House Bill 695

By: Representatives Randall of the 142nd, Dempsey of the 13th, Harbin of the 122nd, Hatchett of the 150th, Rogers of the 29th, and others

A BILL TO BE ENTITLED AN ACT

I	To amend	Title 31	of the	Official	Code o	t Georgia	Annotaated,	, relating t	o health,	so as	tc

- 2 provide for office based surgery procedures; to provide for definitions; to provide for
- 3 exemptions; to provide for application of procedures; to provide for accreditation or
- 4 certification requirements; to provide for competency standards; to provide for sedation
- 5 assessment and management; to provide for separation of surgical and monitoring functions;
- 6 to provide for emergency care and transfer protocols; to provide for medical record
- 7 requirements; to provide for standards of practice; to provide for adverse events and
- 8 advertising requirements; to provide for related matters; to repeal conflicting laws; and for
- 9 other purposes.

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BE IT ENACTED BY THE GENERAL ASSEMBLY OF GEORGIA:

SECTION 1.

- 12 Title 31 of the Official Code of Georgia Annotated, relating to health, is amended by adding
- 13 a new chapter to read as follows:
- 14 "<u>CHAPTER 50</u>
- 15 <u>31-50-1.</u>
- 16 As used in this chapter, the term:
- 17 (1) 'Deep sedation or analgesia' or 'deep sedation' means a drug induced depression of
- consciousness during which patients cannot be easily aroused but can respond
- 19 purposefully following repeated or painful stimulation. The ability to independently
- 20 <u>maintain ventilatory function may be impaired. Patients may require assistance in</u>
- 21 <u>maintaining a patent airway, and spontaneous ventilation may be inadequate.</u>
- 22 <u>Cardiovascular function is usually maintained.</u>
- 23 (2) 'General anesthesia' means a state of unconsciousness intentionally produced by
- 24 <u>anesthetic agents, with absence of pain sensation over the entire body, in which the</u>

patient's protective airway reflexes may be impaired and the patient may be unable to
 maintain a patent natural airway. Sedation that unintentionally progresses to the point at
 which the patient's protective airway reflexes are impaired and the patient is unable to

- 28 <u>maintain a patent natural airway is considered general anesthesia.</u>
- 29 (3) 'Local infiltration' means the process of infusing a local anesthetic agent into the skin
- and other tissues to allow painless wound irrigation, exploration and repair, and other
- 31 procedures. It does not include procedures in which local anesthesia is injected into areas
- of the body other than skin or muscle where significant cardiovascular or respiratory
- 33 <u>complications may result.</u>
- 34 (4) 'Major conduction anesthesia' means the administration of a drug or combination of
- 35 <u>drugs to interrupt nerve impulses without loss of consciousness, such as epidural, caudal,</u>
- or spinal anesthesia, lumbar or brachial plexus blocks, and intravenous regional
- 37 <u>anesthesia. Major conduction anesthesia does not include isolated blockade of small</u>
- 38 <u>peripheral nerves, such as digital nerves.</u>
- 39 (5) 'Minimal sedation' means a drug-induced state during which patients respond
- 40 <u>normally to verbal commands</u>. Although cognitive function and coordination may be
- 41 <u>impaired, ventilatory and cardiovascular functions are unaffected. Minimal sedation is</u>
- 42 <u>limited to oral or intramuscular medications, or both.</u>
- 43 (6) 'Moderate sedation or analgesia' or 'moderate sedation' means a drug induced
- 44 <u>depression of consciousness during which patients respond purposefully to verbal</u>
- 45 <u>commands with or without tactile stimulation. No interventions are required to maintain</u>
- 46 <u>a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is</u>
- 47 <u>usually maintained.</u>
- 48 (7) 'Office based surgery' means any surgery or invasive medical procedure requiring
- 49 <u>analgesia or sedation that is performed in a location other than a hospital or hospital</u>
- 50 <u>associated surgical center or an ambulatory surgical facility licensed as an institution</u>
- 51 pursuant to Article 1 of Chapter 7 of this title.
- 52 (8) 'Physician' means an individual licensed under Chapter 34 of Title 43.
- 53 (9) 'Tumescent anesthesia' means the technique for delivery of local anesthesia to
- 54 <u>achieve extensive regional anesthesia of skin and subcutaneous tissue. The subcutaneous</u>
- 55 <u>infiltration of a large volume of very dilute lidocaine and epinephrine causes the targeted</u>
- 56 <u>tissue to become swollen and firm, or tumescent, and permits procedures to be performed</u>
- 57 <u>on patients often without the need for deep sedation or general anesthesia.</u> For the
- 58 purposes of this chapter, the maximum safe dose of tumescent lidocaine should not
- 59 <u>exceed the published standard of 55 mg/kg.</u>

