GEORGIA COMPOSITE MEDICAL BOARD

EXECUTIVE DIRECTOR
LaSharn Hughes, MBA

BOARD CHAIRPERSON
Alice House, MD

2 Peachtree Street, N.W., 36th Floor • Atlanta, Georgia 30303 • Tel: 404.656.3923 • http://www.medicalboard.georgia.gov
E-Mail: medbd@dch.ga.gov

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 -.05 "Requirements of the Vaccine Protocol Agreement" and Rule 360-34-.10 "Penalties."** An exact copy of the proposed rule changes are 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 **December 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 **November 20, 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 December 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 **October 1, 2015** meeting. The Board will consider at its meeting on **December 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 **December 3, 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: 10/7/15

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

Purpose/Main Feature: The purpose of this amendment is to remove the word "influenza" from the rule. The word is not appropriate in this rule since the vaccine protocol agreements not only cover influenza vaccines but other vaccines as well.

Rule 360-34-.10 "Penalties"

Purpose/Main Feature: The purpose of this amendment to is to remove the word "knowingly" from the rule.

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-.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.

Authority Code Section 31-12-3.1, 31-12-3.2, 43-34-26.2,

360-34-.10. Penalties.
(1) The Board may impose a fine of up to $2,500 against any pharmacist or nurse who knowingly:

(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) Fail

(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 imposes 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. 43-34-5 and 43-34-26.1