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COMMITTEE REPORT

May 15, 2014

**S. 1036**

Introduced by Senator Cleary

S. Printed 5/15/14--H.

Read the first time April 9, 2014.

**THE COMMITTEE ON MEDICAL,**

**MILITARY, PUBLIC AND MUNICIPAL AFFAIRS**

To whom was referred a Bill (S. 1036) to amend the Code of Laws of South Carolina, 1976, by adding Article 3 to Chapter 15, Title 40 so as to enact the “Dental Sedation Act”, to provide, etc., respectfully

**REPORT:**

That they have duly and carefully considered the same and recommend that the same do pass:

LEON HOWARD for Committee.

**STATEMENT OF ESTIMATED FISCAL IMPACT**

ESTIMATED FISCAL IMPACT ON GENERAL FUND EXPENDITURES:

$0 (No additional expenditures or savings are expected)

ESTIMATED FISCAL IMPACT ON FEDERAL & OTHER FUND EXPENDITURES:

$0 (No additional expenditures or savings are expected)

**EXPLANATION OF IMPACT:**

The Department of Labor, Licensing and Regulation estimates this bill will have no fiscal impact on the state general fund or on federal and/or other funds.

*Approved By:*

Brenda Hart

Office of State Budget

**A** **BILL**

TO AMEND THE CODE OF LAWS OF SOUTH CAROLINA, 1976, BY ADDING ARTICLE 3 TO CHAPTER 15, TITLE 40 SO AS TO ENACT THE “DENTAL SEDATION ACT”, TO PROVIDE REQUIREMENTS CONCERNING THE PROVISION OF VARYING LEVELS OF SEDATION TO DENTAL PATIENTS; TO AMEND SECTION 40‑15‑85, RELATING TO DEFINITIONS IN THE DENTISTRY PRACTICE ACT, SO AS TO ADD NECESSARY DEFINITIONS; AND TO DESIGNATE THE EXISTING SECTIONS OF CHAPTER 15, TITLE 40 AS ARTICLE 1 “GENERAL PROVISIONS”.

Be it enacted by the General Assembly of the State of South Carolina:

SECTION 1. This act must be known and may be cited as the “Dental Sedation Act”.

SECTION 2. Chapter 15, Title 40 of the 1976 Code is amended by adding:

“Article 3

Dental Sedation Act

Section 40‑15‑400. (A) For purposes of this section, ‘current’ means the certification course has been taken within two years. Other life support certifications approved by the board may be accepted.

(B)(1) A permit is not required for local anesthesia, nitrous oxide/oxygen, minimal sedation, or any combination thereof, where the patient has a depressed level of consciousness but is able to independently and continually maintain an airway with unaffected ventilatory and cardiovascular function and respond normally to tactile and verbal stimulation.

(2) A dentist who is not administering anesthesia, but is providing anesthesia in his dental office, must conform to the requirements of this chapter except subsections (C)(1), (D)(1), (E)(1), and (E)(2) of this section.

(3) The administration of sedation or anesthesia, or both, in a dentist’s office by a licensed physician shall be administered pursuant to Chapter 47, Title 40. The administration of sedation or anesthesia, or both, in the dentist’s office by a licensed Certified Registered Nurse Anesthetist shall be administered pursuant to Chapter 33, Title 40.

(C) To provide moderate enteral sedation, a dentist must first submit an application with an initial fee to the board with documentation of:

(1) completion of predoctoral, postdoctoral, or continuing education conscious sedation training in an accredited program to include twenty four hours of didactic instruction and ten cases commensurate with each intended route of administration; and

(2) applicable life support training, which must be:

(a) advanced cardiac life support (ACLS) certification that is current if treating adults and children; or

(b) pediatric advanced life support (PALS) certification that is current if treating only children.

