

GEORGIA COMPOSITE MEDICAL BOARD

EXECUTIVE DIRECTOR
LaSharn Hughes, MBA



BOARD CHAIRPERSON
David W. Retterbush, MD

2 Peachtree Street, N.W., 36th Floor • Atlanta, Georgia 30303 • Tel: 404.656.3923 • <http://www.medicalboard.georgia.gov>
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GEORGIA COMPOSITE MEDICAL BOARD NOTICE OF INTENT TO AMEND AND ADOPT RULES

TO ALL INTERESTED PARTIES:

Notice is hereby given that pursuant to the authority set forth below, the Georgia Composite Medical Board (hereinafter "Board") proposes amendments to the Georgia Composite Medical Board Rules, **Rule 360-34 "Vaccine Protocols Agreements."** An exact copy of the proposed rule is attached to this Notice.

This notice, together with an exact copy of the proposed rules and a synopsis of the proposed amendments is forwarded to all persons who have requested, in writing, that they be placed on the interested parties' mailing list. A copy of this notice, an exact copy of the proposed rules and a synopsis of the proposed rules may be reviewed during normal business hours of 8:00 a.m. to 5:00 p.m., Monday through Friday, except official State holidays, at the office of the Georgia Composite Medical Board, 2 Peachtree Street, N.W., 36th Floor, Atlanta, Georgia 30303. These documents will also be available for review on the Board's website at www.medicalboard.georgia.gov.

A public hearing is scheduled to begin at **8:30 a.m. on September 3, 2015** at the 36th Floor Board Room, 2 Peachtree Street, N.W., Atlanta, Georgia 30303, to provide the public an opportunity to comment upon and provide input into the proposed rules. At the public hearing, any interested person who will be affected by these rules may present his or her written comments to the Board no later than **August 24, 2015** or make comments at the public hearing. Comments may be directed to Diane Atkinson, Georgia Composite Medical Board, 2 Peachtree Street, N.W., 36th Floor, Atlanta, Georgia 30303-3465 or may be received by the Board by e-mail at mdatkinson@dch.ga.gov.

The proposed amendments will be considered for adoption by the Board at its meeting scheduled to begin at **8:30 a.m. on September 3, 2015** at the Board offices on the 36th Floor Board Room, 2 Peachtree Street, N.W., Atlanta, Georgia 30303

The Board voted to adopt this Notice of Intent on **July 9, 2015** meeting. The Board will consider at its meeting on **September 3, 2015 at 8:30 a.m.** the comments from the public hearing whether the formulation and adoption of these proposed rule amendments imposes excessive regulatory costs on any license or entity and whether any cost to comply with the proposed rule amendments could be reduced by a less expensive alternative that accomplishes the objectives of the statutes which are the basis of the proposed rule. Additionally at its meeting on **September 3, 2015** the Board will consider

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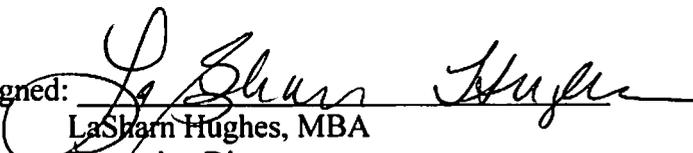
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whether it is legal or feasible in meeting the objectives of the applicable laws to adopt or implement differing actions for businesses as listed in O.C.G.A. § 50-13-4(3) (A) (B)(C)(D). This Notice is adopted and posted in compliance with O.C.G.A. § 50-13-4 of the Georgia Administrative Procedures Act. A synopsis of the proposed rules and an economic impact statement are attached to this Notice.

The authority for promulgation of these rules is O.C.G.A. Authority Section O.C.G.A. Sec. 43-34-5 and 43-34-26.1.

Date: 7-13-15

Signed: 
LaSharn Hughes, MBA
Executive Director
Georgia Composite Medical Board

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ECONOMIC IMPACT AND SYNOPSIS FOR AMENDMENTS TO CHAPTER 360-34 **Flu Vaccine Protocols**

ECONOMIC IMPACT:

The attached rules are promulgated under the authority of the Medical Practice Act, Title 43, Chapter 34. The Composite State Board of Medical Examiners licenses and regulates nine professions. The formulation and adoption of this rule does not impose excessive regulatory cost on any licensee and any cost to comply with the proposed rule cannot be reduced by a less expensive alternative that fully accomplishes the objectives of Article 2 of Chapter 34 of Title 43 of the Official Code of Georgia Annotated. Additionally, it is not legal or feasible to meet the objectives of the Article 2 of Chapter 34 of Title 43 of the Official Code of Georgia Annotated to adopt or implement differing actions for businesses listed at O.C.G.A. § 50-13-4(a)(3)(A), (B), (C) and (D).

