy percent (70%) of the certified market rate. The loan rate must be approved by the state treasurer and, upon placement of the linked deposit, the loan rate shall remain fixed for a period of one (1) year, subject to adjustment under the terms and conditions described in section (4), above.

(6) In a linked deposit loan application made for a residential property developer or a residential property owner, the lending financial institution shall certify the present market borrowing rate applicable on a three (3) year fixed rate loan to that borrower. The lending financial institution shall also certify the interest rate on the loan to be made to the residential property developer or residential property owner under the Linked Deposit Program, but the interest rate on the loan shall be no greater than seventy-five percent (75%) of the certified market rate for a loan up to one hundred thousand dollars (\$100,000), nor greater than seventy percent (70%) of the certified market rate for a loan of one hundred thousand dollars (\$100,000) or more. The loan rate must be approved by the state treasurer and, upon placement of the linked deposit, the loan rate shall remain fixed for a period of up to three (3) years, subject to adjustment under the terms and conditions described in section (4), above.]

AUTHORITY: sections 30.260 and 30.760, RSMo [2000] Supp. 2008. Emergency rule filed March 7, 1986, effective March 27, 1986, expired July 14, 1986. Original rule filed June 26, 1986, effective Oct. 15, 1986. For intervening history, please consult the Code of State Regulations. Emergency amendment filed Oct. 28, 2009, effective Nov. 7, 2009, expires May 5, 2010. Amended: Filed Oct. 28, 2009.

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 comments in support of or in opposition to this proposed amendment. Written comments shall be sent to Angie Heffner Robyn, Office of the Missouri State Treasurer, Missouri State Capitol, Room 229, PO Box 210, Jefferson City, MO 65102. To be considered, comments must be received within thirty (30) days after publication of this notice in the Missouri Register. No public hearing is scheduled.

**Title 20—DEPARTMENT OF INSURANCE,
FINANCIAL INSTITUTIONS AND PROFESSIONAL
REGISTRATION**

**Division 2150—State Board of Registration for the
Healing Arts
Chapter 5—General Rules**

PROPOSED AMENDMENT

20 CSR 2150-5.025 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.

[(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:

(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)](5) 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 addresses 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 [r]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 334.125, RSMo 2000 and sections 338.010, RSMo Supp. 2007] and 338.220, as amended by Senate Bill 296, Ninety-fifth 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 amendment filed Oct. 22, 2009, effective Nov. 1, 2009, expires April 29, 2010. Amended: Filed Oct. 22, 2009.

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 Healing Arts, Tina Steinman, Executive Director, PO Box 4, Jefferson City, MO 65102, by faxing comments to (573) 751-3166, or by emailing comments to healingarts@pr.mo.gov. To be considered, comments must be received within thirty (30) days after publication of this notice in the Missouri Register. No public hearing is scheduled.

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

PROPOSED 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.

[(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:

(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)](5) 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 addresses 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 (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: sections 338.010, [RSMo Supp. 2007 and section] 338.140, [RSMo 2000] and 338.220, as amended by Senate Bill 296, Ninety-fifth 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 amendment filed Oct. 22, 2009, effective Nov. 1, 2009, expires April 29, 2010. Amended: Filed Oct. 22, 2009.

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 notice in the Missouri Register. No public hearing is scheduled.

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

PROPOSED 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.

(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, Ninety-fifth General Assembly, First Regular Session 2009. Emergency rule filed Oct. 23, 2009, effective Nov. 2, 2009, expires April 30, 2010. Original rule filed Oct. 22, 2009.

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

PRIVATE COST: This proposed rule 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 rule 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 notice in the **Missouri Register**. No public hearing is scheduled.*

This section will contain the final text of the rules proposed by agencies. The order of rulemaking is required to contain a citation to the legal authority upon which the order of rulemaking is based; reference to the date and page or pages where the notice of proposed rulemaking was published in the *Missouri Register*; an explanation of any change between the text of the rule as contained in the notice of proposed rulemaking and the text of the rule as finally adopted, together with the reason for any such change; and the full text of any section or subsection of the rule as adopted which has been changed from that contained in the notice of proposed rulemaking. The effective date of the rule shall be not less than thirty (30) days after the date of publication of the revision to the *Code of State Regulations*.

The agency is also required to make a brief summary of the general nature and extent of comments submitted in support of or opposition to the proposed rule and a concise summary of the testimony presented at the hearing, if any, held in connection with the rulemaking, together with a concise summary of the agency's findings with respect to the merits of any such testimony or comments which are opposed in whole or in part to the proposed rule. The ninety (90)-day period during which an agency shall file its order of rulemaking for publication in the *Missouri Register* begins either: 1) after the hearing on the proposed rulemaking is held; or 2) at the end of the time for submission of comments to the agency. During this period, the agency shall file with the secretary of state the order of rulemaking, either putting the proposed rule into effect, with or without further changes, or withdrawing the proposed rule.

