

SOUTH CAROLINA BOARD OF MEDICAL EXAMINERS
PROTOCOL FOR ADMINISTRATION OF INFLUENZA VACCINE BY PHARMACISTS

I. Introduction

In June 2010, in response to the threat of pandemic influenza and the need to expand access to influenza vaccine with proper controls, the South Carolina General Assembly approved an amendment to the Pharmacy Practice Act that authorizes pharmacists under certain conditions to administer influenza vaccine without an order from a licensed practitioner. The Act further provides that the Board of Medical Examiners issue this Protocol governing the administration of influenza vaccines by pharmacists.

II. Authorization

Subject to the requirements of this Protocol, pharmacists meeting the qualifications specified in Section III below and applicable law and regulation may: (a) determine the need for influenza vaccination; (b) administer either trivalent influenza vaccine (TIV) by intramuscular injection or live attenuated influenza vaccine (LAIV) nasally to persons eighteen (18) years of age and older; and (c) administer epinephrine and diphenhydramine in response to acute allergic reactions precipitated by influenza vaccination as delineated in this Protocol.

III. Qualifications

A pharmacist seeking authorization to administer influenza vaccines pursuant to this Protocol shall meet the following qualifications:

- (a) Licensure -The pharmacist must be licensed and in good standing with the South Carolina Board of Pharmacy.
- (b) Basic Life Support (BLS) Certification -The pharmacist must complete the American Heart Association "BLS for Healthcare Providers Course" or the "Red Cross Basic Life Support Course" and possess a valid Course Completion Card. This certification must be renewed every 2 years.
- (c) Training -The pharmacist must complete an approved pharmacy-based immunization training program that is accredited by the Accreditation Council for Pharmacy Education (ACPE). A list of approved programs is specified in Appendix A.
- (d) Continuing Education -The pharmacist must complete at least one hour of CME category I, or ACPE-approved continuing education related to the administration of influenza vaccines as part of his or her annual license requirements.
- (e) Liability Insurance -The pharmacist must maintain liability insurance that covers the administration of influenza vaccines.

-IV. Limitations on Pharmacy-based Vaccination

- (a) Age -The administration of influenza vaccines pursuant to this Protocol must not be to any persons under the age of eighteen (18) years.
- (b) Delegation -A pharmacist may not delegate the administration of influenza vaccines to a pharmacy technician or any other person who is not a pharmacist meeting the requirements of this Protocol and any applicable law and regulation.
- (c) Influenza Vaccine -This Protocol authorizes pharmacists to administer only influenza vaccines.

V. Protocol, Facility and Equipment

Pharmacists who administer influenza vaccine under this Protocol shall maintain a current copy of this Protocol at each location at which a pharmacist administers an influenza vaccine, and an appropriate area for administering vaccines with the supplies and equipment listed in Appendix B .

VI. Eligibility Determination

Prior to administering influenza vaccine, the pharmacist shall determine that the potential vaccinee is an eligible adult age 18 years and older with no history of influenza vaccination for the current influenza season, and that the potential vaccinee has no contraindications or limitations on vaccination as described below:

(a) Screening Questionnaire -The pharmacist shall determine the potential vaccinee's eligibility for vaccination using the required language provided in the questionnaires described in Appendix C (TIV) and Appendix D (LAIV).

(b) Contraindications -

(1) Influenza vaccine (TIV and LAIV) is contraindicated for persons with a history of serious reactions (e.g., anaphylaxis) after ingesting eggs or after receiving a previous dose of influenza vaccine or an influenza vaccine component.

(2) Live attenuated influenza vaccine (LAIV; nasal spray) is contraindicated for an adult who: is pregnant; is age 50 years or older; has chronic pulmonary (including asthma), cardiovascular (excluding hypertension), renal, hepatic, neurologic/neuromuscular, hematologic, or metabolic (including diabetes) disorders; or has immunosuppression, including that caused by medications or HIV.

(c) Precautions -

(1) Precaution must be taken before administering influenza vaccine to potential vaccinees with moderate or severe acute illness, with or without fever. Immunization should be delayed until the illness has resolved.

(2) LAIV should not be administered under this Protocol to individuals who live with or expect to have close contact with a person whose immune system is severely compromised and who must be in protective isolation (e.g., an isolation room of a bone marrow transplant unit). Under these circumstances, immunization should be referred or TIV should be used.

(3) For potential vaccinees who have received influenza antiviral drugs (i.e., amantadine, rimantadine, zanamivir, or oseltamivir) within the previous 48 hours, or who may take these drugs during the following 14 days, immunization with LAIV should be delayed, or TIV should be used.