RULE SYNOPSIS:

Rule Chapter 360-34 “Vaccine Protocol Agreements”

Purpose/Main Feature: The proposed rule is to adopt and implement the directive of House Bill 504 which establishes the requirements for the administration of vaccines by pharmacists or nurses pursuant to a vaccine protocol agreement with a physicians.

O.C.G.A Sec. 43-34-5 and 43-34-26.1.

RULES
OF
GEORGIA COMPOSITE MEDICAL BOARD

CHAPTER 360-34
VACCINE PROTOCOL AGREEMENTS

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360-34-.01 Definitions.

As used in this Chapter, the following definitions apply:

- (1) 'Administer' means the provision of a unit dose of vaccine by a pharmacist or nurse pursuant to a vaccine order contained in a vaccine protocol agreement with a physician.**
- (2) 'Adverse event' means an event that is a negative consequence of the administration of vaccine by a pharmacist or nurse that results in an unintended reaction, injury, or illness, which may or may not have been preventable.**
- (3) 'Board' means the Georgia Composite Medical Board.**
- (4) 'Nurse' means a registered professional nurse as defined in paragraph (9) of Code Section 43-26-3. The term shall also mean a licensed practical nurse as defined in paragraph (5) of Code Section 43-26-32 who is regularly employed by a physician who actively engaged in the private practice of medicine.**
- (5) 'Pharmacist' means an individual licensed under Chapter 4 of Title 26 to engage in the practice of pharmacy in the State of Georgia.**
- (6) 'Pharmacy intern' means a pharmacy intern as defined in paragraph (19) of Code Section 26-4-5.**

(7) 'Physician' means an individual holding a current license to practice medicine and surgery in this state and whose principal place of practice is located in this state.

(8) 'Vaccine' means a specially prepared antigen which upon administration to a person will result in immunity to influenza, pneumococcal disease, shingles, or meningitis. No live attenuated virus shall be administered pursuant to a vaccine protocol unless the patient or his or her parent, if a minor, has signed an informed consent that he or she does not have a contraindication to this vaccine, and such informed consent lists the contraindications to the vaccine.

(9) 'Vaccine order' means a prescription drug order, contained in a vaccine protocol agreement, issued by a physician for a group of patients that meet a certain criteria and to be administered by a pharmacist or a nurse. A vaccine order shall also mean a prescription drug order, contained in a vaccine protocol agreement, for epinephrine issued by a physician for a group of patients that meet a certain criteria and to be administered by a pharmacist or a nurse only upon the occurrence of an actual or perceived anaphylactic adverse reaction to the administered vaccine provided that the vaccine protocol agreement sets forth the signs and symptoms that warrant the administration of epinephrine.

(10) 'Vaccine protocol agreement' means a written document mutually agreed upon and signed by a physician and a pharmacist or by a physician and a nurse, by which document the physician prescribes a vaccine and epinephrine, if determined appropriate by the physician, by means of a vaccine order for administration by a pharmacist or a nurse.

360-34-.02 Qualifications for Physician to enter a protocol

In order for a physician to be eligible to enter into a vaccine protocol agreement, the physician must:

(1) Hold a current license to practice medicine in the State of Georgia;

(2) Have his/her principal place of practice in the State of Georgia;

(3) Be registered with the vaccination registry established by the Georgia Department of Public Health ("DPH") O.C.G.A. Section 31-12-3.1, commonly known as the Georgia Registry of Immunization Transactions and Services ("GRITS");

(4) Not be employed by the pharmacist(s) or nurse(s) with whom he/she is entering into the vaccine protocol agreement;

(5) Not be an employee of a pharmacy that also employs the pharmacist(s) or nurse(s) with whom he/she is entering into the vaccine protocol agreement; and

(6) Be available for immediate consultation or have designated another qualified physician as an alternate physician who is available for immediate consultation.

360-34-.03. Qualifications for a Pharmacist to enter a protocol.

In order for a pharmacist to be eligible to enter into a vaccine protocol agreement, the pharmacist must:

- (1) Hold a current license to practice as a pharmacist in the State of Georgia;
- (2) Hold a current certification in Basic Cardiac Life Support;
- (3) Have completed a course of training in immunization administration approved by the Georgia State Board of Pharmacy;
- (4) Have 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; and
- (5) Have individual liability insurance coverage in an amount not less than \$250,000 to cover claims arising from the administration of vaccines, or have individual coverage from his/her employer's liability insurance in an amount not less than \$250,000 to cover claims arising from the administration of vaccines.

