Dear Pharmacists:

The Missouri Pharmacy Association’s Professional Affairs Immunization Committee has worked to develop an example written protocol for members to use as a guide for administration of viral influenza vaccine pursuant to MO rule 20 CSR 2220-6.050. It is recommended that you review Missouri Board of Pharmacy rules prior to vaccinating. This example protocol should be reviewed and individualized to reflect your practice. Please note there are identified sections where you will need to insert in your site-specific information such as pharmacy name and address.

The Missouri rules state the following information must be included in the protocol:

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 which may be administered;
4. The identity of the patient or groups of patients to receive the authorized viral influenza vaccination;
5. The identity of the authorized routes and anatomic sites of administration allowed;
6. A provision to create a prescription for each administration under the authorizing physician’s name;
7. A provision establishing a course of action the pharmacist shall follow to address emergency situations including, but not limited to, adverse reactions, anaphylactic reactions, and accidental needle sticks;
8. A provision establishing a length of time the pharmacist shall observe an individual for adverse events following an injection;
9. A provision establishing the disposal of used and contaminated supplies;
10. The street address of the pharmacy at which the pharmacist may administer the authorized viral influenza vaccination;
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.

The protocol 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.

References

1. Epidemiology and Prevention of Vaccine-Preventable Diseases
   The Pink Book: Course Textbook
   http://www.cdc.gov/vaccines/pubs/pinkbook/
2. Centers for Disease and Control
   www.cdc.gov
   Advisory Committee on Immunization Practices (ACIP)
   http://www.cdc.gov/vaccines/recs/ACIP/
3. Occupational and Safety & Health Administration
   www.osha.gov
   Model Plans and Programs for the OSHA Bloodborne Pathogen Standards
   http://www.osha.gov/Publications/osha3186.pdf
4. Missouri Board of Pharmacy Rules
   http://www.pr.mo.gov/pharmacists-admin.asp

Should you make significant changes to this protocol and are willing to share those changes with MPA, for future continuous quality improvement of the example protocol, please contact:
Robyn Silvey
robyn@morx.com
573-636-7522 ext 227

Thank you
Protocol for Administration of Viral Influenza Vaccine

[date]

This protocol is for administration of viral influenza vaccine between pharmacists ______________ listed at the end of this agreement and [Dr. ____]. Policies herein follow rules established in 20 CSR 2220-6.050.

This written protocol shall serve as a prescription order for each administration of the following:

1. Trivalent inactivated influenza vaccine (TIV) to be administered intramuscularly in the right or left deltoid muscle to qualified patients 12 years of age or older. If a contraindication exists for deltoid administration, TIV may be administered in the right or left upper and outer gluteal muscle. Pregnant women will be given a preservative free viral influenza vaccine per Missouri law.
2. Live attenuated influenza vaccine (LAIV) to be administered intranasally to qualified patients 12 to 49. Intranasal 0.2 ml total dose is to be administered as a nasal mist. Approximately 0.1 ml is administered into each nostril while the recipient is in an upright position.
3. Epinephrine in emergency situations as described herein.

To protect people from preventable infectious diseases that cause needless death and morbidity, qualified pharmacists listed herein and employed by <insert company name> may administer TIV or LAIV, or epinephrine to consenting adolescents and adult patients (12 years of age or older) in the target group.

Following ACIP recommendations [review target group each year], the target group consists of adolescents (age 12 or older) or adults that meet any of the following criteria:
   a. Want to reduce the likelihood of becoming ill with influenza or of transmitting it to others
   b. Age 50 years or older
   c. Having any of the following conditions:
      • chronic disorder of the pulmonary or cardiovascular system, including asthma
      • chronic metabolic disease (e.g., diabetes), renal dysfunction, hemoglobinopathy, or immunosuppression (e.g., caused by medications, HIV)
      • any condition that compromises respiratory function or the handling of respiratory secretions or that can increase the risk of aspiration (e.g., cognitive dysfunction, spinal cord injury, seizure disorder or other neuromuscular disorder)
   d. Residence in a nursing home or other chronic-care facility that houses persons of any age who have chronic medical conditions
   e. In an occupation or living situation that puts one in proximity to persons at high risk, including
      • a healthcare worker, caregiver, or household member in contact with person(s) at high risk of developing complications from influenza
      • a household contact or out-of-home caretaker of a child age 0–59 months or of an adult age 50 years or older
   f. Children and adolescents (aged 12-18 years) receiving long-term aspirin therapy who therefore might be at risk for experiencing Reye’s Syndrome after influenza virus infection;
   g. Women who will be pregnant during the influenza season.*

*[Optional policy to remove pregnant women from protocol and vaccinate under MO Rule 20 CSR 2220.6.0040]*

Note: Although ACIP recommends TIV administration during pregnancy, pregnant women may not be included in the target population of this agreement. Pregnant women may be vaccinated with a prescription from their physician, under 20 CSR 2220-6.030.

