GEORGIA COMPOSITE MEDICAL BOARD
VACCINE PROTOCOL AGREEMENT

GENERAL INFORMATION

You do not have to use the Board's vaccine protocol agreement template, but the Board suggests utilizing the **approved** standard vaccine protocol agreement template posted on our Board website at www.medicalboard.georgia.gov.

FOR APRNs, if there is an existing protocol agreement under O.C.G.A. Secs 43-34-23 or 43-34-25 with a physician, no new protocol agreement is required.

Physician's offices are not subject to a protocol agreement. If you are not a physician's office, you need to complete the requirements listed above.

CHECKLIST - VACCINE PROTOCOL AGREEMENT

- ❑ **Vaccine Protocol Agreement Fee. $100.** Make your check or money order payable to: Georgia Composite Medical Board. **NOTE:** No protocol agreement will be processed without the fee. **All fees are non-refundable and subject to change.**

- ❑ **Vaccine Protocol Agreement.** The Vaccine Protocol Agreement must be submitted to the Georgia Composite Medical Board.

- ❑ **Signed Affidavit.** An original signed affidavit from each pharmacist or nurse covered by the protocol attesting to maintenance of liability insurance, current certification in Basic Cardiac Life Support and for pharmacists, completion of immunology training. (An affidavit form is available on the Board website.)

- ❑ **Proof of insurance.** Proof that each pharmacist or nurse holds individual liability insurance coverage or is individually covered by the employer's liability insurance coverage in an amount not less than $250,000.00 to cover claims arising from administration of vaccines.

MAILING INFORMATION

Mail the complete Vaccine Protocol Agreement and all required documents to:

Georgia Composite Medical Board
ATTENTION: VACCINE PROTOCOL AGREEMENTS
2 Peachtree Street, N.W., 36th Floor
ATLANTA, GA 30303

Vaccine Protocol Agreement

This 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").

I. QUALIFICATIONS OF PHYSICIAN, PHARMACIST AND NURSE

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 and is engaged in the active practice of medicine and his/her principal place of practice is located in Georgia.
2. His/her principal place of practice is _____, Georgia.(List the city and the county)
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 a Vaccine Protocol Agreement 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 not employed by the pharmacy that also employs the pharmacists and/or nurses identified in this Protocol.
8. He/she is available for immediate consultation at the following phone numbers: _____.
9. 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 has completed a training program recognized by the Centers for Disease Control and Prevention in the basics of immunology which focuses on practice implementation and legal and regulatory issues, composed of (a) at least 12 hours of self-study and an assessment exam; (b) at least eight hours of a live seminar with a final exam; and (c) a hands-on assessment of intramuscular and subcutaneous injection technique.
6. He/she will not delegate the administration of the 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 vaccine to anyone except an RN who may delegate administration to a LPN who is under such RN’s direct on-site supervision.

II. VACCINE ORDERS

The Physician hereby authorizes the undersigned Pharmacists and/or Nurses to issue vaccine orders for vaccines which when administered will result in immunity to (check all that apply):

(_____) Influenza

(_____) Pneumococcal disease

(_____) Shingles

(_____) Meningitis

III. ELIGIBLE PERSONS AND CONSENT

The vaccines can only be administered to eligible persons thirteen (13) years of age and older, and as outlined below. For purposes of this protocol, the eligible person for the pneumococcal disease vaccine and the meningitis vaccine must be eighteen (18) years of age or older. An eligible person for the influenza vaccine must be thirteen (13) years of age and older.

No live vaccine may be administered unless the patient or his or her parent, if the patient is a minor, has signed an informed consent that he or she does not have a contraindication to this vaccine and such informed consent form must list the contraindications to the vaccine.

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 or must have an individual prescription for the vaccine.

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 Pharmacists/Nurses shall obtain consent from the patient's parent or legal guardian prior to the administration an influenza vaccination.

IV. EQUIPMENT AND EMERGENCY SUPPLIES

All Pharmacists 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 auto injector. If an epinephrine auto injector is to be stocked, at least four adult auto injectors (delivering a single dose of 0.3 mg/0.3 mL,) should be available whenever adult immunizations are given.
- Oral Diphenhydramine (Benadryl)
- Syringes, alcohol swabs and bandages
- Blood pressure monitoring device
- Ambu-bag
- CPR Kit

V. PATIENT HISTORY

The Pharmacists/Nurses shall take a complete case history, including whether the patient has had a physical examination by a physician, physician's assistant or advanced practice registered nurse within the year preceding the date for the vaccine administration, and emergency contact information for the patient in the event of an emergency. The questions necessary for the case history and to determine patient's eligibility prior to vaccine administration include but not limited to, the following questions:

1. Who is your primary care physician or treating physician and what is his/her contact number? (If the patient fails to disclose this information, the pharmacist/nurse must make reasonable efforts to obtain this name and number and document such efforts.)
2. When did you have the last physical examination?
3. Do you have a fever or acute illness?
4. Do you know of any allergies to any vaccine?
5. Are you allergic to chicken eggs or egg products?
6. Do you know of any allergy to Thimerosal?
7. Have you ever had a serious reaction after receiving a vaccination?
8. Have you ever been diagnosed with Guillain-Barre' syndrome or other neurological disorder related to a vaccine?
9. Have you ever had a seizure or have you been diagnosed with a seizure disorder?
10. Are you pregnant?
11. What are your current illnesses and/or medical conditions?
12. Do you have any known drug allergies?

13. What medications are you currently taking?
14. Do you have any known immunosuppression state or disease?
15. Have you had any antiviral treatment within the past 24 hours?
16. Have you had a pneumococcal vaccine within the past 5 years?
17. Have you ever had the shingles or meningitis vaccine?
18. When did you have your last influenza vaccine?