(4) Potential vaccinees with a history of Guillain-Barre syndrome within 6 weeks of a previous influenza vaccine should not receive the influenza vaccine under this Protocol.

(d) Referrals -Potential vaccinees, who are younger than 18 years, and those with any contraindications and/or complex medical issues including immunosuppression or history of Guillaine-Barre syndrome as described above, must be referred to their primary care practitioner or a health department clinic.

VII. Informed Consent

Before receiving influenza vaccine, the vaccinee (or his or her legal representative) must be given information about the risks and benefits associated with vaccination.

(a) Consent Form -Any pharmacist administering influenza vaccines pursuant to this Protocol must document the vaccinee's or legal representative's informed consent in writing prior to administration of influenza vaccine. The required language is provided in the consent form in Appendix E.

(b) Vaccine Information Statements - Each vaccinee, or his or her legal representative, must be provided with a copy of the most current Vaccine Information Statement (VIS) for the vaccine provided. The vaccinee or legal representative must be given the opportunity to read the VIS prior to administration of the vaccine, and the pharmacist must provide answers to any questions raised. Non-English speaking persons must receive a copy of the VIS in their native language, if available.

VIII. Pharmacy-based Vaccination Record

A pharmacist administering influenza vaccine pursuant to this Protocol must create a vaccination record for each vaccinee, and must maintain this record for a period of at least six (6) years. This vaccination record must be readily accessible and shall include the following:

- (a) The name, address, date of birth, and telephone number of the vaccinee;
- (b) A copy of the vaccinee's responses to eligibility questionnaires;
- (c) The name, dose, manufacturer, and lot number of the vaccine administered;
- (d) The date of the administration of the vaccine and the injection site;
- (e) A signed and dated consent form by which the vaccine recipient acknowledges receipt of the VIS and consents to the administration of the influenza vaccine;
- (f) A record of any adverse events or complications that arose following vaccination;
- (g) The name, address, license number, and telephone number of the administering pharmacist; and
- (h) A copy of the notification letter sent to the vaccinee's designated primary care practitioner of any influenza vaccine administered.

IX. Reporting Requirements

(a) Personal Immunization Record -The pharmacist must encourage all vaccinees to carry a personal immunization record card in their wallet. The pharmacist must record the date of vaccination on the vaccinee's personal immunization record card.

(b) Medical Home Notification -Vaccinees must be informed regarding the importance of having a medical home and receiving other preventive medical services. Each time an adult receives a dose of influenza vaccine, this shall be reported to their designated primary care practitioner. The required language is provided in the reporting form in Appendix F.

(c) Immunization Registry -Pharmacists shall report influenza vaccine to the statewide immunization registry established by the Department of Health and Environmental Control as the department may require.

(d) Adverse Event Reporting -The pharmacist shall report any clinically significant event that occurs following influenza vaccine to the Vaccine Adverse Event Reporting System (VAERS), even if it is not certain that the event was caused by the vaccine. Clinically significant events include, but are not

limited to: death, hypersensitivity reactions, Guillain-Barre syndrome, and those events described in the manufacturer's package insert as contraindications to additional doses of vaccine.

X. Vaccination Safety

(a) Infection Control and Sterile Technique -Pharmacists administering influenza vaccine must follow appropriate precautions to minimize risk for spread of disease. Hands must be cleansed with an alcohol-based waterless antiseptic hand rub or washed with soap and water between each contact. Gloves must be worn if the pharmacist administering influenza vaccine is likely to come into contact with potentially infectious body fluids or have open lesions on their hands. Needles used for injections must be sterile and disposable to minimize the risk for contamination.

(b) Prevention of Needle-stick Injuries -To prevent inadvertent needle-stick injury or reuse, needles and syringes must be discarded immediately after use in labeled, puncture-proof containers located in the same room where the vaccine is administered. Needles must not be recapped before being placed in the container. Safety needles or needle-free injection devices should be used to reduce the risk for injury.

(c) Hepatitis B Vaccine -Pharmacists who administer influenza vaccine shall receive the hepatitis B vaccine series unless: (1) the pharmacist has previously received the complete hepatitis B vaccination series, (2) antibody testing has revealed that the pharmacist is immune, (3) the vaccine is contraindicated for medical reasons, or (4) the pharmacist signs a Hepatitis B Vaccine Declination statement.

