

# GEORGIA COMPOSITE MEDICAL BOARD

EXECUTIVE DIRECTOR  
LaSharn Hughes, MBA



BOARD CHAIRPERSON  
John T. Perry, MD

2 Peachtree Street, N.W., 36<sup>th</sup> 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 by the Georgia Composite Medical Board that it intends to amend Chapter 360-11 entitled "Flu Vaccine Protocols." An exact copy of the proposed amendments is attached to this Notice.

This notice, together with an exact copy of the proposed rules and a synopsis of the proposed rules are being emailed to all persons who have requested, in writing, that they be placed on the 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 5:00p.m., Monday through Friday, except official State holidays, at the office of the Georgia Composite Medical Board, 2 Peachtree Street, N.W., 36<sup>th</sup> Floor, Atlanta, Georgia 30303.

Any interested person who will be affected by these rules may present his or her comments to the Board no later than **October 26, 2009** or make comments at the public hearing. Comments may be directed to Diane Atkinson, Georgia Composite Medical Board, 2 Peachtree Street, N.W., 36<sup>th</sup> Floor, Atlanta, Georgia 30303-3465 or may be received by the Board by e-mail at [matkinson@dch.ga.gov](mailto:matkinson@dch.ga.gov).

A public hearing is scheduled to begin at **8:15 a.m.** on **November 5, 2009** 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.

The Board voted to adopt this Notice of Intent on **September 3, 2009**. The Board will consider at its meeting on **November 5, 2009** at **8:15 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 **October 2, 2009**, the Board will consider 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).

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The authority for promulgation of these rules is O.C.G.A. §§ 43-34-26.1 and the specific statutes cited in the proposed rules.

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.

Date: 10-2-09

A handwritten signature in cursive script that reads "LaSharn Hughes".

Signed: \_\_\_\_\_

LaSharn Hughes, MBA  
Executive Director  
Georgia Composite Medical Board

ECONOMIC IMPACT AND SYNOPSIS FOR  
AMENDMENTS TO CHAPTER 360-11  
**Flu Vaccine Protocols**

**ECONOMIC IMPACT:**

The attached rules are promulgated under the authority of the Medical Practice Act, Title 43, Chapter 34. The Georgia Composite Medical Board 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).

**CHAPTER SYNOPSIS:**

**Rule Chapter 360-8**

**Purpose/Main Feature:** The proposed rule is adopted to implement the directive of a new state law regarding House Bill 217.

Authority OCGA 43-34-26.1

**RULES**  
**OF**  
**GEORGIA COMPOSITE MEDICAL BOARD**  
  
**CHAPTER 360-11**  
**FLU VACCINE PROTOCOLS**

**360-11-.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 a vaccine administered by injection that contains inactivated influenza viruses that is prepared for the applicable season and that is administered to produce or increase immunity to the influenza virus.
- (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.

**360-32-.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 Department of Community Health ("DCH") under O.C.G.A. Section 31-12-3.1, commonly known as the Georgia Registry of Immunization Transactions and Services ("GRITS").

**360-32-.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 (i);

(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

#### **360-32-.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 DCH;

(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.

**360-32-05 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.

**360-32-.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.

**360-32-.07. Template.**

Below is the Board's standard protocol template:

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