(D) To provide moderate parenteral sedation, a dentist must first submit an application with an initial fee to the board with documentation of:

(1) completion of predoctoral, postdoctoral, or continuing education conscious sedation training in an accredited program to include sixty hours of didactic instruction and twenty cases commensurate with each intended route of administration; and

(2) applicable life support training, which must be:

(a) advanced cardiac life support (ACLS) certification that is current if treating adults and children; or

(b) pediatric advanced life support (PALS) certification that is current if treating only children.

(E) To provide deep sedation/general anesthesia, a dentist must first submit an application with an initial fee to the board with documentation of:

(1) completion of one year of advanced training in anesthesiology and related academic subjects or complete an oral and maxillofacial surgery residency program, or be a Diplomate of the American Board of Oral and Maxillofacial Surgery; provided, however, that the training must include sixty hours of didactic instruction and twenty cases commensurate with each intended route of administration;

(2) sixty hours of pediatric didactic training and twenty cases commensurate with each intended route of administration for children under thirteen years of age in order to provide pediatric deep sedation/general anesthesia; and

(3) applicable life support training, which must be:

(a) advanced cardiac life support (ACLS) certification that is current if treating adults and children; or

(b) pediatric advanced life support (PALS) certification that is current if treating only children.

(4) To provide deep sedation/general anesthesia, the applicant may pursue an advanced education route by means of various residencies, a specific oral and maxillofacial surgery residency, or may become a Diplomate of the American Board of Oral and Maxillofacial Surgery.

(F) Permit fees must be remitted biennially with the dental license renewal. These fees initially must be determined by the board pursuant to Section 40‑1‑50(D).

Section 40‑15‑410. (A) The applicant for a sedation permit must submit verification to the board that the applicant’s facilities meet the requirements of this section.

(B) The board must determine the qualifications of a facility inspector and biennially inspect each facility. All costs and expenses of the board and department incurred in performing these inspections must be paid exclusively with revenue from permit fees received pursuant to Section 40‑15‑400(F). The department may not conduct these inspections until sufficient funding from the receipt of these fees exist.

(C) To offer minimal sedation, a facility must have available:

(1) with respect to equipment:

(a) a positive‑pressure oxygen delivery system suitable for the patient being treated;

(b) when inhalation equipment is used, it must have a fail‑safe system that is appropriately checked and calibrated, and also must have either:

(i) a functioning device that prohibits the delivery of less than thirty percent oxygen; or

(ii) an appropriately calibrated and functioning in‑line oxygen analyzer with audible alarm; and

(c) an appropriate scavenging system must be available if gases other than oxygen or air are used; and

(2) with respect to preoperative preparation:

(a) the patient, parent, guardian, or caregiver must be advised regarding the procedure associated with the delivery of any sedative agents and informed consent for the proposed sedation must be obtained;

(b) the availability of an adequate oxygen supply and equipment necessary to deliver oxygen under positive pressure must be determined;

(c) baseline vital signs must be obtained unless the patient’s behavior prohibits the determination;

(d) a focused physical evaluation must be performed as considered appropriate;

(e) preoperative dietary restrictions must be considered based on the sedative techniques prescribed; and

(f) preoperative verbal and written instructions must be given to the patient, parent, escort, guardian, or caregiver.

(D)(1) In a facility offering minimal sedation under this chapter:

(a) a qualified dentist or an appropriately trained individual, at the discretion of the dentist, must continuously assess the patient’s level of consciousness and remain in the operatory during active dental treatment to monitor the patient continuously until the patient meets the criteria for discharge to the recovery area. The appropriately trained individual must be familiar with monitoring techniques and equipment. Monitoring must include:

(i) continuous evaluation of the color of mucosa, skin, or blood;

(ii) required oxygen saturation by pulse oximetry;

(iii) continuous observation of chest excursions by the dentist, an appropriately trained individual, or both;

(iv) continuous verification of respiration by the dentist, an appropriately trained individual, or both;

(v) preoperative, intraoperative, and postoperative evaluation of blood pressure and heart rate as necessary, unless the patient is unable to tolerate the monitoring;

(vi) maintenance of an appropriate sedative record, including the names of all drugs administered, including local anesthetics, dosages, and monitored physiological parameters;