- 60 31-50-2.
- This chapter shall not apply to physicians when:
- 62 (1) Performing surgery and medical procedures that require only infiltration of local
- anesthetic around peripheral nerves or nonmixed sensory nerves. Infiltration around
- 64 peripheral nerves or nonmixed sensory nerves does not include infiltration of local
- anesthetic agents in an amount that exceeds the manufacturer's published
- 66 <u>recommendations.</u>
- 67 (2) Performing surgery in a hospital or licensed hospital associated surgical center or
- 68 <u>licensed ambulatory surgical facility.</u>
- 69 (3) Performing oral and maxillofacial surgery and the physician:
- 70 (A) Is licensed both as a physician under Chapter 34 of Title 43 and as a dentist under
- 71 <u>Chapter 11 of Title 43; or</u>
- 72 (B) Complies with dental quality assurance commission regulations; and
- 73 (C) Holds a valid:
- 74 (i) Moderate sedation permit;
- 75 (ii) Moderate sedation with parenteral agents permit; or
- 76 (iii) General anesthesia and deep sedation permit; and
- 77 (D) Practices within the scope of his or her specialty.
- 78 <u>31-50-3.</u>
- 79 This chapter shall apply to physicians practicing independently or in a group setting who
- 80 perform office based surgery employing one or more of the following levels of sedation or
- 81 <u>anesthesia:</u>
- 82 (1) Moderate sedation or analgesia;
- 83 (2) Deep sedation or analgesia;
- 84 (3) Major conduction anesthesia;
- 85 (4) Tumescent anesthesia; or
- 86 (5) General anesthesia.
- 87 <u>31-50-4.</u>
- 88 (a) Physicians who perform any procedures under this chapter shall ensure that the
- 89 procedure is performed in a facility that is appropriately equipped and maintained to ensure
- 90 patient safety. Achieving accreditation by an appropriate agency, including any one or
- 91 more of the following, is one method to demonstrate facility preparedness and staff
- 92 <u>competency:</u>
- 93 (1) The Joint Commission;
- 94 (2) The Accreditation Association for Ambulatory Health Care;

95 (3) The American Association for Accreditation of Ambulatory Surgery Facilities; or

- 96 (4) The Centers for Medicare and Medicaid Services.
- 97 (b) When an anesthesiologist or certified registered nurse anesthetist is not present, the
- 98 physician performing office based surgery and using moderate sedation or analgesia shall
- 99 <u>be competent and qualified to oversee the administration of intravenous sedation or</u>
- analgesia through one of the following training pathways:
- (1) Completion of a continuing medical education course in conscious sedation including
- moderate sedation or analgesia;
- 103 (2) Relevant training in a residency training program;
- (3) Having privileges for conscious sedation and moderate sedation or analgesia granted
- by hospital medical staff; or
- 106 (4) Sedation assessment and management.
- (c) Sedation is a continuum. Depending on the patient's response to drugs, the drugs
- administered, and the dose and timing of drug administration, it is possible that a deeper
- level of sedation will be produced than initially intended. Consequently, if an
- anesthesiologist or certified registered nurse anesthetist is not present, a physician
- intending to produce a given level of sedation shall be able to return a patient who enters
- a deeper level of sedation than intended.
- (d) If a patient enters into a deeper level of sedation than planned, the physician shall
- return the patient to a lighter level of sedation as quickly as possible, while closely
- monitoring the patient to ensure the airway is patent, the patient is breathing, and that
- oxygenation, heart rate, and blood pressure are within acceptable values. A physician who
- returns a patient to a lighter level of sedation in accordance with this subsection does not
- violate the standard of care pursuant to this chapter.
- (e) A physician performing a surgical procedure under this chapter shall administer the
- intravenous sedation or monitor the patient.
- 121 (f) A licensed health care practitioner, designated by the physician to administer
- intravenous medications and monitor the patient who is under moderate sedation, may
- 123 <u>assist the operating physician with minor, interruptible tasks of short duration once the</u>
- 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 medications and monitors a patient under deep sedation or
- analgesia shall not perform or assist in the surgical procedure.
- (g) A physician performing office based surgery shall ensure the following in the event of
- 129 <u>a complication or emergency:</u>
- (1) At least one licensed health care practitioner currently certified in advanced
- resuscitative techniques appropriate for the patient's age group shall be present or