The following is a list of contraindications to the LAIV [optional section though recommended].

1. Recipients of the LAIV should avoid being in close (same household) contact with immunocompromised individuals for 3 weeks following vaccination.
2. The LAIV will not be administered in the pharmacy if a severely immunocompromised employee is on duty.
3. The following is a list of contraindications to receiving the LAIV per this protocol:
   a. Are less than 12 years of age
   b. Are 50 years of age or older
   c. Have an allergy or history of allergic reaction to chicken eggs or egg products or any component to the vaccine. Symptoms of a severe allergic reaction may include shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue or other parts of the body, skin rash, itching or hives
   d. Are a child or adolescent who regularly takes aspirin or products containing aspirin
   e. Have a history of Guillain-Barre syndrome
   f. Have a known of suspected immune deficiency disease or condition such as combine immunodeficiency, agammaglobulinemia, HIV infection, thymic abnormalities, malignancy, leukemia, or lymphoma
   g. Are immunosuppressed or have altered or compromised immune status due to treatment with systemic corticosteroids, alkylating drugs, antimetabolites, radiation or other immunosuppressive therapies
   h. Have a history of asthma or reactive airways disease
Pharmacy Program Coordinator: {optional section}

a. Pharmacists in this agreement meet the requirements to administer vaccines established in Missouri rule 20 CSR 2220-6.050. They have received certificate training, and have current and valid CPR training and are licensed.
b. Pharmacists receive continuing education of a minimum of 2 hours every year pertaining to viral influenza vaccination, which is reported to the pharmacy program coordinator as well as the authorizing physician.
c. Pharmacist immunizer will endeavor not to disrupt existing patient-physician relationships. The pharmacist will refer patients needing medical consultation to a physician. The pharmacist will make special efforts to identify susceptible people who have not previously been offered immunizations.

Protocol Procedures

1. All vaccine patients will receive an updated “Vaccine Information Statement” and be given the opportunity to ask questions prior to receiving the vaccine.

2. All adult vaccine patients (18 years of age or older) will be required to sign an informed consent form. Children ages 12 to 17 must be accompanied by a parent or legal guardian who must sign an informed consent form for the child.

3. All vaccine patients will be asked a standard set of screening questions to assess appropriateness for the vaccination. The answers to the screening questions will be verified by the vaccine administrator.

4. A standard form will be utilized to document immunizations and will contain an informed consent. The documentation will indicate the following information if available from the patient: name, date of birth, address, phone number, primary care provider name and address and telephone number. Additional information documented on the form includes: date, vaccine name, dose, manufacturer, vaccine lot number, vaccine expiration date, anatomical site of administration, route, date faxed to physician, name and title of administrator.

5. Patients receiving the influenza vaccine will be advised to remain in the pharmacy area for at least 15 minutes for observation of adverse reactions.

6. In accordance with rules, the pharmacist will ensure that the patient’s identified physician, if different from the protocol physician, is notified within 14 days of administration at the pharmacy, if the patient provides a physician name. The physician will be notified by hand delivery, fax, mail, or phone call of the patient’s name, date of birth, date of immunization, route, anatomical site, dose and identification of the vaccine given.

7. In accordance with rules, the pharmacist will ensure that the protocol physician is notified within 72 hours of administration at the pharmacy. The physician will be notified by hand delivery, fax, mail, or phone call of the patient’s name, date of birth, date of immunization, route, anatomical site, dose and vaccine given.

8. All vaccine recipients will be given a written immunization record upon request.

9. After vaccination occurs, if any adverse reactions are identified, the patient’s physician as well as the authorizing physician will be notified. The nature of the adverse reaction and who was notified will be documented on the documentation form. If applicable, a VAERS report will be filled out.

10. Pharmacists will maintain records of administration separate from prescription files of the pharmacy for no less than 2 years. In addition to the administration records, the pharmacist will write a prescription under the authorizing physician to be maintained on file in the perpetual records. The prescription will be maintained according to Missouri Board of Pharmacy Rules.

11. The pharmacist and protocol physician must maintain a copy of this protocol from the beginning of implementation until a minimum of eight (8) years after termination of the protocol.