(vii) immediate availability of oxygen and suction equipment if a separate recovery area is used;

(viii) monitoring of the patient during recovery by a qualified dentist or appropriately trained clinical staff until the patient is ready for discharge by the dentist;

(ix) determination and documentation by the qualified dentist of the patient’s satisfactory level of consciousness, oxygenation, ventilation, and circulation before discharge;

(x) provision of postoperative verbal and written instructions to the patient, parent, escort, guardian, or caregiver; and

(xi) cessation of the dental procedure if a patient enters a deeper level of sedation than the dentist is qualified to provide, until the patient returns to the intended level of sedation;

(b) a qualified dentist is responsible for the sedative management, adequacy of the facility and staff, diagnosis, and treatment of emergencies related to the administration of minimal sedation and providing the equipment and protocols for patient rescue; and

(c) for children under thirteen years of age, the board supports the American Dental Association’s stance that supports the use of the American Academy of Pediatrics/American Academy of Pediatric Dentistry ‘Guidelines for Monitoring and Management of Pediatric Patients During and After Sedation for Diagnostic and Therapeutic Procedures’.

(E) To offer moderate sedation, a facility must have available:

(1) with respect to equipment:

(a) a positive‑pressure oxygen delivery system suitable for the patient being treated;

(b) when inhalation equipment is used, it must have a fail‑safe system that is appropriately checked and calibrated, and also must have either:

(i) a functioning device that prohibits the delivery of less than thirty percent oxygen; or

(ii) an appropriately calibrated and functioning in‑line oxygen analyzer with audible alarm;

(c) an appropriate scavenging system must be available if gases other than oxygen or air are used; and

(d) equipment necessary to establish intravenous access; and

(2) with respect to preoperative preparation:

(a) the patient, parent, guardian or caregiver must be advised regarding the procedure associated with the delivery of any sedative agents and informed consent for the proposed sedation must be obtained;

(b) the availability of an adequate oxygen supply and equipment necessary to deliver oxygen under positive pressure must be determined;

(c) baseline vital signs must be obtained unless the patient’s behavior prohibits the determination;

(d) a focused physical evaluation must be performed as considered appropriate;

(e) preoperative dietary restrictions must be considered based on the sedative techniques prescribed; and

(f) preoperative verbal and written instructions must be given to the patient, parent, escort, guardian, or caregiver.

(F)(1) In a facility offering moderate sedation under this chapter:

(a) a qualified dentist or an appropriately trained individual, at the discretion of the dentist, must remain in the operatory during active dental treatment to monitor the patient continuously until the patient meets the criteria for discharge to the recovery area. The appropriately trained individual must be familiar with monitoring techniques and equipment. Monitoring must include:

(i) continuous assessment of level of consciousness, such as responsiveness to verbal commands;

(ii) continuous evaluation of color of mucosa, skin, or blood and oxygen saturation by pulse oximetry;

(iii) continuous observation by the dentist of chest excursions and ventilation monitoring, which can be accomplished by auscultation of breath sounds, monitoring end‑tidal CO2, or by verbal communication with the patient;

(iv) continuous evaluation of blood pressure and heart rate if tolerable by the patient and if noted in the time‑oriented anesthesia record;

(v) continuous EKG monitoring for patients with significant cardiovascular disease;

(vi) maintenance of an appropriate time‑oriented anesthetic record, including the names of all drugs, dosages, and their administration times, including local anesthetics, dosages, and monitored physiological parameters;

(vii) continuous documentation of pulse oximetry, heart rate, respiratory rate, blood pressure, and level of consciousness; and

(viii) cessation of the dental procedure if a patient enters a deeper level of sedation than the dentist is qualified to provide, until the patient returns to the intended level of sedation;

(2) a qualified dentist is responsible for the sedative management, adequacy of the facility and staff, diagnosis and treatment of emergencies related to the administration of moderate sedation, and providing the equipment, drugs, and protocol for patient rescue; and

(3) for children under thirteen years of age, the board supports the American Dental Association’s stance that supports the use of the American Academy of Pediatrics/American Academy of Pediatric Dentistry ‘Guidelines for Monitoring and Management of Pediatric Patients During and After Sedation for Diagnostic and Therapeutic Procedures’.

