### NOTICE OF INTENT TO AMEND RULE OF THE GEORGIA BOARD OF DENTISTRY RULE 150-13-.01 CONSCIOUS SEDATION PERMITS

### TO ALL INTERESTED PERSONS AND PARTIES:

Notice is hereby given that pursuant to the authority set forth below, the Georgia Board of Dentistry (hereinafter "Board") proposes amendments to Georgia Board of Dentistry Rule 150-13-.01 CONSCIOUS SEDATION PERMITS (hereinafter "proposed amendments").

This notice, together with an exact copy of the rule including the proposed amendments and a synopsis of the rule including the proposed amendments, is being forwarded to all persons who have requested, in writing, that they be placed on an interested parties list. A copy of this notice, an exact copy of the rule including the proposed amendments, and a synopsis of the rule including the proposed amendments, and a synopsis of the rule including the proposed amendments, and a synopsis of the rule including the proposed amendments, and a synopsis of the rule including the proposed amendments 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 Department of Community Health at 2 Martin Luther King, Jr. Drive SE, East Tower, 11th Floor, Atlanta, GA 30334. These documents will also be available for review on the Georgia Board of Dentistry's web page at http://gbd.georgia.gov/.

<u>A public hearing is scheduled to begin at 10:00 AM on October 6, 2023</u> at the Department of Community Health at 2 Martin Luther King, Jr. Drive SE, East Tower, 11th Floor, Atlanta, GA 30334 to provide the public an opportunity to comment upon and provide input into the proposed amendments. During the public hearing, anyone may present data, make a statement, comment or offer a viewpoint or argument whether orally or in writing. Lengthy statements or 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. Written comments are welcome. To ensure their consideration, written comments must be received prior to September 29, 2023. Written comments should be addressed to Executive Director of the Georgia Board of Dentistry at 2 Martin Luther King, Jr. Drive SE, East Tower, 11th Floor, Atlanta, GA 30334. You may email your comments to <u>elacefield@dch.ga.gov</u>.

The proposed rule amendments will be considered by the Georgia Board of Dentistry during its meeting <u>scheduled to begin at 10:00 AM on October 6, 2023</u> at the Department of Community Health at 2 Martin Luther King, Jr. Drive SE, East Tower, 11th Floor, Atlanta, GA 30334. According to the Department of Law, State of Georgia, the Georgia Board of Dentistry has the authority to adopt the proposed rule amendments pursuant to authority contained in O.C.G.A §§ 43-11-1, 43-11-7, 43-11-21, and 43-11-21.1.

At its meeting on May 5, 2023, the Board voted that the formulation and adoption of these amendments do not impose excessive regulatory cost on any licensee and any cost to comply with the proposed amendments cannot be reduced by a less expensive alternative that fully accomplishes the objectives of O.C.G.A §§ 43-11-7 and 43-11-9.

At its meeting on May 5, 2023, the Board also voted that it is not legal or feasible to meet the objectives of O.C.G.A. §§43-11-7 and 43-11-9 to adopt or implement differing actions for

businesses as listed at O.C.G.A. § 50-13-4(a)(3)(A), (B), (C) and (D). The formulation and adoption of these amendments will impact every licensee in the same manner, and each licensee is independently licensed, owned and operated and dominant in the field of dentistry.

For further information, contact the Board office at 404-651-8000.

This notice is given in compliance with O.C.G.A. §50-13-4.

This 5 day of Sodember, 2023.

Eric R. Lacefield Executive Director Georgia Board of Dentistry

Posted: <u>Sept. 5</u>, 2023

## SYNOPSIS OF PROPOSED AMENDMENTS OF THE GEORGIA BOARD OF DENTISTRY RULE 150-13-.01 CONSCIOUS SEDATION PERMITS.

- Purpose: To restrict administration of certain pharmacologic agents known to exhibit a particularly narrow margin for maintaining patient consciousness from use in conscious sedation procedures. This change is in accord with O.C.G.A. § 43-11-21's mandate that "the dentist shall ensure that the pharmacologic agents and methods used to administer such agents shall include a margin of safety so that loss of consciousness of the patient is unlikely."
- Main Features: Specification of certain pharmacologic agents which may not be administered in conscious sedation procedures unless the administering dentist holds a general anesthesia permit.

# DIFFERENCES OF PROPOSED AMENDMENTS OF THE GEORGIA BOARD OF DENTISTRY RULE 150-13-.01 CONSCIOUS SEDATION PERMITS.

NOTE: Struck through text is proposed to be deleted. Underlined text is proposed to be added.

A copy of the draft rule approved by the Board is attached hereto.