**Title 2—DEPARTMENT OF AGRICULTURE
Division 80—State Milk Board
Chapter 2—Grade A Pasteurized Milk Regulations**

ORDER OF RULEMAKING

By the authority vested in the State Milk Board under section 196.939, RSMo 2000, the board hereby amends a rule as follows:

2 CSR 80-2.010 Definitions is amended.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on September 1, 2009 (34 MoReg 1788). No changes have been made to the text of the proposed amendment, so it is not reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: No public hearing was held. No written comments were received during the comment period.

**Title 2—DEPARTMENT OF AGRICULTURE
Division 80—State Milk Board
Chapter 2—Grade A Pasteurized Milk Regulations**

ORDER OF RULEMAKING

By the authority vested in the State Milk Board under section 196.939, RSMo 2000, the board hereby amends a rule as follows:

2 CSR 80-2.020 Sale of Adulterated, Misbranded Milk or Milk Products is amended.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on September 1, 2009 (34 MoReg 1788-1789). No changes have been made to the text of the proposed amendment, so it is not reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: No public hearing was held. No written comments were received during the comment period.

**Title 2—DEPARTMENT OF AGRICULTURE
Division 80—State Milk Board
Chapter 2—Grade A Pasteurized Milk Regulations**

ORDER OF RULEMAKING

By the authority vested in the State Milk Board under section 196.939, RSMo 2000, the board hereby amends a rule as follows:

2 CSR 80-2.030 Permits is amended.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on September 1, 2009 (34 MoReg 1789). No changes have been made to the text of the proposed amendment, so it is not reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: No public hearing was held. No written comments were received during the comment period.

**Title 2—DEPARTMENT OF AGRICULTURE
Division 80—State Milk Board
Chapter 2—Grade A Pasteurized Milk Regulations**

ORDER OF RULEMAKING

By the authority vested in the State Milk Board under section 196.939, RSMo 2000, the board hereby amends a rule as follows:

2 CSR 80-2.040 Labeling is amended.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on September 1, 2009 (34 MoReg 1789-1790). No changes have been made to the text of the proposed amendment, so it is not reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: No public hearing was held. No written comments were received during the comment period.

**Title 2—DEPARTMENT OF AGRICULTURE
Division 80—State Milk Board
Chapter 2—Grade A Pasteurized Milk Regulations**

ORDER OF RULEMAKING

By the authority vested in the State Milk Board under section 196.939, RSMo 2000, the board hereby amends a rule as follows:

2 CSR 80-2.050 Inspection Frequency and Procedure is amended.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on September 1, 2009 (34 MoReg 1790). No changes have been made to the text of the proposed amendment, so it is not reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: No public hearing was held. No written comments were received during the comment period.

**Title 2—DEPARTMENT OF AGRICULTURE
Division 80—State Milk Board
Chapter 2—Grade A Pasteurized Milk Regulations**

ORDER OF RULEMAKING

By the authority vested in the State Milk Board under section 196.939, RSMo 2000, the board hereby amends a rule as follows:

2 CSR 80-2.060 The Examination of Milk and Milk Products
is amended.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on September 1, 2009 (34 MoReg 1790). No changes have been made to the text of the proposed amendment, so it is not reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: No public hearing was held. No written comments were received during the comment period.

**Title 2—DEPARTMENT OF AGRICULTURE
Division 80—State Milk Board
Chapter 2—Grade A Pasteurized Milk Regulations**

ORDER OF RULEMAKING

By the authority vested in the State Milk Board under section 196.939, RSMo 2000, the board hereby amends a rule as follows:

2 CSR 80-2.070 Standards for Milk and Milk Products
is amended.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on September 1, 2009 (34 MoReg 1790–1793). No changes have been made to the text of the proposed amendment, so it is not reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: No public hearing was held. No written comments were received during the comment period.

**Title 2—DEPARTMENT OF AGRICULTURE
Division 80—State Milk Board
Chapter 2—Grade A Pasteurized Milk Regulations**

ORDER OF RULEMAKING

By the authority vested in the State Milk Board under section 196.939, RSMo 2000, the board hereby amends a rule as follows:

2 CSR 80-2.080 Animal Health **is amended.**

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on September 1, 2009 (34 MoReg 1793). No changes have been made to the text of the proposed amendment, so it is not reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: No public hearing was held. No written comments were received during the comment period.

**Title 2—DEPARTMENT OF AGRICULTURE
Division 80—State Milk Board
Chapter 2—Grade A Pasteurized Milk Regulations**

ORDER OF RULEMAKING

By the authority vested in the State Milk Board under section 196.939, RSMo 2000, the board hereby amends a rule as follows:

2 CSR 80-2.091 Milk and Milk Products Which May Be Sold
is amended.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on September 1, 2009 (34 MoReg 1793). No changes have been made to the text of the proposed amendment, so it is not reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: No public hearing was held. No written comments were received during the comment period.

**Title 2—DEPARTMENT OF AGRICULTURE
Division 80—State Milk Board
Chapter 2—Grade A Pasteurized Milk Regulations**

ORDER OF RULEMAKING

By the authority vested in the State Milk Board under section 196.939, RSMo 2000, the board hereby amends a rule as follows:

2 CSR 80-2.101 Transferring; Delivery Containers; Cooling
is amended.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on September 1, 2009 (34 MoReg 1793–1794). No changes have been made to the text of the proposed amendment, so it is not reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: No public hearing was held. No written comments were received during the comment period.