360-34-.04. Qualifications for a Nurse to enter a protocol

In order for a nurse to be eligible to enter into a vaccine protocol agreement, the nurse must:

- (1) Hold a current license to practice as a registered professional nurse; or be licensed to practice as a licensed practical nurse while regularly employed by the physician in the protocol;
- (2) Hold a current certification in Basic Cardiac Life Support; and
- (3) Have individual liability insurance coverage in an amount not less than \$250,000 to cover claims arising from the administration of vaccines, or have individual coverage from his/her employer's liability insurance in an amount not less than \$250,000 to cover claims arising from the administration of vaccines.

360-34-.05. Requirements of the Vaccine Protocol Agreement.

The protocol agreement must:

- (1) Contain the current names, addresses, telephone numbers, and professional license numbers of the physician and the pharmacist or nurse;
- (2) Contain a provision for immediate consultation with the physician or an alternate physician;

(3) Require the pharmacist or nurse to take a complete case history and determine whether a patient has had a physical examination within the past year;

(4) Provide that no vaccine shall be administered to a patient with any condition for which the vaccine is contraindicated;

(5) Require the pharmacist or nurse to provide the vaccine recipient with the appropriate and current Vaccine Information Statement (VIS) as provided by the federal Centers for Disease Control and Prevention;

(6) Require the pharmacist or nurse to provide written information to the vaccine recipient developed by the Department of Public Health on the importance of having and periodically seeing a primary care physician;

(7) Require the pharmacist or nurse to provide each new vaccine recipient with a personal immunization card on card stock paper containing the vaccine recipient's name, the pharmacist's or nurse's name and phone number, the name and dosage of the vaccine, the location of the injection on the vaccine recipient and the date of administration of the vaccine in a format made available by the Department of Public Health. In the event the patient already has an immunization card, the pharmacist or nurse shall update the card;

(8) Require the pharmacist or nurse to retain documentation of each dose administered with such documentation to include the following:

(a) the administering pharmacist's or nurse's name, address, telephone number and professional license number;

(b) the name, dose, manufacturer, and lot number of the vaccine;

(c) the vaccine recipient's name, address, date of birth, and telephone number;

(d) the date of administration and injection site;

(e) the signed and dated consent form that acknowledges receipt of the VIS, consents to the administration of the vaccine and authorizes the pharmacist or nurse to notify the vaccine recipient's primary care provider of the vaccine administered to the vaccine recipient; and

(f) any adverse events or complications that occur;

(9) Require the pharmacist or nurse to make documented reasonable efforts to obtain the name of the vaccine recipient's primary care provider and to notify such primary care provider of the vaccine administered by the pharmacist or nurse within 72 hours of the administration;

(10) Require the pharmacy or nurse to administer the vaccine to a patient in a private room, area with a privacy screen or other interior area in which the patient's privacy can be maintained

unless there is a declared public health emergency or where immunizations are being administered for purposes of training for a short period of time;

(11) Prohibit the administration of the vaccine to a patient while the patient is in his or her personal vehicle;

(12) Require the pharmacist or nurse to enter the patient's vaccine information in Georgia Registry of Immunization Transactions and Services ("GRITS") within the time designated by the Department of Public Health;

(13) Require that the vaccine recipient remain under observation for not less than 15 minutes immediately subsequent to the administration of the vaccine;

(14) Contain procedures to follow in the event of an adverse event or complication;

(15) Provide for prioritization of influenza vaccine recipients in the event of a limitation in the supply of the vaccine;

(16) Require that the pharmacist or nurse maintains individual liability insurance coverage in an amount not less than \$250,000 to cover claims arising from the administration of vaccines, or has individual coverage from his/her employer's liability insurance in an amount not less than \$250,000 to cover claims arising from the administration of vaccines;

(17) Require that the pharmacist or nurse maintain a copy of the proof of insurance with the name of the insurer and policy number onsite at his or her primary location;

(18) Require that the pharmacist or nurse post proof of the vaccine protocol agreement, including a list of the vaccines authorized to be administered, in a conspicuous location within the pharmacy, local health department, or other setting in which the vaccine is being administered;

(19) Require the submission of a signed and notarized affidavit by the pharmacist or nurse to the physician attesting to:

_____ (a) the maintenance of liability insurance;

_____ (b) current certification in Basic Cardiac Life Support, and for pharmacists, verification of completion of immunology training;

_____ (c) the maintenance of a copy of the vaccine protocol agreement; and

_____ (d) the identification of the locations where the pharmacist or nurse will be administering vaccinations pursuant to the protocol;

(20) Provide that the pharmacist cannot delegate the administration of the vaccine to another individual except a pharmacy intern under his/her direct supervision, and that the nurse cannot delegate the administration of the vaccine except a registered professional nurse may delegate the administration to a licensed practical nurse under the direct on-site supervision of the registered professional nurse; and

(21) Provide for the expiration, renewal or revision of the protocol on at least a biennial basis.