(G) To offer deep sedation/general anesthesia, a facility must have:

(1) with respect to equipment:

(a) a positive‑pressure oxygen delivery system suitable for the patient being treated;

(b) when inhalation equipment is used, it must have a fail‑safe system that is appropriately checked and calibrated. The equipment also must have either:

(i) a functioning device that prohibits the delivery of less than thirty percent oxygen; or

(ii) an appropriately calibrated and functioning in‑line oxygen analyzer with audible alarm;

(c) an appropriated scavenging system must be available if gases other than oxygen or air are used;

(d) equipment necessary to establish intravenous access;

(e) equipment and drugs necessary to provide advanced airway management;

(f) advanced cardiac life support and reversal agents, if applicable;

(g) a capnograph must be used and an inspired agent analysis monitor should be considered if volatile anesthetic agents are used;

(h) resuscitation medications and an appropriate defibrillator must be immediately available;

(i) EKG for deep sedation/general anesthesia; and

(j) a chair or operating table that allows for CPR to be performed on the patient; and

(2) with respect to preoperative preparation:

(a) the patient, parent, guardian, or caregiver must be advised regarding the procedure associated with the delivery of any sedative agents and informed consent for the proposed sedation must be obtained;

(b) availability of adequate oxygen supply and equipment necessary to deliver oxygen under positive pressure must be determined;

(c) baseline vital signs must be obtained unless the patient’s behavior prohibits the determination;

(d) a focused physical evaluation must be performed as considered appropriate;

(e) preoperative dietary restrictions must be considered based on the sedative techniques prescribed;

(f) preoperative verbal and written instructions must be given to the patient, parent, escort, guardian, or caregiver; and

(g) an intravenous line, which is secured throughout the procedure, must be established except as provided in subsection (I).

(H) In a facility offering deep sedation/general anesthesia under this chapter:

(1) a dentist or an appropriately trained individual, in the discretion of the dentist, must remain in the operatory during active dental treatment to monitor the patient continuously until the patient meets the criteria for discharge to the recovery area. The appropriately trained individual must be familiar with monitoring techniques and equipment. Monitoring must include:

(a) continuous evaluation of color of mucosa, skin, or blood and oxygen saturation by pulse oximetry;

(b) continuous monitoring and evaluation of:

(i) end‑tidal CO2 for intubated patient; and

(ii) breath sounds by means of auscultation, end‑tidal CO2, or both for nonintubated patient;

(c) continuous monitoring and evaluation of respiration rate;

(d) continuous evaluation of heart rate and rhythm by means of EKG throughout the procedure, as well as pulse rate by means of pulse oximetry and blood pressure;

(e) ready availability of a device capable of measuring body temperature during the administration of deep sedation/general anesthesia;

(f) availability and use of equipment to continuously monitor body temperature whenever triggering agents associated with malignant hyperthermia are administered;

(g) maintenance of an appropriate time‑oriented anesthetic record, including the names of all drugs, dosages, and their administration times, including local anesthetics and monitored physiological parameters; and

(h) continuous recording of:

(i) pulse oximetry and end‑tidal CO2 measurements, if taken;

(ii) heart rate;

(iii) respiratory rate; and

(iv) blood pressure;

(2) when a mental or physical challenge precludes a dental patient from having a comprehensive physical examination or appropriate laboratory tests before undergoing deep sedation/general anesthesia, the dentist responsible for administering that anesthesia should document the reasons preventing the recommended preoperative management; and

(3) use of deep sedation/general anesthesia without establishing an indwelling intravenous line may be warranted in selected circumstances, including very brief procedures or the establishment of intravenous access after deep sedation/general anesthesia has been induced because of poor patient cooperation.