(d) OSHA Compliance -Pharmacists must document compliance with OSHA regulations and applicable state law and regulations regarding the storage and disposal of injection supplies and the disposal of, and prevention of exposure to, biological hazards.

XI. Vaccination Procedure

The pharmacist shall follow the manufacturer's recommendations regarding the storage, dosing, and administration of influenza vaccine.

(a) Intramuscular Influenza Vaccine -The deltoid muscle should be used for administering intramuscular influenza vaccination. For men and women weighing <130 lb (<60 kg) a 5/8-inch to 1-inch needle is sufficient to ensure intramuscular injection. For women weighing 130 to 200 lb (60 to 90 kg) and men 130 to 260 lb (60 to 118 kg), a 1-inch to 1 ½ -inch needle is needed. For women weighing >200 lb (>90 kg) or men weighing >260 lb (>118 kg), a 1 ½ -inch needle is required. Intramuscular injections are administered at a 90-degree angle to the skin. Aspiration before injection of vaccines (i.e., pulling back on the syringe plunger after needle insertion, before injection) is not required because no large blood vessels exist at the recommended injection sites. "Pre-drawing" vaccine is discouraged.

(b) Intranasal Influenza Vaccine -Healthy adults younger than age 50 years without contraindications may be given the live attenuated influenza vaccine. LAIV is supplied in a prefilled, single-use sprayer containing 0.2 mL of vaccine. Approximately 0.1 mL (i.e., half of the total sprayer contents) is sprayed into the first nostril while the recipient is in the upright position. An attached dose-divider clip is removed from the sprayer to administer the second half of the dose into the other nostril.

XII. Management of Adverse Events All vaccines have the potential to cause an adverse reaction. In order to minimize adverse reactions, vaccinees must be carefully screened for

precautions and contraindications before the vaccine is administered. Even with careful screening, reactions may occur. These reactions can vary from trivial and inconvenient (e.g., soreness, itching) to severe and life threatening (e.g., myophylaxis). If reactions occur, the pharmacist must be prepared with procedures for their management. The procedures for managing adverse reactions are set forth in Appendix G.

XIII. Supply Considerations

(a) The annual supply of influenza vaccine and the timing of its distribution cannot be guaranteed. If supplies of seasonal influenza vaccine are delayed or limited, the pharmacist must comply with state and national guidance and directives for the tiered use of influenza vaccine, and must cooperate with health officials and local practitioners to insure that limited supplies of vaccine are targeted to and reserved for those persons at higher risk for influenza or influenza-related complications.

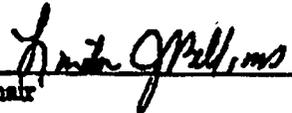
(b) Decisions regarding the determination of persons at higher risk must be made by a physician.

(c) During shortages of TIV, LAIV should be used preferentially when feasible for all healthy on-pregnant adults less than 50 years old to increase the availability of inactive vaccine for persons at high risk.

XIV. Approval

This Protocol has been recommended by the Joint Pharmacist Administered Influenza Vaccines Committee and approved by the Board of Medical Examiners. This Protocol is intended to comply with current guidelines of the Advisory Committee on Immunization Practices of the U.S. Centers for Disease Control and Prevention (CDC), and will be reviewed and revised as needed and on an annual basis.

**RECOMMENDED
BY THE JOINT PHARMACIST ADMINISTERED INFLUENZA VACCINES COMMITTEE**



Chair

11/10/2010

Date

APPROVED BY THE SOUTH CAROLINA BOARD OF MEDICAL EXAMINERS



President

11/10/2010

Date

APPENDIX A

APPROVED PHARMACY-BASED IMMUNIZATION TRAINING PROGRAMS

The Pharmacy Practice Act requires that pharmacists seeking authorization to administer influenza vaccine complete an accredited training course. The course must comply with current Centers for Disease Control guidelines, as those guidelines may be revised from time to time, and must include study materials, hands-on training, and techniques for administering influenza vaccines, and must provide instruction and experiential training in the following content areas: (a) mechanisms of action for influenza vaccines, contraindications, drug interactions, and monitoring after vaccine administration; (b) standards for adult immunization practices; (c) basic immunology and vaccine protection; (d) vaccine preventable diseases; (e) recommended immunization schedules; (f) vaccine storage management; (g) biohazard waste disposal and sterile techniques; (h) informed consent; (i) physiology and techniques for vaccine administration; (j) prevaccine and post vaccine assessment and counseling; (k) immunization record management; (l) management of adverse events, including identification, appropriate response, emergency procedures, documentation, and reporting; (m) understanding of vaccine coverage by federal, state, and local entities; and (n) needle stick management.

