

GEORGIA COMPOSITE MEDICAL BOARD



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 "Flu Vaccine Protocols."** 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 8:00a.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 April 2, 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 **March 26, 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 matkinson@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 April 2, 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 **February 5, 2015** meeting. The Board will consider at its meeting on **April 2, 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 **April 2, 2015** the Board will consider

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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: 2/9/15

Signed: *LaSharn Hughes*
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 “Flu Vaccine Protocols”

Purpose/Main Feature: The proposed rule is to adopt and to implement the directive of state law regarding flu protocols.

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

RULES
OF
GEORGIA COMPOSITE MEDICAL BOARD

CHAPTER 360-34
FLU VACCINE PROTOCOLS

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360-34-.01 Definitions. As used in this Chapter the term:

(1) 'Board' means the Georgia Composite Medical Board.

(2) 'Influenza 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 influenza vaccine, epinephrine, and/or diphenhydramine if determined appropriate by the physician, by means of an influenza vaccine order for administration by a pharmacist or a nurse.

(3) "Influenza vaccine" means an inactivated virus administered by injection or a live attenuated virus administered by nasal spray that is prepared for the applicable season and that is administered to produce or increase immunity to the influenza virus; provided, however, that a live attenuated virus shall not be administered pursuant to this Code section to any individual younger than 13 or older than 49 years of age; and provided, further, that a live attenuated virus shall not be administered pursuant to this Code section 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. The informed consent form shall list the contraindications to the vaccine.

(4) 'Influenza vaccine order' means a prescription drug order, contained in an influenza vaccine protocol agreement, for influenza vaccine issued by a physician for a group of patients that meet a certain criteria and to be administered by a pharmacist or a nurse. An influenza vaccine order shall also mean a prescription drug order, contained in an influenza vaccine protocol agreement, for epinephrine and/or diphenhydramine 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 influenza vaccine provided

that the influenza vaccine protocol agreement sets forth the signs and symptoms that warrant the administration of epinephrine.

(5) 'Administer' means the provision of a unit dose of influenza vaccine by a pharmacist or nurse pursuant to an influenza vaccine order contained in an influenza vaccine protocol agreement with a physician.

(6) 'Physician' means an individual licensed to practice medicine in this state and whose principal place of practice is located in this state.

(7) 'Pharmacist' means an individual licensed under Chapter 4 of Title 26 to engage in the practice of pharmacy in the State of Georgia.

(8) 'Pharmacy intern' means a pharmacy intern as defined in paragraph (19) of Code Section 26-4-5.

(9) '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.

(10) 'Adverse event' means an event that is a negative consequence of the administration of influenza vaccine by a pharmacist or nurse that results in an unintended reaction, injury, or illness, which may or may not have been preventable.

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

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

(1) Must be licensed to practice medicine in the State of Georgia,

(2) Must have his/her principal place of practice in the State of Georgia, and

(3) Must 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").

360-34-.03. Physician Requirements for the Influenza Vaccine Protocol Agreement. A qualified physician may enter into a vaccine protocol agreement with a Georgia licensed pharmacist or a Georgia registered nurse or licensed practical nurse in his/her office under the following conditions:

(1) The physician shall not enter influenza 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 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 not be employed by the pharmacist(s) or nurse(s) with whom he/she is entering into the influenza vaccine protocol agreement;

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

(6) The physician must be available for immediate consultation or have designated another qualified physician as an alternate physician who is available for immediate consultation

360-34-.04. Requirements of the Influenza 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 provide the influenza vaccine recipient with the appropriate and current Vaccine Information Statement (VIS) as provided by the federal Centers for Disease Control and Prevention;

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

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

(b) name, dose, manufacturer, and lot number of the influenza 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 for receipt of the VIS and consent to the administration of the influenza vaccine; and

(f) any adverse events or complications that occur;

(5) Require the pharmacist or nurse to enter the patient's influenza vaccine information in GRITS within the time designated by DPH;

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

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

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

(9) 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 licensed practical nurse under the direct on-site supervision of the registered professional nurse; and

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

360-34-05 Filing of Influenza Vaccine Agreements with the Board.

The influenza vaccine protocol agreement must be filed with the Board within thirty (30) days of its execution.

360-34-06 Limitations

(1) Nothing in this Code section shall be construed to authorize a physician to prescribe any vaccines or other drugs pursuant to an influenza vaccine protocol agreement or influenza vaccine order contained in an influenza vaccine protocol agreement other than influenza vaccines, epinephrine, and diphenhydramine.

(2) No influenza vaccine protocol agreement entered into pursuant to this Code section shall permit a pharmacist or nurse to administer an influenza vaccine to any child under the age of 13 without an individual prescription from a physician, and consent of the child's parent or legal guardian shall be a condition precedent to the administration of an influenza vaccine to a child under the age of 18.

360-34-07. Template.

The Board's standard protocol template is available at www.medicalboard.georgia.gov.

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

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

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.