(I) A facility inspection is not required for the administration of anesthesia at those hospitals, dental schools, and other dental settings approved by the Joint Commission on Accreditation of Healthcare Organizations or the Commission on Dental Accreditation.

Section 40‑15‑420. (A) All dental staff who provide direct, hands‑on patient care must be certified in cardiopulmonary resuscitation and the basic life support level by a board‑approved training course. The certification must have been received in the immediately preceding two years.

(B) The operating dentist shall provide training for staff with hands‑on patient care commensurate with the level and mode of sedation administered. This training must be documented and available for inspection by the department upon request.

(C) The dentist must include four hours in pharmacology, anesthesia, emergency medicine, or sedation every two years as part of the continuing educational requirements of this chapter.

Section 40‑15‑430. (A) For minimal sedation and moderate sedation, at least one person trained in Basic Life Support for Healthcare Providers must be present in addition to the dentist.

(B) For deep sedation/general anesthesia, at least two support personnel adequately trained in Basic Life Support for Healthcare Providers must be present in addition to the dentist. If the same individual administering the deep sedation/general anesthesia is performing the dental procedure, one of the additional appropriately trained team members must be designated for patient monitoring.

(C) During recovery and discharge the dentist must determine and document whether the patient:

(1) has stable vital signs, is mentally alert, and has stable levels of oxygenation, ventilation, circulation, and temperature;

(2) has a minimum of one adequately trained support personnel who must be present with the patient;

(3) is fully recovered from anesthetic drugs before discharged to the care of a responsible adult available to provide assisted care to the patient;

(4) support personnel assists the patient into the vehicle transporting him from the facility; and

(5) written postoperative instructions are given to and are reviewed with the patient and the adult responsible for the patient.

Section 40‑15‑440. A dentist shall give written notice to the board at least thirty days before he may relocate, add to, or significantly change a facility where procedures under this chapter are performed.

Section 40‑15‑450. (A) A dentist shall:

(1) maintain timely, legible, accurate, and complete patient records; and

(2) timely provide these records to the patient, another dentist, or a designated medical professional in response to a lawful request for the records by the patient or his legal representative or designee.

(B) A dental practice must have a procedure for initiating and maintaining a health record for every patient evaluated or treated. For procedures requiring patient consent, there must be an informed consent documented in the patient record.

(C) The health record of a patient required under subsection (B) must include appropriate information to:

(1) identify the patient, support the diagnosis, and justify the treatment;

(2) identify the procedure code or suitable narrative description of the procedure; and

(3) document the outcome and required follow‑up care.

(D) If moderate sedation or deep sedation/general anesthesia is provided, the health record of a patient also must include documentation of:

(1) patient weight;

(2) type of anesthesia used;

(3) type and dosage of drugs administered, if any;

(4) fluid administered, if any;

(5) a record of vital signs monitoring;

(6) patient level of consciousness during the procedure;

(7) duration of the procedure;

(8) complications related to the procedure or anesthesia, if any; and

(9) time‑oriented anesthesia record.”

SECTION 3. Section 40‑15‑85 of the 1976 Code is amended to read:

“Section 40‑15‑85. For purposes of this chapter:

(1) ‘Analgesia’ means the diminution or elimination of pain with full consciousness maintained by the patient.

(2) ‘Deep sedation’ means a drug‑induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. Reflex withdrawal from a painful stimulus is not considered a purposeful response. The ability to independently maintain ventilator function may be impaired. Patients may require assistance in maintaining patients’ airways. Spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.

(~~1~~3) ‘Direct supervision’ means that a dentist is in the dental office, personally diagnoses the condition to be treated, personally authorizes the procedure, and before the dismissal of the patient, evaluates the performance of the auxiliary. This requirement does not mandate that a dentist be present at all times, but he or she must be on the premises actually involved in supervision and control.

(4) ‘Enteral’ means a route of administration that includes any technique in which the agent is absorbed through the gastrointestinal tract or oral mucosa.

