Georgia Composite Medical Board

Interim Executive Director
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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 **Chapter 360-41 "Sedation in Physician Offices and Medispas"**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 **January 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 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 5 minutes per person. Additional comments should be presented in writing. To ensure their consideration, submit all written comments by **January 5, 2021 to pwhite@dch.ga.gov** via mail to the Georgia Composite Medical Board Rules Committee at 2 Peachtree Street, N.W., 6th Floor, Atlanta, Georgia 30303.

The Board voted to adopt this Notice of Intent on **December 2, 2021**. Upon conclusion of the public hearing on **January 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 August 6, 2021.

Jonathan McGehee
Interim Executive Director
Georgia Composite Medical Board

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ECONOMIC IMPACT AND SYNOPSIS FOR

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:

Chapter 360-41 "Sedation in Physician Offices and Medispas"
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

Chapter 360-41 SEDATION IN PHYSICIAN OFFICES AND MEDISPAS

Rule 360-41-.01 Definitions

For purposes of this Chapter, the following definitions apply:

(1) "Medispa" means a facility that offers a range of services for the purpose of improving an individual's well-being or appearance including medical and surgical procedures such as liposuction, laser procedures, intense pulsed light, and injection of cosmetic filling agents and neurotoxins in a nontraditional setting.

(2) "Sedation" means minimal sedation, moderate sedation/analgesia, or general anesthesia. This term shall not include local infiltration.

(3) "Minimal sedation" means a drug-induced state during which the patient responds normally to verbal commands.

(4) "Moderate sedation/analgesia" means a drug-induced depression or consciousness during which the patient responds purposefully to verbal commands, either alone or accompanied by tactile stimulation.

(5) "Deep sedation/analgesia" means a drug-induced depression of consciousness during which the patient cannot be easily aroused but can respond purposefully following repeated or painful stimulation.

(6) "General anesthesia" means a state of unconsciousness intentionally produced by anesthetic agents with absence of pain sensation over the entire body, in which the patient's protective airway reflexes may be impaired and the patient may be unable to maintain a natural airway. Other sedation that progresses to the point at which the patient's protective airway reflexes are impaired and the patient is unable to maintain a patent natural airway is considered general anesthesia.

(7) "Major conduction anesthesia" means the administration of a drug or combination of drugs to interrupt nerve impulses without loss of consciousness, such as epidural, caudal, or spinal anesthesia, lumbar or brachia! plexus blocks, and intravenous regional anesthesia. Major conduction anesthesia does not include isolated blockade of small peripheral nerves, such as digital nerves.

(8) "Rescue" means an intervention by a practitioner proficient in airway management and advanced life support to correct adverse physiologic consequences of the deeper-than-intended level of sedation and to return the patient to the originally intended level of sedation.

(9) "Office based surgery" means any surgery or invasive medical procedure requiring sedation when performed in any location, including but not limited to physician offices and medispas, other than a hospital, hospital associated surgical center, or an ambulatory surgical facility.

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 surgery in an office setting or medispa employing one or more of the following levels of sedation or anesthesia:
(a) Moderate sedation/analgesia; or
(b) Deep sedation/ analgesia; or
(c) Major conduction anesthesia; or
(d) General anesthesia.

(2) Accreditation or certification. Physicians who perform any procedures utilizing moderate sedation/analgesia, deep sedation/analgesia, or general anesthesia must insure that the procedure is performed in a facility that is appropriately equipped and maintained to ensure patient safety. Once method to demonstrate facility preparedness and staff competency is achieving accreditation by an appropriate agency including any of the following:
(a) The Joint Commission;
(b) The Accreditation Association for Ambulatory Care;
(c) The American Association for Accreditation of Ambulatory Surgery Facilities
(d) The Centers for Medicare and Medicaid Services

(3) Competency. When an anesthesiologist or certified registered nurse anesthetist is not present, the physician performing surgery in an office or medispa using moderate sedation/analgesia, deep sedation/analgesia, 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) Relevant training 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 or 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 should be able to 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.

(6) Emergency care and transfer protocols. A physician performing surgery in an office or medispa must insure 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 and documented plan to timely and safely transfer patients to an appropriate hospital.

(c) The plan must include:

(i) a proven accessible route for stretcher transport of the patient out of the office;

(ii) arrangement for emergency medical services and appropriate escort of the patient to the hospital;

(iii) a compliance process to notify the Board or an adverse event as specified in 360-41-.04.

(d) Resuscitative 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 an office or medispa must have received appropriate training and education in the safe and effective performance of all procedures performed in the facility. Such training and education should include:

(a) Indications and contraindications for each procedure;

(b) Identification or realistic and expected outcomes or 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;

(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, whichever comes first.

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

Rule 360-41-.03 Medical Records

(1) The physician performing surgery in a medical office or a medispa must maintain a legible, complete, comprehensive and accurate medical record for each patient. The medical record must include:

(a) Identity of the patient;

(b) History and physical, diagnosis and plan;

(c) Appropriate labs, x-rays, or other diagnostic reports;

(d) Appropriate pre-anesthesia evaluation;

(e) Narrative description of procedure;

(f) Pathology reports if relevant;

(g) Documentation of which, if any, tissues and specimens have been submitted for histopathologic diagnosis;

(h) Provisions for continuity of postoperative care; and

(i) Documentation of the outcome and the follow-up plan.

(2) When moderate or deep sedation or major conduction anesthesia is used, the patient medical record must include a separate anesthesia record which

includes:

(a) The type of sedation or anesthesia used; and

(b) Drugs (name and dose) and time of administration; and

(c) The patient's vital signs at regular intervals including, at a minimum, blood pressure, heart rate, respiratory rate and oxygen saturation; and

(d) Return to appropriate level of consciousness and readiness for discharge from acute care.

Rule 360-41-.04 Exemptions

These Rules shall not apply to physicians when:

(1) Performing surgery and medical procedures that require only infiltration of local anesthesia around peripheral nerves or non-mixed sensory nerves in an amount that does not exceed the manufacturer's published recommendations.

(2) Performing surgery in a hospital-associated surgical center or a licensed ambulatory surgical center.

(3) Performing oral and maxillofacial surgery and the physician:

(a) Is licensed both as a physician under Title 43 Chapter 34 and a dentist under Title 43 Chapter 11; or

(b) Complies with dental quality assurance regulations; and

(c) Holds a valid:

(i) Moderate sedation permit; or

(ii) Moderate sedation with parental agents permit; or

(iii) General anesthesia and deep sedation permit; and

(iv) Practices within the scope of his or her specialty.