### **Rule 150-13-.01 Conscious Sedation Permits**

- (1) When the intent is minimal sedation (anxiolysis), which is defined as a minimally depressed level of consciousness that retains the patient's ability to independently and continuously maintain an airway with unaffected ventilatory and cardiovascular function and respond normally to tactile and verbal stimulation, a permit for conscious sedation is not required.
  - (a) When the intent is minimal sedation for adults, the initial dosing is no more than the maximum recommended dose (MRD) of a drug that can be prescribed for unmonitored home use. Nitrous oxide/oxygen may be used in combination with a single enteral drug in minimal sedation. For adults, supplemental dosing that may be necessary for prolonged procedures should not exceed one-half of the initial drug dose and should not be administered until the dentist has determined that the clinical half-life of the initial dosing has passed. The total aggregate dose must not exceed 1.5x the MRD on the day of treatment.
  - (b) The use of preoperative sedatives for children (age 12 and under) except in extraordinary situations must be avoided due to the risk of unobserved respiratory obstruction during transport by untrained individuals. Children can become moderately sedated despite the intended level of minimal sedation. Should this occur, the guidelines for moderate sedation apply. For children, the American Dental Association supports the use of the American Academy of Pediatrics/American Academy of Pediatric Dentists Guidelines for Monitoring and Management of Pediatric Patients During and After Sedation for Diagnostic and Therapeutic Procedures.
- (2) No dentist shall administer conscious sedation at the moderate level in Georgia in accordance with the definition of conscious sedation as defined by O.C.G.A. 43-11-1 unless such dentist possesses a permit based on a credentials review. The permits issued are Moderate Enteral Conscious Sedation or Moderate Parenteral Conscious Sedation.
- (3) Moderate Conscious Sedation is defined as a drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.
- (4) Moderate Enteral Conscious Sedation is any technique of administration in which the drugs are absorbed through the gastrointestinal tract or oral mucosa, i.e. oral, rectal, and sublingual.
  - (a) To obtain a Moderate Enteral Conscious Sedation Permit for adults, a dentist must provide certification of the following:

- 1. Completion of an ADA-accredited postdoctoral training program, which affords comprehensive training necessary to administer and manage moderate enteral conscious sedation; or
- Completion of a continuing education course approved by the board from a board approved organization, which consists of a minimum of twenty-four (24) hours of didactic instruction, of which eight (8) hours must be in-person, plus management of at least ten (10) adult patient experiences which provides competency in moderate enteral conscious sedation which may include simulated cases.
- (b) To obtain a Moderate Enteral Conscious Sedation Permit for pediatric patients (age 12 and under), a dentist must provide certification of the following:
  - 1. Completion of an ADA-accredited postdoctoral training program, which affords comprehensive training and experience in pediatric sedation commensurate with the requirements of Rule 150-13-.01(4)(b)(2), and necessary to administer and manage moderate enteral conscious sedation of pediatric patients; or
  - Completion of a continuing education course approved by the board from a board approved organization, which consists of a minimum of twenty-four (24) hours of pediatric-specific didactic instruction, of which eight (8) hours must be in-person, after adult training and ten (10) pediatric patient experiences, which include supervised administration of sedation to at least five (5) patients.
- (5) Moderate Parenteral Conscious Sedation is any technique utilizing multiple sedation modalities, including intravenous, enteral, parenteral, and inhalation.
  - (a) To obtain a Moderate Parenteral Conscious Sedation Permit for adults, a dentist must provide certification of the following:
    - 1. Completion of an ADA-accredited postdoctoral training program, which affords comprehensive training to administer and manage moderate parenteral conscious sedation; or
    - 2. Completion of a continuing education course approved by the board from a board approved organization which consists of a minimum of sixty (60) hours of didactic instruction, of which twenty (20) hours must be in-person, plus management of at least twenty (20) adult patient experiences which provides competency in moderate parenteral conscious sedation.
  - (b) To obtain a Moderate Parenteral Conscious Sedation Permit for pediatric patients (age 12 and under), a dentist must provide certification of the following:
    - 1. Completion of an ADA-accredited postdoctoral training program, which affords comprehensive training and experience in pediatric sedation

commensurate with requirements of Rule 150-13-.01(5)(b)(2) and necessary to administer and manage moderate parenteral conscious sedation of pediatric patients; or