The following courses are approved by the Board of Medical Examiners for the purpose of meeting the training criteria for this Protocol:

I. A certificate of achievement for the American Pharmacists Association's "Pharmacy-based Immunization Delivery" training program.

Alternative training programs must be approved in advance by the Board of Medical Examiners.

APPENDIX B REQUIRED SUPPLIES AND EQUIPMENT

The following items must be available in the area where influenza vaccines are administered:

- (1) A current copy of this Protocol.
- (2) A supply of the most current federal Vaccine Information Statements for influenza vaccines, or electronic access to these statements.
- (3) Aqueous epinephrine USP (1:1000), in ampules, vials of solution, or prefilled devices (i.e., EpiPen). If an EpiPen is to be stocked, at least three adult EpiPens (delivering a single dose of 0.3 mg/0.3 mL) should be available.
- (4) Diphenhydramine (Benadryl) injectable solution (50 mg/mL) and oral 25-or 50-mg tablets.
- (5) Syringes: 1-mL and 3-mL, 22g and 25g, 1-inch, 1 ½ -inch, and 2-inch needles for epinephrine and diphenhydramine.
- (6) Alcohol swabs and bandages.
- (7) Blood pressure monitoring device or stethoscope and sphygmomanometer (with adult and extra-larger cuffs).
- (8) Adult size pocket mask with one-way valve.
- (9) Flashlight with extra batteries (for examination of mouth and throat).
- (10) Wrist watch with ability to count seconds.
- (11) Telephone access.
- (12) Equipment to enable the vaccinee to sit or lie down if he or she experiences an adverse reaction to the vaccine.

APPENDIX C

SCREENING QUESTIONNAIRE FOR INACTIVATED INJECTABLE INFLUENZA VACCINATION

The following questions shall be used to determine if there is any reason an inactivated injectable influenza vaccination should not be given:

- (1) Is the person to be vaccinated under the age of 18 years?
- (2) Is the person to be vaccinated sick today?
- (3) Does the person to be vaccinated have an allergy to eggs or to a component of the vaccine?
- (4) Has the person to be vaccinated ever had a serious reaction to influenza vaccine in the past?
- (5) Has the person to be vaccinated ever had Guillain-Barre syndrome?

If a person answers "yes" to any of these questions, the pharmacist must comply with Section VI of this Protocol.

APPENDIX D

SCREENING QUESTIONNAIRE FOR LIVE

ATTENUATED INTRANASAL INFLUENZA VACCINATION

The following questions shall be used to determine if there is any reason a live attenuated intranasal influenza vaccine should not be given:

- (1) Is the person to be vaccinated sick today?
- (2) Does the person to be vaccinated have an allergy to eggs or to a component of the influenza vaccine?
- (3) Has the person to be vaccinated ever had a serious reaction to intranasal influenza vaccine (FluMist) in the past?
- (4) Is the person to be vaccinated younger than age 18 years or older than age 49 years?
- (5) Does the person to be vaccinated have a long-term health problem with heart disease, lung disease, asthma, kidney disease, neurologic or neuromuscular disease, liver disease, metabolic disease (e.g., diabetes), or anemia or another blood disorder?
- (7) Does the person to be vaccinated have a weakened immune system because of HIV/AIDS or another disease that affects the immune system, long-term treatment with drugs such as high-dose steroids, or cancer treatment with radiation or drugs?
- (8) Is the person to be vaccinated receiving antiviral medications?
- (9) Is the person to be vaccinated pregnant or could she become pregnant within the next month?
- (10) Has the person to be vaccinated ever had Guillain-Barre syndrome?
- (11) Does the person to be vaccinated live with or expect to have close contact with a person whose immune system is severely compromised and who must be in protective isolation (e.g., an isolation room of a bone marrow transplant unit)?
- (12) Has the person to be vaccinated received any other vaccinations in the past 4 weeks?

If a person answers "yes" to any of these questions, the pharmacist must comply with Section VI of this Protocol.

APPENDIX E

CONSENT FOR INFLUENZA VACCINE

I have read, or had explained to me, the Vaccine Information Statement for influenza vaccine. I understand the risks and benefits, and have been provided an opportunity to ask questions, and they have been answered to my satisfaction. I wish to receive the influenza vaccine and hereby give consent for [Pharmacist's Name] to administer the influenza vaccine and communicate the administration of the vaccine to my primary care practitioner, who is listed below.