immediately available with age- and size-appropriate resuscitative equipment throughout

- the procedure and until the patient has met the criteria for discharge from the facility;
- (2) All office personnel are familiar with a written and documented plan to timely and
- safely transfer patients to an appropriate hospital; and
- 136 (3) The plan must include:
- (A) A proven accessible route for stretcher transport of the patient out of the office;
- (B) Arrangements for emergency medical services and appropriate escort of the patient
- to the hospital; and
- (C) A compliance process to notify the Georgia Composite Medical Board of an
- adverse event as specified in Code Section 31-50-7.
- (h) Resuscitative equipment shall be evaluated for functionality every six months, and
- records of such evaluations shall be maintained by the facility.
- 144 <u>31-50-5.</u>
- 145 (a) The physician performing office based surgery shall maintain a legible, complete,
- comprehensive, and accurate medical record for each patient.
- 147 (b) The medical record shall include the following:
- 148 (1) Identity of the patient;
- (2) History and physical, diagnosis, and treatment plan;
- 150 (3) Appropriate lab, X-ray, or other diagnostic reports;
- (4) Appropriate preanesthesia evaluation;
- 152 (5) Narrative description of procedure;
- 153 (6) Pathology reports, if relevant;
- (7) Documentation of which, if any, tissues and other specimens have been submitted for
- 155 <u>histopathologic diagnosis;</u>
- (8) Provision for continuity of postoperative care; and
- (9) Documentation of the outcome and the follow-up plan.
- (c) When moderate sedation or deep sedation or major conduction anesthesia is used, the
- patient medical record shall include a separate anesthesia record that documents the
- 160 <u>following:</u>
- (1) Type of sedation or anesthesia used;
- 162 (2) Each drug name, dose, and time of administration;
- 163 (3) The patient's vital signs at regular intervals including, at a minimum, blood pressure,
- heart rate, respiratory rate, and oxygen saturation; and
- 165 (4) Return to appropriate level of consciousness and readiness for discharge from acute
- 166 <u>care.</u>

- 167 <u>31-50-6.</u>
- Any licensed physician engaging in office based surgery shall have received appropriate
- training and education in the safe and effective performance of all surgical procedures
- performed in the office facility. Such training and education shall include the following:
- (1) Indications and contraindications for each procedure;
- (2) <u>Identification of realistic and expected outcomes of each procedure;</u>
- (3) Selection, maintenance, and utilization of products and equipment;
- 174 (4) Appropriate technique for each procedure, including infection control and safety
- 175 <u>precautions</u>;
- 176 (5) Pharmacological intervention specific to each procedure;
- (6) Identification of complications and adverse reactions for each procedure; and
- (7) Emergency procedures to be used in the event of the following:
- 179 (A) Complications;
- 180 (B) Adverse reactions;
- 181 (C) Equipment malfunction; or
- (D) Any other interruption of a procedure.
- 183 <u>31-50-7.</u>
- Any incident within the facility that results in the patient's death or transport of the patient
- to a hospital for observation or treatment for a period in excess of 24 hours shall be
- reported to the Georgia Composite Medical Board in writing within ten working days of
- the death or hospitalization, whichever comes first.
- 188 <u>31-50-8.</u>
- 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 in writing
- 192 <u>to all patients."</u>
- 193 **SECTION 2.**
- 194 All laws and parts of laws in conflict with this Act are repealed.