Georgia Composite Medical Board

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NOTICE OF INTENT TO AMEND AND/OR 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 adopting **Rule 360-41-.02 "Regulations for Facilities and Physicians."** 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 https://medicalboard.georgia.gov/board/notice-intent-amendadopt-rules.

A public hearing is scheduled to begin at **8:30 a.m. on January 5, 2023, 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 **December 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 **December 1, 2022**. Upon conclusion of the public hearing on **January 5, 2023**, 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 December 1, 2022.

Daniel R. Dorsey
Executive Director

ECONOMIC IMPACT AND SYNOPSIS FOR

RULE CHAPTER 360-41
Sedation in Physician Offices and Medispas

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 360-41-.02 "Regulations for Facilities and Physicians"

Purpose/Main Features: The purpose of the proposed rule is to provide guidance for the use of sedation, analgesia and/or anesthesia in physician offices and medispas.

Authority: O.C.G.A. § 43-34-47

Rule 360-41-.02 Regulations for Facilities and Physicians

(1) Application of rules. These rules apply to physicians practicing independently or in a group setting who perform office based surgery employing one or more of the following levels of sedation or anesthesia:
(a) Moderate sedation/analgesia;
(b) Deep sedation/ analgesia;
(c) Major conduction anesthesia; or
(d) General anesthesia.

(2) Accreditation or certification. Physicians who perform any procedures utilizing moderate sedation/analgesia, deep sedation/analgesia, major conduction anesthesia, or general anesthesia must ensure that the procedure is performed in a facility that is appropriately equipped and maintained to ensure patient safety, which may be demonstrated by accreditation by any of the following entities:
(a) The Joint Commission;
(b) The Accreditation Association for Ambulatory Care;
(c) The American Association for Accreditation of Ambulatory Surgery Facilities; or
(d) The Centers for Medicare and Medicaid Services

(3) Competency. When an anesthesiologist or certified registered nurse anesthetist is not present, the physician performing office based surgery using moderate sedation/analgesia, deep sedation/analgesia, major conduction anesthesia, or general anesthesia must be competent and qualified to oversee the administration of intravenous sedation/analgesia through one of the following training pathways:
(a) Completion of a continuing medical education course in conscious sedation;
(b) Training in conscious sedation in a residency program; or
(c) Having privileges for conscious sedation granted by a hospital medical staff.

(4) Separation of surgical and monitoring functions.
(a) The physician performing the surgical procedure must not administer the intravenous sedation or monitor the patient.
(b) The licensed health care practitioner designated by the physician to administer the intravenous sedation and monitor the patient may assist the physician with minor interruptible tasks for short duration once the patient's level of sedation and vital signs have been stabilized, provided that adequate monitoring of the patient's condition is maintained. The licensed health care practitioner who administers intravenous medication under deep sedation/analgesia or general anesthesia must not perform or assist with the procedure.

(5) Sedation assessment and management.
(a) Sedation is a continuum. Depending on the patient's response to drugs, the drugs administered, and the dose and timing of administration, it is possible that a deeper level of sedation will be produced than initially intended.
(b) If an anesthesiologist or certified registered nurse anesthetist is not present, a physician intending to produce a given level of sedation shall rescue a patient that enters a deeper level of sedation than intended.
(c) If a patient enters into a deeper level of sedation than planned, the physician must return the patient to the lighter level of sedation as quickly as possible while closely monitoring the patient

to make sure the airway is patent, the patient is breathing, and that oxygenation, heart rate, and blood pressure are within acceptable values.

(d) Instructions to avoid driving, operating machinery, consuming alcoholic beverages, and making important decisions for 24 hours should be provided for patients who undergo deep sedation/analgesia.

(6) Emergency care and transfer protocols. A physician performing office based surgery must ensure that in the event of a life-threatening complication or emergency that:

(a) At least one health care provider certified in advanced resuscitative techniques appropriate for the patient age group (i.e ACLS, PALS, or APLS) must be present or immediately available with age-size-appropriate resuscitative equipment throughout the procedure and until the patient has met the criteria for discharge from the facility.

(b) All office personnel are familiar with a written, documented plan to timely and safely transfer patients to an appropriate hospital that includes a proven accessible route for stretcher transport of the patient out of the office, arrangement for emergency medical services and appropriate escort of the patient to the hospital, and a compliance process to notify the Board of an adverse event as specified in 360-41-.04; and

(c) Resuscitative equipment is immediately available. Such equipment should be evaluated for functionality every 6 months and records of such evaluations should be maintained within the facility.

(7) Standard of practice. Any licensed physician engaging in surgery in office based surgery must have received appropriate training and education in the safe and effective performance of all procedures performed in the facility. Such training and education shall include:

(a) Indications and contraindications for each procedure;

(b) Identification of realistic and expected outcomes for each procedure;

(c) Selection, utilization, and maintenance of products and equipment;

(d) Appropriate technique for each procedure, including infection control and safety precautions;

(e) Pharmacologic intervention specific to each procedure;

(f) Identification of complications and adverse reactions for each. procedure; and

(g) Emergency procedures to be used in the event of:

(i) Complications;

(ii) Adverse reactions;

(iii) Equipment malfunctions; or

(iv) Any other interruption of a procedure.

(8) Adverse events. Any incident within the facility that results in a patient death or transport of the patient to the hospital for observation or treatment for a period in excess of 24 hours shall be reported to the Board in writing within 10 working days of the death or hospitalization.

(9) Truth in advertising. The credentials, education and training received, specialty board certification, and proficiency evaluations of all personnel involved in performing surgical procedures shall be accurately presented in any form of advertising and shall be readily available inwriting to all patients.