Vaccine recipient's name

Vaccine recipient's date of birth

Recipient's (or legal representative's) signature

Date

VIS Date

Vaccine recipient's designated primary care practitioner

APPENDIX F
NOTIFICATION LETTER

Dear Healthcare Provider at [vaccinee's primary care clinic]:

We have recently provided vaccination services to one of your patients. A personal immunization record card was filled out and given to the patient. We want to make certain that you also have this information so that you can update your patient's medical record. Please contact us if you have any questions about this information.

Vaccinee's name: _____

Vaccinee's Date of Birth: _____

The vaccine that was given on _____ is checked below.

Trivalent influenza vaccine(TIV)

Live attenuated influenza vaccine(LAIV)

Administering Pharmacist

Contact Information for Administering Pharmacist

APPENDIX G

PROCEDURES FOR MANAGEMENT OF ADVERSE REACTIONS

TO INFLUENZA VACCINATION

Anaphylactic Reactions

Signs and symptoms of anaphylactic reaction include: the sudden or gradual onset of generalized itching, erythema (redness), or urticaria (hives); angioedema (swelling of the lips, face, or throat); bronchospasm (wheezing); shortness of breath; shock; abdominal cramping; or cardiovascular collapse. The following procedures should be used to manage anaphylactic reactions following influenza vaccination:

1. If itching and swelling are confined to the injection site where the vaccination was given, observe the vaccinee closely for at least 30 minutes, watching for the development of generalized symptoms.
2. If symptoms are generalized, activate the emergency medical system (e.g., call 911) immediately. This should be done by a second person, while the pharmacist assesses the airway, breathing, circulation, and level of consciousness of the vaccinee.
3. Place vaccinee in a recumbent position and elevate legs.
4. Administer aqueous epinephrine 1: 1000 dilution subcutaneously or intramuscularly (usually in the upper arm), 0.01 mL/kg/dose (adult dose ranges from 0.3 mL to 0.5 mL, with maximum single dose of 0.5 mL). The site of injection can be gently massaged to facilitate absorption. The dose may be repeated 2 or 3 times at 10 to 15 minute intervals.
5. Administer diphenhydramine either orally or by intramuscular injection; the standard dose is 1 mg/kg, up to 100 mg maximum single dose. Do not attempt to give oral medications to a vaccinee who is not fully alert and able to swallow safely.
6. Monitor the vaccinee closely and check vital signs (blood pressure, pulse, and respirations) every 2 to 5 minutes.
7. Stay with vaccinee until EMS arrives.
8. If necessary, maintain airway and perform cardiopulmonary resuscitation (CPR).
9. Keep vaccinee in supine position unless he or she is having breathing difficulty. If breathing is difficult, vaccinee's head may be elevated, provided blood pressure is adequate to prevent loss of consciousness. If blood pressure is low, elevate legs.
10. If EMS has not arrived and symptoms are still present, repeat dose of epinephrine every 10 to 15 minutes for up to 3 doses, depending on vaccinee's response.
11. Record all vital signs, medications administered to the vaccinee (including the time, dosage, response, and the name of the person who administered the medication), and other relevant clinical information.
12. Notify the vaccinee's primary care practitioner as soon as possible. All vaccinees experiencing anaphylactic reactions must be referred for evaluation, even if symptoms resolve completely.

Syncope

Syncope (fainting) and near-syncope can occur prior to and following vaccination.

1. Vaccinees who appear fearful before vaccination should be placed in a sitting or supine position when being vaccinated.
2. When a vaccinee exhibits extreme paleness, sweating, coldness of the hands and feet, nausea, lightheadedness, dizziness, weakness, or visual disturbances, the pharmacist should have the vaccinee lie flat or sit with head between knees for several minutes. Loosen any tight clothing and maintain an open airway. Apply cool, damp cloths to vaccinee's face and neck.
3. Vaccinees who fall (with or without loss of consciousness) should be examined to determine if injury is present before attempting to move the vaccinee. The vaccinee should then be placed flat on back with feet elevated. Call 911 if vaccinee does not recover immediately.

Local Reactions

Local reactions are usually minor and can be managed as follows:

1. Soreness, redness, itching, or swelling at the injection site may be treated with cold compress to the injection site and a non-prescription analgesic or antipruritic medication.
2. Bleeding from the injection site should be treated with an adhesive compress over the injection site. For continued bleeding, place a thick layer of gauze pads over site and maintain direct and firm pressure with the bleeding injection site (e.g., arm) above the level of the vaccinee's heart.