**Title 2—DEPARTMENT OF AGRICULTURE
Division 80—State Milk Board
Chapter 2—Grade A Pasteurized Milk Regulations**

ORDER OF RULEMAKING

By the authority vested in the State Milk Board under section 196.939, RSMo 2000, the board hereby amends a rule as follows:

2 CSR 80-2.110 Milk and Milk Products From Points Beyond the
Limits of Routine Inspection **is amended.**

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on September 1, 2009 (34 MoReg 1794). No changes have been made to the text of the proposed amendment, so it is not reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: No public hearing was held. No written comments were received during the comment period.

**Title 2—DEPARTMENT OF AGRICULTURE
Division 80—State Milk Board
Chapter 2—Grade A Pasteurized Milk Regulations**

ORDER OF RULEMAKING

By the authority vested in the State Milk Board under section 196.939, RSMo 2000, the board hereby amends a rule as follows:

2 CSR 80-2.121 Future Dairy Farms and Milk Plants is amended.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on September 1, 2009 (34 MoReg 1794–1795). No changes have been made to the text of the proposed amendment, so it is not reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: No public hearing was held. No written comments were received during the comment period.

**Title 2—DEPARTMENT OF AGRICULTURE
Division 80—State Milk Board
Chapter 2—Grade A Pasteurized Milk Regulations**

ORDER OF RULEMAKING

By the authority vested in the State Milk Board under section 196.939, RSMo 2000, the board hereby amends a rule as follows:

2 CSR 80-2.130 Personnel Health is amended.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on September 1, 2009 (34 MoReg 1795). No changes have been made to the text of the proposed amendment, so it is not reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: No public hearing was held. No written comments were received during the comment period.

**Title 2—DEPARTMENT OF AGRICULTURE
Division 80—State Milk Board
Chapter 2—Grade A Pasteurized Milk Regulations**

ORDER OF RULEMAKING

By the authority vested in the State Milk Board under section 196.939, RSMo 2000, the board hereby amends a rule as follows:

**2 CSR 80-2.141 Procedure When Infection is Suspected
is amended.**

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on September 1, 2009 (34 MoReg 1795). No changes have been made to the text of the proposed amendment, so it is not reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: No public hearing was held. No written comments were received during the comment period.

**Title 2—DEPARTMENT OF AGRICULTURE
Division 80—State Milk Board
Chapter 2—Grade A Pasteurized Milk Regulations**

ORDER OF RULEMAKING

By the authority vested in the State Milk Board under section 196.939, RSMo 2000, the board hereby amends a rule as follows:

2 CSR 80-2.151 Enforcement is amended.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on September 1, 2009 (34 MoReg 1795–1796). No changes have been made to the text of the proposed amendment, so it is not reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: No public hearing was held. No written comments were received during the comment period.

**Title 2—DEPARTMENT OF AGRICULTURE
Division 80—State Milk Board
Chapter 2—Grade A Pasteurized Milk Regulations**

ORDER OF RULEMAKING

By the authority vested in the State Milk Board under section 196.939, RSMo 2000, the board hereby amends a rule as follows:

2 CSR 80-2.161 Penalty is amended.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on September 1, 2009 (34 MoReg 1796). No changes have been made to the text of the proposed amendment, so it is not reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: No public hearing was held. No written comments were received during the comment period.

**Title 2—DEPARTMENT OF AGRICULTURE
Division 80—State Milk Board
Chapter 2—Grade A Pasteurized Milk Regulations**

ORDER OF RULEMAKING

By the authority vested in the State Milk Board under section 196.939, RSMo 2000, the board hereby amends a rule as follows:

2 CSR 80-2.170 Separability Clause is amended.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on September 1,

2009 (34 MoReg 1796–1797). No changes have been made to the text of the proposed amendment, so it is not reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: No public hearing was held. No written comments were received during the comment period.

**Title 12—DEPARTMENT OF REVENUE
Division 10—Director of Revenue
Chapter 3—State Sales Tax**

ORDER OF RULEMAKING

By the authority vested in the acting director of revenue under section 144.270, RSMo Supp. 2008, the director rescinds a rule as follows:

12 CSR 10-3.562 No Waiver of Tax **is rescinded**.

A notice of proposed rulemaking containing the proposed rescission was published in the *Missouri Register* on August 17, 2009 (34 MoReg 1729). No changes have been made in the proposed rescission, so it is not reprinted here. This proposed rescission becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: No comments were received.

**Title 13—DEPARTMENT OF SOCIAL SERVICES
Division 70—MO HealthNet Division
Chapter 3—Conditions of Provider Participation,
Reimbursement and Procedure of General Applicability**

ORDER OF RULEMAKING

By the authority vested in the MO HealthNet Division under sections 208.201, 208.431, and 208.435, RSMo Supp. 2008, the division amends a rule as follows:

13 CSR 70-3.170 Medicaid Managed Care Organization Reimbursement Allowance **is amended**.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on August 3, 2009 (34 MoReg 1578–1581). No changes have been made in the text of the proposed amendment, so it is not reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: No comments were received.