VI. ADMINISTRATION OF VACCINE

The Pharmacists/Nurses' 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). **No vaccine may be administered if contraindicated by the answers to the case history and screening questions.** If indicated below, the physician hereby also identifies the following additional conditions/patients/circumstances in which he/she will not authorize the administration of the vaccine:

_____

_____

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 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.

The Pharmacists/Nurses must administer vaccines only in a private room, area with a privacy screen, or other interior area in which the patient's privacy can be maintained. No vaccines may be administered to a patient in a motor vehicle.

VII. POST-VACCINATION

The Pharmacists/Nurses will require, as a condition of the administration of the vaccine, that the 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 (V1S), written information developed by the Department of Public Health on the importance of having and periodically seeing a primary care physician, and a personal immunization card. The personal immunization card shall contain the vaccine recipient's name, the name and phone number of the pharmacist/nurse, the name and dosage of the vaccine, the location of the injection on the vaccine recipient, and the date of the administration of the vaccine. If the vaccine recipient already has a personal immunization card, then the Pharmacist/Nurse may update the existing card.

VIII. NOTIFICATIONS AND DOCUMENTATION

Pharmacists/Nurses shall notify the vaccine recipient's primary care provider of the administration of the vaccine within 72 hours of administration. The Pharmacists/Nurses shall make at least two attempts at notification with the 72 hours after administration of a vaccine. If the Pharmacists/Nurses are unable to notify the primary care provider, documented efforts of notification attempts shall be retained by the Pharmacists/Nurses.

The Pharmacists/Nurses shall retain the following documentation for a period of two (2) years:

1. A copy of the patient's responses to the eligibility questions and the complete case history;
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 vaccine and authorizes the pharmacist/nurse to notify the vaccine recipient's primary care provider of the vaccine administered to the vaccine recipient;
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 vaccination information in the Georgia Registry of Immunization Transactions and Services ("GRITS") within fifteen (15) days of administration of the vaccination. The GRITS registry is found at ImmReg@dhr.state.ga.us or at telephone number (888) 223-8644.

IX. ADVERSE REACTIONS

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.

X. LIABILITY INSURANCE

The Pharmacist/Nurse agrees that he/she has (check one):

(___) Individual liability insurance coverage in an amount not less than $250,000 to cover claims arising from my administration of vaccines; or

(___) Individual coverage from my employer's liability insurance in an amount not less than $250,000 to cover claims arising from my administration of vaccines.

The Pharmacist/Nurse also agrees to retain proof of insurance coverage, including the name of the insurer and policy number onsite at his or her primary location for administration of vaccines covered under this protocol agreement.

XI. AFFIDAVIT AND POSTING OF PROTOCOL AGREEMENT

The Pharmacists/Nurses shall post proof of the vaccine protocol agreement in a conspicuous place at the locations where the vaccines are being administered.

The undersigned Pharmacists/Nurses affirm that an original affidavit as required in O.C.G.A. Section 43-34-26.1(d)(16) has been submitted to the delegating physician and agree that a copy shall be maintained by the Pharmacists/Nurses onsite at the location where vaccines are being administered.

XII. TERM OF PROTOCOL AGREEMENT

This Protocol shall be valid for two (2) years from the date filed with Georgia Composite Medical Board, unless revoked in writing by a party to this Protocol. This Protocol may be renewed by resigning and filing with the Georgia Composite Medical Board. This Protocol may also be revised and updated biennially. If not renewed, the vaccine protocol agreement shall expire.

XIII. PARTIES AND LOCATION WHERE VACCINES WILL BE ADMINISTERED

PHYSICIAN	**ALTERNATE DESIGNATED PHYSICIAN**
_____	_____
Physician Signature	Physician Signature
_____	_____
Physician Name	Physician Name
License No._____	License No._____
Address:_____	Address:_____
_____	_____
Telephone No._____	Telephone No._____

Date:_____ Date:_____

PHARMACIST	NURSE
_____ Pharmacist Signature	_____ Nurse Signature
_____ Pharmacist Name	_____ Nurse Name
Pharmacist Address for Vaccine Administration _____ _____ City, State, Zip code	Nurse Address for Vaccine Administration _____ _____ City, State, Zip code
_____ Telephone Number	_____ Telephone Number
_____ Pharmacy License Number	_____ Nurse License Number
_____ Date	_____ Date

(Additional Signatures may be added here.)

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 **Vaccine Protocol Agreement** ("Protocol") to issue a prescription drug order and administer medications, including epinephrine. 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 epinephrine auto injector is used, use the adult autoinjector for persons over 65 pounds (over 30 kg.), and use the pediatric auto injector for children (persons 65 pounds and under)(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 (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 DIPHENHYRDRAMINE.**

- 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.

FLOW SHEET FOR MANAGEMENT OF SEVERE ALLERGY/ANAPHYLAXIS

PATIENT NAME:_____

Patient weight:_____ Patient is □ Adult □ Minor

Prior to Administration: Patient BP:_____ Patient Pulse:_____ Patient Respirations: _____

Itching and swelling→ Yes → Confined to extremities → Wait 30 minutes → Result: _____

↓

No, the symptoms are generalized:

→ Call EMS Time called:_____ Time arrived:_____

→ Administer epinephrine. Amount:_____ Time:_____

→ Put patient in supine position

→ Additional dose of epinephrine. Amount:_____ Time:_____

Vitals at Start of reaction: BP:_____ Pulse:_____

Vitals at 5 Minutes: BP:_____ Pulse:_____

Vitals at 10 Minutes: BP:_____ Pulse:_____

Notification made to Primary Care Doctor _____Yes _____No

Referral for Medical Evaluation _____Yes _____No

Signature:_____ Date:_____ Time:_____

Printed Name:_____ Title:_____