360-34-.06. Limitations of the Vaccine Protocol Agreement.

- (1) The physician shall not enter vaccine protocol agreements with more than ten (10) pharmacists and/or nurses except as provided in O.C.G.A. Section 43-34-26.1 (j).
- (2) The physician must be in the same public health district as the pharmacists and/or nurses identified in the protocol; or the nurses and/or pharmacists are located in the same or contiguous county as the physician’s registration with the vaccination registry.
- (3) The physician shall have verified that the pharmacist(s) or nurse(s) have had Basic Cardiac Life Support training and any other training required by law.
- (4) The physician shall verify that the pharmacist or nurse administering the protocol has policies and procedures for the handling and disposal of contaminated equipment and supplies.
- (5) No vaccine protocol agreement shall permit a pharmacist or nurse to administer a vaccine, including the influenza vaccine, to any child under the age of 13 without an individual prescription from a physician.
- (6) No vaccine protocol agreement shall permit a pharmacist or nurse to administer a pneumococcal disease vaccine or meningitis vaccine to a child under the age of 18.
- (7) No vaccine protocol agreement shall permit a pharmacist or nurse to administer a vaccine to a child under the age of 18 without consent from the child’s parent or legal guardian.

360-34-.07. Filing of Vaccine Agreements with the Board.

The vaccine protocol agreement must be filed with the Board within thirty (30) days of its execution and shall be renewable as provided by the Board.

360-34-.08. Template.

The Board’s standard protocol template is available at www.medicalboard.georgia.gov. A physician may make further changes restricting the administration of the vaccine from patients with certain medical conditions.

360-34-.09. Exemptions.

The requirements of this Chapter shall not apply to activities conducted within a hospital and its facilities, physician’s office, nursing home or other health care facilities designated by the Department of Public Health.

360-34-.10. Penalties.

- (1) The Board may impose a fine of up to \$2,500 against any pharmacist or nurse who:

_____ (a) Fails to maintain individual liability insurance or fails to be individually covered by his/her employer in an amount not less than \$250,000 to cover claims arising from the administration of vaccines;

_____ (b) Fails to provide proof of such coverage to the physician entering into the vaccine protocol agreement; or

_____ (c) Fails to maintain a copy of the proof of insurance onsite at the primary location.

_____ (d) Administers a vaccine without a vaccine protocol agreement.

(2) The Board may impose the following sanctions against a pharmacist or nurse who fails to provide a legible immunization card to a vaccine recipient as provided by law:

_____ (a) Upon the first violation, the issuance of a warning;

_____ (b) Upon the second violation, a fine up to \$500; and

_____ (c) Upon a third or subsequent violation, the Board may prohibit the pharmacist or nurse from administering vaccines for a period up to one year.

(3) The Board may impose the following sanctions against a pharmacist or nurse who knowingly fails to post the vaccine protocol agreement as provided by law:

_____ (a) Upon the first or second violation, the issuance of a warning; and

_____ (b) Upon the third or subsequent violation, the Board may prohibit the pharmacist or nurse from administering vaccines for a period up to six months.

(4) The Board may impose a fine of up to \$2,500 and may prohibit a pharmacist or nurse from administering vaccines for up to one year if the pharmacist or nurse knowingly administers a vaccine without a vaccine protocol agreement as required by O.C.G.A. Section 43-34-26.1 and filed with the Board.

(5) Sanctions imposed pursuant to this Chapter shall not be contested cases. The Board shall issue a citation with the identified offense and the sanction, including when any fine is due, which citation shall be mailed to the pharmacist's or nurse's address of record with the appropriate licensing board. A pharmacist or nurse may request an appearance before the Board to contest the finding or sanction within thirty (30) days after the issuance of the sanction. Failure to request an appearance or pay any fine imposed shall be considered a violation of a lawful order of the Board. If an appearance is requested, the Board shall schedule the appearance, and thereafter issue a decision on the imposition of sanctions.

(6) Nothing in this rule prevents the Board from forwarding any investigation to the professional licensing board of the licensed pharmacist or nurse for further disciplinary action.

(7) Nothing in this chapter shall be construed to limit the authority of the Board to take disciplinary action against any physician who is a party to a vaccine protocol agreement for a violation of the law and rules.

Authority: O.C.G.A. Sections 43-34-5 and 43-34-26.1.

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 (VIS), 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 I.

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 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.