(5) ‘General anesthesia’ means a drug‑induced loss of consciousness during which patients are not aroused, even by painful stimulation. The ability to independently maintain ventilatory functions is often impaired. Patients often require assistance in maintaining patients’ airways; positive pressure ventilation may be required because of depressed spontaneous ventilation or drug‑induced depression of neuromuscular function. Cardiovascular function may be impaired.

(a) Because sedation and general anesthesia are on a continuum, it is not always possible to predict how an individual patient will respond. Hence, practitioners intending to produce a given level of sedation should be able to diagnose and manage the physiologic consequences for patients whose level of sedation becomes deeper than initially intended.

(b) For all levels of sedation, the practitioner must have the training, skills, drugs, and equipment to identify and manage such an occurrence until either assistance arrives or the patient returns to the intended level of sedation without airway or cardiovascular complications.

(~~2~~6) ‘General supervision’ means that a licensed dentist or the South Carolina Department of Health and Environmental Control’s public health dentist has authorized the procedures to be performed but does not require that a dentist be present when the procedures are performed.

(7) ‘Inhalation’ means a route of administration in which a gaseous or volatile agent introduced into the lungs and whose primary effect is due to absorption through the interface of gas and blood.

(8) ‘Local anesthesia’ means the elimination of sensation, especially pain, in one part of the body by the topical application or regional as applies to dental, oral, or maxillofacial injection of a drug.

(9) ‘Minimal sedation’ means a minimally depressed level of consciousness, produced by a pharmacological method, that retains the patient’s ability to independently and continuously maintain an airway and respond normally to tactile stimulation and verbal command. Although cognitive functions and coordination may be modestly impaired, ventilator and cardiovascular functions are unaffected.

(a) When the intent is minimal sedation for adults, the appropriate initial dosing of a single enteral drug is no more than the maximum recommended dose of a drug that can be prescribed for unmonitored home use.

(b) The use of preoperative sedatives for children under thirteen years of age before arrival in the dental office, except in extraordinary situations, must be avoided due to the risk of unobserved respiratory obstruction during transport by untrained individuals.

(c) Children under thirteen years of age may become moderately sedated despite the intended level of minimal sedation; should this occur, the guidelines for moderate sedation apply.

(d) For children under thirteen years of age, the board supports the American Dental Association’s stance that supports the use of the American Academy of Pediatrics/American Academy of Pediatric Dentistry’s ‘Guidelines for Monitoring and Management of Pediatric Patients During and After Sedation for Diagnostic and Therapeutic Procedures’.

(e) Nitrous oxide, oxygen, or both may be used in combination with a single enteral drug in minimal sedation.

(f) Nitrous oxide, oxygen, or both, when used in combination with a sedative agent may produce minimal, moderate, or deep sedation/general anesthesia.

(10) ‘Moderate sedation’ means 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 patients’ airways, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.

(~~3~~11) ‘Oral prophylaxis’ means the removal of any and all hard and soft deposits, accretions, toxins, and stain from any natural or restored surfaces of teeth or prosthetic devices by scaling and polishing as a preventive measure for the control of local irritational factors.

(12) ‘Parenteral’ means a route of administration in which the drug bypasses the gastrointestinal tract.

(13) ‘Titration’ means the administration of moderate or greater sedation. The term means administration of incremental doses of a drug until a desired effect is reached. Knowledge of each drug’s time of onset, peak response, and duration of action is essential to avoid oversedation. Although the concept of titration of a drug to effect is critical for patient safety, when the intent is moderate sedation, one must know whether the previous dose has taken full effect before administering an additional drug increment.

(14) ‘Transdermal’ means a route of administration in which the drug is administered by patch or iontophoreis through skin.

(15) ‘Transmucosal’ means a route of administration in which the drug in administered across mucosa such as intranasal, sublingual or rectal.”

SECTION 4. Sections 40‑15‑10 through 40‑15‑380 of the 1976 Code are designated as Article 1, entitled “General Provisions”.

SECTION 5. The provisions of this act take effect January 1, 2015.

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