

## **Influenza Vaccine Protocol Agreement (O.C.G.A. Section 43-34-26.1)**

This Influenza Vaccine Protocol Agreement (the "Protocol") authorizes the Georgia licensed pharmacists (the "Pharmacists") or nurses ("Nurses") identified on the following pages of this Protocol to act as delegated agents for the undersigned physician (the "Physician").

By signing this Protocol, the undersigned physician swears and affirms that:

1. He/she is currently licensed to practice medicine in the State of Georgia.
2. His/her principal place of practice is \_\_\_\_\_.
3. He/she is registered with the vaccination registry (O.C.G.A. Section 31-12-3.1) commonly known as the Georgia Registry of Immunization Transactions and Services, if established.
4. He/she has not entered into an Influenza Vaccine Protocol Agreements with more than 10 pharmacists and/or nurses except as provided in O.C.G.A. Section 43-34-26.1 (j).
5. He/she is in the same public health district as the pharmacists and/or nurses identified in this Protocol; or the nurses and/or pharmacists are located in the same or contiguous county as the physician's registration with the vaccination registry.
6. He/she is not employed by the pharmacists and/or nurses identified in this Protocol.
7. He/she is available for immediate consultation at the following phone numbers: \_\_\_\_\_.
8. If he/she is not available, the following alternate delegated physician, \_\_\_\_\_, is available for immediate consultation at: \_\_\_\_\_.

By signing this Protocol, the undersigned pharmacist swears and affirms that:

1. He/she is currently licensed as a pharmacist in the State of Georgia.
2. He/she is located within the county of the physician's place of registration with the vaccination registry or a county contiguous thereto; or that he/she is in the same public health district as the physician.
3. He/she holds a current certification in Basic Cardiac Life Support.
4. He/she has completed a course of training in immunization administration approved by the Georgia State Board of Pharmacy.
5. He/she will not delegate the administration of the influenza vaccine to any individual other than a pharmacy intern under his/her direct supervision.

By signing this Protocol, the undersigned nurse swears and affirms that:

1. He/she hold a current license to practice as a registered professional nurse; or is licensed to practice as a licensed practical nurse and is regularly employed by the physician in this protocol.
2. He/she holds a current certification in Basic Cardiac Life Support.
3. He/she is located within the county of the physician's place of registration with the vaccination registry or a county contiguous thereto; or that he/she is in the same public health district as the physician.
4. He/she will not delegate the administration of the influenza vaccine to anyone except an RN may delegate administration to a LPN who is under such RN's direct on-site supervision.

The Physician hereby authorizes the undersigned Pharmacists and/or Nurses to issue an influenza vaccine order and to administer the Inactivated influenza Vaccine (0.5 mL administered IM in the deltoid muscle) to eligible persons who are thirteen (13) years of age or older. Patients requesting vaccination by the Pharmacist and/or Nurses who are under the age of thirteen (13) will be referred to a physician for vaccination administration. Patients who are considered ineligible through the screening questions below will be referred to a physician for vaccination administration. For patients who are under the age of eighteen (18), the Pharmacist/Nurse shall obtain consent from the patient's parent or legal guardian prior to the administration an influenza vaccination.

All pharmacist and/or nurses who are parties to this protocol shall maintain onsite at the area where vaccines are to be administered the following emergency supplies, which supplies shall be checked monthly for quantities and expiration dates:

- Scales to weigh patients
- Epinephrine, Injection USP 1:1000. May be in ampules, prefilled syringes, vials of solution or in an epipen. If an epipen is to be stocked, at least four adult epipens (delivering a single dose of 0.3 mg/0.3 mL,) should be available whenever adult immunizations are given.

- Diphenhydramine (Benadryl) injectable solution (50 mg/mL) and oral 25- or 50 mg- tablets
- Syringes, alcohol swabs and bandages
- Blood pressure monitoring device

The Pharmacists/Nurses shall determine patient's eligibility prior to vaccine administration through the use of questions, including but not limited to, the following screening questions:

1. Does the patient have a fever or acute illness?
2. Does the patient have any allergies to any vaccine?
3. Is the patient allergic to chicken eggs or egg products?
4. Is the patient allergic to Thimerosal?
5. Has the patient ever had a serious reaction after receiving a vaccination?
6. Has the patient ever been diagnosed with Guillain-Barre' syndrome or other neurological disorder related to the influenza vaccine?
7. Has the patient had a seizure?

If the patient answers "yes" to any of the above questions, then the patient shall be referred to a physician for vaccination administration. The patient should also be asked when the patient's last immunization was. The influenza vaccine should not be given more frequently than recommended in the CDC guidelines.

The Pharmacists/Nurses will require, as a condition of the administration of the influenza vaccine, that the influenza vaccine patient remain under the observation of the administering Pharmacist/Nurse for a period of time not less than 15 minutes immediately subsequent to the administration of the vaccine. Pharmacists/Nurses shall provide each vaccine recipient with the appropriate and current Vaccine Information Statement (VIS). Pharmacists/Nurses shall, with the consent of the patient, make a reasonable effort to notify the patient's primary care physician of the patient's immunization.

The Pharmacists/Nurses shall retain the following documentation:

1. A copy of the patient's responses to the eligibility questions;
2. The name, dose, manufacturer, and lot number of the vaccine administered;
3. The name, address, date of birth, and telephone number of the patient;
4. The date of the administration of the vaccine and the injection site;
5. A signed and dated consent form by which the patient acknowledges receipt of the VIS and consents to the administration of the influenza vaccine;
6. Any adverse event or complications that arose; and
7. The name, address, license number and telephone number of the administering pharmacist and/or nurse.

