

## CHAPTER 64B5-14 ANESTHESIA

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### 64B5-14.001 Definitions.

- (1) Anesthesia – The loss of feeling or sensation, especially loss of the sensation of pain.
- (2) General anesthesia – A controlled state of unconsciousness, produced by a pharmacologic agent, accompanied by a partial or complete loss of protective reflexes, including inability to independently maintain an airway and respond purposefully to physical stimulation or verbal command. This modality includes administration of medications via parenteral routes; that is: intravenous, intramuscular, subcutaneous, submucosal, or inhalation, as well as enteral routes, that is oral, rectal, or transmucosal.
- (3) Deep Sedation – A controlled state of depressed consciousness accompanied by partial loss of protective reflexes, including either or both the inability to continually maintain an airway independently or to respond appropriately to physical stimulation or verbal command, produced by pharmacologic or non-pharmacologic method or combination thereof. Deep sedation includes administration of medications via parenteral routes; that is intravenous, intra muscular, subcutaneous, submucosal, or inhalation, as well as enteral routes, that is oral, rectal, or transmucosal.
- (4) Conscious sedation – A depressed level of consciousness produced by the administration of pharmacologic substances, that retains the patient’s ability to independently and continuously maintain an airway and respond appropriately to physical stimulation and verbal command. This modality includes administration of medications via all parenteral routes, that is, intravenous, intramuscular, subcutaneous, submucosal, or inhalation, as well as enteral routes, that is oral, rectal, or transmucosal. The drugs, and techniques used should carry a margin of safety wide enough to render unintended loss of consciousness unlikely.
- (5) Pediatric Conscious Sedation – A depressed level of consciousness produced by the administration of pharmacologic substances, that retains a child patient’s ability to independently and continuously maintain an airway and respond appropriately to physical stimulation or verbal command. This modality includes administration of medication via all parenteral routes; that is intravenous, intramuscular, subcutaneous, submucosal, or inhalation, and all enteral routes; that is oral, rectal, or transmucosal. The drugs, doses, and techniques used should carry a margin of safety wide enough to render unintended loss of consciousness unlikely. For the purposes of this chapter, a child is defined as an individual under 18 years of age, or any person who has special needs, which means having a physical or mental impairment that substantially limits one or more major life activities.
- (6) Nitrous-oxide inhalation analgesia – The administration by inhalation of a combination of nitrous-oxide and oxygen producing an altered level of consciousness that retains the patient’s ability to independently and continuously maintain an airway and respond appropriately to physical stimulation or verbal command.
- (7) Local anesthesia – The loss of sensation of pain in a specific area of the body, generally produced by a topically applied agent or injected agent without causing the loss of consciousness.
- (8) Analgesia – Absence of sensibility of pain, designating particularly the relief of pain without loss of consciousness.
- (9) Office team approach – A methodology employed by a dentist in the administration of general anesthesia, deep sedation, conscious sedation, and pediatric sedation whereby the dentist uses one or more qualified assistants/dental hygienists who, working under the direct supervision of the dentist, assist the dentist, and assist in emergency care of the patient.
- (10) Minimal Sedation (anxiolysis) – The perioperative use of medication to relieve anxiety before or during a dental procedure which does not produce a depressed level of consciousness and maintains the patient’s ability to maintain an airway independently and to respond appropriately to physical and verbal

stimulation. This minimal sedation shall include the administration of a single enteral sedative or a single narcotic analgesic medication administered in doses appropriate for the unsupervised treatment of anxiety and pain. If clinically indicated, an opioid analgesic may also be administered during or following a procedure if needed for the treatment of pain. Except in extremely unusual circumstances, the cumulative dose shall not exceed the maximum recommended dose (as per the manufacturers recommendation). It is understood that even at appropriate doses a patient may occasionally drift into a state that is deeper than minimal sedation. As long as the intent was minimal sedation and all of the above guidelines were observed, this shall not automatically constitute a violation. A permit shall not be required for the perioperative use of medication for the purpose of providing anxiolysis.

(11) Titration of Oral Medication – The administration of small incremental doses of an orally administered medication until an intended level of conscious sedation is observed.

(12) Physician anesthesiologist – Any physician licensed pursuant to Section 458 or Section 459, Florida Statutes, who is currently board certified or board eligible by the American Board of Anesthesiology or the American Osteopathic Board of Anesthesiology, or is credentialed to administer anesthesia in a hospital or ambulatory surgical facility licensed by the Department of Health.