- 2. Completion of a continuing education course approved by the board from a board approved organization, which consists of a minimum of sixty (60) hours of pediatric-specific didactic instruction, of which twenty (20) hours must be in person, after adult training and twenty (20) pediatric patient experiences to include supervised administration of sedation to at least ten (10) patients.
- (6) The dentist issued a permit in either Moderate Enteral Conscious Sedation or Moderate Parenteral Conscious Sedation shall maintain a properly equipped facility for the administration of such sedation, staffed with appropriately trained and supervised personnel. The facility must have equipment capable of delivering positive pressure oxygen ventilation, a pulse oximeter, suction equipment that allows aspiration of the oral and pharyngeal cavities, an operating table or chair that allows for the patient to be positioned to maintain an airway, a firm platform for cardiopulmonary resuscitation, a failsafe inhalation system if nitrous oxide/oxygen is used, equipment necessary to establish intravascular access, equipment to continuously monitor blood pressure and heart rate, appropriate emergency drugs per ACLS or PALS protocol, a manual or automatic external defibrillator, and a recovery area with available oxygen and suction. The facility shall have continual monitoring of end tidal CO2 (expired carbon dioxide) unless invalidated by the nature of the patient, procedure, or equipment. "Continual" shall mean "repeated regularly and frequently in steady rapid succession." All of the aforementioned equipment, drugs, and supplies must be stationary and not subject to transfer from one facility to another. The applicant must submit verification that the facility meets the above requirements and shall be subject to an on-site inspection. The dentist and all support personnel must be certified in cardiopulmonary resuscitation at the basic life support healthcare provider level given by a board approved sponsor with update not to exceed two years per board rules 150-3-.08, 150-3-.09, 150-5-.04, 150-5-.05. Additionally, the dentist must have current certification in advanced cardiovascular life support (ACLS) for adult permits or pediatric advanced life support (PALS) for pediatric permits or an appropriate dental sedation/anesthesia emergency management course as approved by the board. Any dental hygienist or dental assistant, expanded or general, performing phlebotomy or venipuncture procedures must be in compliance with O.C.G.A. § 43-11-23.
  - (a) The dentist must take four (4) hours of continuing education every two (2) years in pharmacology, anesthesia, emergency medicine or sedation, as part of the 40 hour requirement for license renewal, to maintain certification for the Enteral and/or Parenteral Conscious Sedation Permits. Certification of this continuing education must be submitted at renewal.

- (b) The Georgia Board of Dentistry shall be given a written, thirty (30) day advance notification of the relocation of a facility, the addition of a facility or significant change to the facility.
- (c) When a Certified Registered Nurse Anesthetist (CRNA) is permitted to function under the direction and responsibility of a dentist for the administration of conscious sedation, the operating dentist must have completed training and hold a valid conscious sedation permit issued by the board that incorporates the level and mode of sedation administered by the CRNA.
- (d) The dentist must be certified in cardiopulmonary resuscitation at the basic and advanced levels and all support personnel who provide direct hands-on patient care must be certified in cardiopulmonary resuscitation at the basic life support level given by a board approved provider with an update not to exceed two years. While any conscious sedation procedure is underway, a minimum of two support personnel certified in basic cardiopulmonary resuscitation must be present.
- (7) A licensed dentist shall not delegate to a dental assistant or a dental hygienist the administration of any medication or drugs given to a patient through phlebotomy and venipuncture procedures.
- (8) The requirements as set forth in this rule apply to all new permit applicants upon its effective date. Current, active sedation permit holders are grandfathered for educational requirements and will have until December 31, 2011 to comply with facility requirements including monitoring and emergency equipment, drugs, and supplies, and periodic emergency training requirements for the dentist and all support personnel.
- (9) Permit fees: As shown in the schedule of fees adopted by the Board of Dentistry.
- (10) Renewal Fees: As shown in the schedule of fees adopted by the Board of Dentistry.
- (11) Late Renewal Fees: As shown in the schedule of fees adopted by the Board of Dentistry.
- (12) Drug Restriction: No dentist issued a conscious sedation permit pursuant to this Rule shall administer any general anesthetic agent which has been identified by the Board of Dentistry in Rule 150-13-.01(13) as exhibiting a narrow margin for maintaining consciousness, unless such dentist simultaneously holds a permit to perform deep sedation / general anesthesia procedures in that location, pursuant to Rule 150-13-.02.
- (13) The following anesthetic agents have been identified by the Board of Dentistry as exhibiting a narrow margin for maintenance of patient consciousness:
  - (a) Alkylphenols propofol (Diprivan) including precursors or derivatives;
  - (b) Dissociative anesthetics Ketamine;
  - (c) Dexmedetomidine;
  - (d) Any barbiturate drug classified as "ultrashort acting," including, but not limited to:

- 1. Sodium methohexital;
- 2. Thiamylal; or
- 3. Thiopental.
- (e) Etomidate; or
- (f) Volatile inhalational agents.