The Pharmacist shall also maintain any prescription information required by the Georgia State Board of Pharmacy. The Pharmacist/Nurse shall enter the patient's influenza vaccination information in the Georgia Registry of Immunization Transactions and Services ("GRITS") within fifteen (15) days of administration of the influenza vaccination.

The Pharmacist/Nurse' administration of vaccinations is intended to comply with the current guidelines from the Advisory Committee on Immunization Practices of the U.S. Centers for Disease Control and Prevention (CDC). In the event that multiple influenza vaccinations are recommended, the Pharmacists/Nurses will request additional patient information concerning the last influenza vaccine received and the type of influenza vaccine from the patient and any other available resources prior to administering additional vaccines. The Pharmacists/Nurses shall not administer additional influenza vaccines in a time frame closer than that recommended by the CDC. In the event of vaccine shortage, the Pharmacists/Nurses shall prioritize vaccine administration according to the tiered structure set forth by the CDC, and document such prioritization.

In the event of adverse reactions subsequent to vaccine administration, the Pharmacists/Nurses shall refer to the procedures outlined in the Protocol for Management of Severe Allergic/Anaphylactic Reaction to Injectable Vaccine, incorporated into this protocol by reference as Addendum 1. This Protocol shall be valid for 2 (two) years from the date below, unless revoked in writing by a party to this Protocol.

PHYSICIAN

ALTERNATE DESIGNATED PHYSICIAN

\_\_\_\_\_

Physician

\_\_\_\_\_

Signature

Physician Signature

\_\_\_\_\_

Physician

\_\_\_\_\_

Name

Physician Name

License No. \_\_\_\_\_

License No. \_\_\_\_\_

Address: \_\_\_\_\_

Address: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Telephone No. \_\_\_\_\_

Telephone No. \_\_\_\_\_

Date: \_\_\_\_\_

Date: \_\_\_\_\_

# Influenza Vaccine Protocol Agreement

## Pharmacist

\_\_\_\_\_  
Pharmacist Signature

\_\_\_\_\_  
Pharmacist Name

\_\_\_\_\_  
Pharmacist Work Address

\_\_\_\_\_  
City, State, Zip code

\_\_\_\_\_  
Telephone Number

\_\_\_\_\_  
Pharmacy License Number

\_\_\_\_\_  
Date

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## Nurse

\_\_\_\_\_  
Nurse Signature

\_\_\_\_\_  
Nurse Name

\_\_\_\_\_  
Nurse Work Address

\_\_\_\_\_  
City, State, Zip code

\_\_\_\_\_  
Telephone Number

\_\_\_\_\_  
Nurse License Number

\_\_\_\_\_  
Date

## ADDENDUM 1

### **Protocol for Management of Severe Allergic/Anaphylactic Reaction to Vaccine Administration**

This Addendum (Protocol for Management of Severe Allergic/Anaphylactic Reaction to Vaccine Administration) authorizes the Georgia licensed pharmacists ("Pharmacists") and/or Nurses identified in the **Influenza Vaccine Protocol Agreement** ("Protocol") to administer medications in response to a severe allergic or anaphylactic reaction to the vaccine administration.

#### **Signs and Symptoms of Anaphylactic Reaction**

**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; cardiovascular collapse; or unexpected loss of consciousness.**

If an allergic reaction to vaccine administration occurs, the following, protocol shall be followed:

- A. If itching and swelling are confined to the extremity of administration, observe the patient closely for 30 minutes, watching for generalized symptoms. If none occur, go to Step C.
- B. If symptoms are generalized, activate the emergency response system (911 or equivalent). Another person should do this, while the pharmacist/nurse treats and observes the patient. The following treatment should be instituted:
  - Administer epinephrine (USP 1:1000) subcutaneously or intramuscularly in the anterior thigh or deltoid area: For an adult: 0.01 mg/kg/dose; 0.3 to 0.5 mg standard adult dose; maximum single dose is 0.5 mg. for an adult. If an epipen is used, use the adult epipen for persons over 65 pounds (over 30 kg.).  
**Caution: It is recommended that you administer epinephrine to individuals with cardiac conditions or persons over 40 years of age; however, be prepared to support cardiac response if necessary. Epinephrine effect is blunted in patients on beta adrenergic blockers. Be prepared to repeat the dose at shorter intervals based on patient response in patients on beta blockers.**
  - In cases of systemic anaphylaxis, after the administration of epinephrine, for adults- administer diphenhydramine 50-100 mg. orally or 50-100 mg. IM. (1 to 2 mg/kg, 100 mg maximum single dose).  
**Do not administer anything by mouth if the patient is not fully alert or has respiratory distress.**
  - Monitor the patient closely until EMS arrives. Perform CPR if necessary and maintain airway. Keep the patient in supine position unless he/she is having difficulty breathing. If breathing is difficult, patient's head may be elevated if blood pressure is adequate to prevent loss of consciousness. If blood pressure is low, elevate legs. Monitor blood pressure and pulse at least every 5 minutes.
  - Repeat dose of epinephrine every, 5-20 minutes for up to 3 doses until EMS arrives or symptoms resolve, depending on patient response.  
**DO NOT repeat administration of DIPHENHYDRAMINE.**
  - Record all vital signs and medications administered to patient including time, dosage, response, name of the medical personnel who administered the medication and other relevant clinical information. Maintain this information in the pharmacy and/or clinic and forward to attending physician.
- C. Refer patient for medical evaluation, even if symptoms resolve completely.
- D. Notify the patient's primary care physician.
- E. If appropriate, activate the Vaccine Adverse Event Reporting System (VAERS) and refer to the procedures in the Immunization Reference & Procedures Guide for appropriate documentation and follow up.