*Specific Authority 466.004(4), 466.017(3) FS. Law Implemented 466.017(3) FS. History–New 1-31-80, Amended 4-7-86, Formerly 21G-14.01, Amended 12-31-86, 6-1-87, 9-1-87, 2-1-93, Formerly 21G-14.001, Amended 12-20-93, Formerly 61F5-14.001, Amended 8-8-96, Formerly 59Q-14.001, Amended 3-9-03, 11-4-03, 7-1-06, 6-11-07.*

#### **64B5-14.002 Prohibitions.**

(1) General anesthesia or deep sedation. No dentists licensed in this State shall administer general anesthesia or deep sedation in the practice of dentistry until they have obtained a permit as required by the provisions of this rule chapter.

(2) Conscious sedation. No dentists licensed in this State shall administer conscious sedation in the practice of dentistry until they have obtained a permit as required by the provisions of this rule chapter.

(3) No dentist licensed in this state shall administer Pediatric Conscious Sedation in the practice of dentistry until such dentist has obtained a permit as required by the provisions of this rule chapter.

(4) Nitrous-oxide inhalation analgesia. No dentists licensed in this State shall administer nitrous-oxide inhalation analgesia in the practice of dentistry until they have complied with the provisions of this rule chapter.

(5) Local anesthesia. Dentists licensed in this State may use local anesthetics to produce local anesthesia in the course of their practice of dentistry.

(6) The only agents that can be used for inhalation analgesia pursuant to Rule 64B5-14.003, F.A.C., below are nitrous-oxide and oxygen.

(7) Titration of Oral Medication. The Board of Dentistry has determined that the perioperative titration of oral medication(s) with the intent to achieve a level of conscious sedation poses a potential overdosing threat due to the unpredictability of enteral absorption and may result in an alteration of the state of consciousness of a patient beyond the intent of the practitioner. Such potentially adverse consequences may require immediate intervention and appropriate training and equipment. Beginning with the effective date of this rule, no dentist licensed in this state shall use any oral medication(s) to induce conscious sedation until such dentist has obtained a permit as required by the provisions of this rule chapter. The use of enteral sedatives or narcotic analgesic medications for the purpose of providing minimal sedation (anxiolysis) as defined by and in accordance with subsection 64B5-14.001(10), F.A.C., shall not be deemed titration of oral medication and shall not be prohibited by this rule.

(8) The following general anesthetic drugs shall not be employed on or administered to a patient by a dentist unless the dentist possesses a valid general anesthesia permit issued by the Board pursuant to the requirements of this chapter: propofol, methohexital, thiopental, or etomidate.

*Specific Authority 466.004(4), 466.017(3) FS. Law Implemented 466.017(3) FS. History–New 1-31-80, Amended 4-20-81, 2-13-86, Formerly 21G-14.02, 21G-14.002, Amended 12-20-93, Formerly 61F5-14.002, Amended 8-8-96, Formerly 59Q-14.002, Amended 3-9-03, 11-4-03, 6-15-06, 12-25-06.*

#### **64B5-14.003 Training, Education, Certification, and Requirements for Issuance of Permits.**

(1) General Anesthesia Permit.

(a) A permit shall be issued to an actively licensed dentist authorizing the use of general anesthesia or deep sedation at a specified practice location or locations on an outpatient basis for dental patients provided the dentist:

1. Has completed a minimum of one year of advanced training in anesthesiology and related academic subjects beyond the undergraduate dental school level in a training program as described in Part II of the "Guidelines for Teaching the Comprehensive Control in Pain and Anxiety in Dentistry" as published by American Dental Association; or
2. Is a diplomate of the American Board of Oral and Maxillofacial Surgery; or
3. Is eligible for examination by the American Board of Oral and Maxillofacial Surgery; or
4. Is a member of the American Association of Oral and Maxillofacial Surgeons; or
5. Is a Fellow of the American Dental Society of Anesthesiology.

(b) A dentist employing or using general anesthesia or deep sedation shall maintain a properly equipped facility for the administration of general anesthesia, staffed with supervised assistant/dental hygienist personnel, capable of reasonably handling procedures, problems and emergencies incident thereto. The facility must have the equipment capability of delivering positive pressure oxygen ventilation. Administration of general anesthesia or deep sedation requires at least three individuals, each appropriately trained: the operating dentist, a person responsible for monitoring the patient, and a person to assist the operating dentist.

