

Georgia Composite Medical Board

Executive Director
Daniel R. Dorsey, MBA



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Matthew Norman, MD

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2 Peachtree Street, NW • 6th Floor • Atlanta, Georgia 30303 • (404) 656-3913 • www.medicalboard.georgia.gov

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 by amending **Rule 360-34-.05 "Requirements of the Vaccine Protocol Agreement"**. 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 may be reviewed between 8:00 a.m. and 4:00 p.m., Monday through Friday, except official state holidays, at 2 Peachtree Street, NW, 6th Floor, Atlanta, GA 30303. These documents can also be reviewed online at <http://medicalboard.georgia.gov/notice-intent-amendadopt-rules>.

A public hearing is scheduled to begin at **8:30 a.m. on October 6, 2022, via TEAMS** to provide the public an opportunity to comment upon and provide input into the proposed rules. At the public hearing, any interested person may present data, make a statement or comment, or offer a viewpoint or argument orally or in writing. Lengthy statements and statements of a considerable technical or economic nature, as well as previously recorded messages, must be submitted for the official record. Oral statements should be concise and will be limited to five minutes per person. Additional comments should be presented in writing. To ensure their consideration, submit all written comments by **September 22, 2022, to Kierra.Battle@dch.ga.gov** or via mail to the Georgia Composite Medical Board Rules Committee at 2 Peachtree Street, NW, 6th Floor, Atlanta, Georgia 30303.

The Board voted to adopt this Notice of Intent on **September 1, 2022**. Upon conclusion of the public hearing on **October 6, 2022**, the Board will consider 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, 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), and (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. Secs. 43-34-5, 43-34-103, and 43-34-108.

Issued this day September 1, 2022.

Daniel R. Dorsey
Executive Director

ECONOMIC IMPACT AND SYNOPSIS FOR

RULE CHAPTER 360-34 Vaccine Protocol Agreements

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 these rules do 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 in 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 Agreement”

Purpose/Main Features: The first proposed amendment to this rule eliminates the requirement that a vaccine recipient, who is not a patient with a hospital or health system, be issued a personal immunization card on card stock paper. This originally was a statutory provision, O.C.G.A. § 43-34-26.1(d)(5)(2016). However, the rewrite of this code section in 2021 eliminated the requirement for a personal immunization card from the code section.

The second proposed amendment to this rule adds the new requirement for checking GRITS prior to the administration of the vaccine, as now required by O.C.G.A. § 43-34-26.1(o)(2)(C) (2021).

The third proposed amendment to this rule eliminates the phrase “local health department” from the provision requiring the posting of the vaccine protocol agreement; the language now directly tracks the statutory language in O.C.G.A. § 43-34-26.1(d)(14).

Authority O.C.G.A. §§ 43-34-5; 43-34-26.1

Rule 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;~~
- (7) 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;

(89) 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;

(910) 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;

(1011) Prohibit the administration of the vaccine to a patient while the patient is in his or her personal vehicle;

(1112) Require the pharmacist, ~~or nurse,~~ or his or her designee to check the Georgia Registry of Immunization Transactions and Services prior to administration of the vaccine and to enter the patient's vaccine information in Georgia Registry of Immunization Transactions and Services ("GRITS")-the vaccination registry within the time designated by the Department of Public Health; provided, however, that a pharmacist, nurse, or his or her designee shall not be required to check the Georgia Registry of Immunization Transactions and Services during:

(a) A public health emergency, as defined in Code Section 31-12-1.1, for any vaccine administered to address the cause of the threat of an illness or health condition or the infectious agent or biological toxin which resulted in such public health emergency; or

(b) A vaccination event for influenza that is anticipated to serve 75 or more patients;

(1213) Require that the vaccine recipient remain under observation for not less than 15 minutes immediately subsequent to the administration of the vaccine;

(1314) Contain procedures to follow in the event of an adverse event or complication;

(1415) Provide for prioritization of vaccine recipients in the event of a limitation in the supply of the vaccine;

(1516) 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;

(1617) 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;

(1718) 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;

(1819) 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;

| (~~1920~~) 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

| (~~2021~~) Provide for the expiration, renewal or revision of the protocol on at least a biennial basis.

Authority: §§ 31-12-3.1, 31-12-3.2, 43-34-26.2.