Pharmacy Locations

This protocol is only to be carried out at the following licensed pharmacy locations:

<insert all applicable pharmacy locations>

<include pharmacy address, phone, and license number>
Management of Allergic Reactions and Anaphylaxis

In case of a life threatening emergency such as anaphylaxis, 911 will be dialed. In the course of treating an anaphylactic reaction following immunization,

I. Supplies to stock
   a. Pharmacies must have enough epinephrine in stock to treat anaphylaxis, or the vaccine will not be given. These supplies can include the following:
      i. Adult doses Epinephrine Injection USP 1:1000 auto-injector such as and Epi-pen®. (Minimum of 2)
      ii. Child doses Epinephrine Injection USP 1:2000 auto-injector such as an Epi-Pen Jr. (Minimum of 2 when immunizing children, 4 if only epinephrine product)
      iii. Epinephrine 1:1000 (1 mg/mL) in 1 mL ampoules, filter syringes and syringes.
   b. Blood Pressure Cuffs, adult regular and large, and child cuffs, with stethoscope.
   c. CPR mask.

II. Recognition of anaphylactic reaction
   d. All pharmacy personnel will be trained to identify signs of anaphylactic reaction, including:
      i. Sudden onset of itching, redness, with or without hives, within several minutes after injecting a vaccine. The symptoms may be localized or generalized.
      ii. Angiodema (swelling of lips, face, throat), anxiety, difficulty swallowing, syncope, fall in blood pressure, lightheadedness, paresthesia, flushing, sweating, palpitations.
      iii. Bronchospasm, wheezing, tightness in chest, shock.

III. Emergency Treatment
   e. If itching and swelling are confined to the extremity where the immunization was given, observe patient closely for 30 minutes, watching for generalized symptoms. If none occur, go to g.
   f. If symptoms are generalized, activated the emergency response system (911) and notify the patient's primary care provider and the physician on the protocol. This should be done by another employee while the vaccinator is treating/observing the patient.
   g. Administer epinephrine according to weight:
      i. Use epinephrine ampoules based on weight. Administer aqueous epinephrine 1:1000 dilution (i.e. 1mg/ml) intramuscularly; the standard dose is 0.01 mg/kg body weight, up to 0.3 mg maximum single dose in children and 0.5 mg maximum in adolescents.
      ii. May use one adult epinephrine auto-injector Epi-Pen 0.3mg 1:1000 USP intramuscularly in the anterior-lateral.
      iii. Administer child epinephrine auto-injector, EpiPen Jr 0.15 mg 1:2000 USP intramuscularly.
   h. Do not give anything by mouth, including water, if the patient is not fully alert or if the patient is in respiratory distress.
   i. Monitor patient until EMS arrives: perform CPR and maintain airway if necessary.
      i. Keep patient in supine position unless he or she is having breathing difficulty. If breathing is difficult, patient’s head may be elevated, provided blood pressure is adequate to prevent loss of consciousness. If blood pressure is low, elevate legs.
      ii. Monitor and record vital signs frequently. Monitor blood pressure and pulse every 5 minutes.
      iii. If EMS has not arrived and symptoms are still present, repeat the dose of epinephrine every 5-20 minutes up to 3 doses depending on response. Note: Beta blockers antagonize epinephrine and may necessitate a larger dose or more frequent dosing.
   j. Patients will be referred for medical evaluation even signs of a or b appear above and even if symptoms resolve completely. Symptoms may recur after epinephrine wears off up to 24 hours later.
   k. In the event of an adverse event, the nature of the adverse event reported and the name of the person who the adverse event was reported to must be documented on the patients documentation form. The pharmacist will also fill out a VAERS report.
   l. The patient’s primary care physician and protocol physician, if different, will be notified by the pharmacist within 24 hours of learning about an anaphylactic reaction or any adverse event.
   m. A VAERS report will be completed and filed by the administering vaccinator. A copy of the report will be sent to the primary care physician and protocol physician within 24 hours of the report being filed.

Management of Contaminated Supplies

Immunization Administrators will follow and refer to the <insert company name> Bloodborne Pathogen Policy for disposal of used and contaminated supplies. All contaminated supplies will be placed promptly into a Biohazard Sharps Container.

<insert key excerpts of company bloodborne pathogen policy discussing disposal of used and contaminated supplies and brief explanation of procedures if a needle stick occur.:>
Addendum to Protocol for Administration of Viral Influenza Vaccine

Protocol Agreement:
By signing this protocol, each person signifies that they are aware of the protocol content and agree to follow the terms of the protocol.

The authorization shall be valid for 1 year from the date signed by the physician below unless revoked in writing earlier by either the individual pharmacist or the physician. Both parties must agree upon any changes in the protocol.

Physician License
I represent that I am licensed to prescribe legend drugs the state of MO pursuant to Chapter 334, RSMo and in good standing. I am actively engaged in the practice of medicine for the time of the agreement.

Authorizing Physician:

Name: ____________________________________________________________
Address: _________________________________________________________
Phone: ___________________________________________________________
License number: __________________________________________________
Physician’s Signature: _____________________________________________ Date: __________________

Authorized Pharmacists:

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