(c) A dentist employing or using general anesthesia or deep sedation and all assistant/dental hygienist personnel shall be certified in an American Heart Association or American Red Cross or equivalent Agency sponsored cardiopulmonary resuscitation course at the basic life support level to include one person CPR, two person CPR, infant resuscitation and obstructed airway, with a periodic update not to exceed two years. Starting with the licensure biennium commencing on March of 2000, a dentist and all assistant/dental hygienist personnel shall also be trained in the use of either an Automated External Defibrillator or a defibrillator and electrocardiograph as part of their cardiopulmonary resuscitation course at the basic life support level. In addition to CPR certification, a dentist utilizing general anesthesia or deep sedation must be currently trained in ACLS (Advanced Cardiac Life Support) or ATLS (Advanced Trauma Life Support).

(d) A dentist permitted to administer general anesthesia or deep sedation under this rule may administer conscious sedation and nitrous-oxide inhalation conscious sedation.

(e) A dentist employing or using deep sedation shall maintain an active and current permit to perform general anesthesia.

(f) A dentist who has not met the requirements specified in subsection (1)(a) of this rule may treat patients under deep/general anesthesia as defined in Rule 64B5-14.001(2) and (3), F.A.C., in his practice if a physician anesthesiologist, as defined in 64B5-14.001(12), F.A.C., is present and is responsible for the administration of the anesthetic and if the conditions as set forth in both 1. and 2. below are met. Failure to comply with these conditions may result in disciplinary action against the dentist.

1. The dentist is a holder of a valid sedation permit.
2. The dentist complies with the requirements for the appropriate equipment, supplies and facilities, as set forth in Rule 64B5-14.008, F.A.C., when the physician anesthesiologist is administering anesthesia/sedation in the dentist's office.

(2) Conscious Sedation Permit.

(a) A permit shall be issued to a dentist authorizing the use of conscious sedation at a specified practice location or locations on an outpatient basis for dental patients provided such dentist:

1. Has received formal training in the use of conscious sedation; and
2. Is certified by the institution where the training was received to be competent in the administration of conscious sedation; and
3. Is competent to handle all emergencies relating to conscious sedation.

(b) Such certification shall specify the type, the number of hours, the number of patients treated and the length of training. The minimum number of didactic hours shall be sixty. Clinical training shall include personal administration for at least twenty patients including supervised training, clinical experience and demonstrated competence in airway management of the compromised airway.

(c) This formal training program shall be sponsored by or affiliated with a university, teaching hospital or other facility approved by the Board of Dentistry or part of the undergraduate curriculum of an accredited dental school.

(d) A dentist utilizing conscious sedation shall maintain a properly equipped facility for the administration of conscious sedation, staffed with supervised assistant/dental hygienist personnel, capable of reasonably handling procedures, problems, and emergencies incident thereto. The facility must have the equipment capability of delivering positive pressure oxygen ventilation. Administration of conscious sedation requires at least two individuals: a dentist, and an auxiliary trained in basic cardiac life-support. It shall be incumbent upon the operating dentist to insure that the patient is appropriately monitored.

(e) A dentist utilizing conscious sedation and his assistant/dental hygienist personnel shall be certified in an American Heart Association or American Red Cross or equivalent agency sponsored cardiopulmonary resuscitation course at the basic life support level to include one man CPR, two man CPR, infant resuscitation, and obstructed airway with a periodic update not to exceed two years. Starting with the licensure biennium commencing on March of 2000, a dentist and all assistant/dental hygienist personnel shall also be trained in the use of either an Automated External Defibrillator or a defibrillator and electrocardiograph as part of their cardiopulmonary resuscitation course at the basic life support level. In addition to CPR certification, a dentist utilizing conscious sedation must be currently trained in ACLS (Advanced Cardiac Life Support) or ATLS (Advanced Trauma Life Support).

(f) Dentists permitted to administer conscious sedation may administer nitrous-oxide inhalation conscious sedation.

(g) Dentists permitted to administer conscious sedation may administer pediatric conscious sedation in compliance with Rule 64B5-14.010, F.A.C.

### (3) Pediatric Conscious Sedation Permit.

(a) A permit shall be issued to a dentist authorizing the use of pediatric conscious sedation at a specified practice location or locations on an outpatient basis for dental patients provided such dentist:

1. Has received formal training in the use of pediatric conscious sedation. This formal training program shall be sponsored by or affiliated with a university, teaching hospital or other facility approved by the Board of Dentistry or part of the undergraduate curriculum of an accredited dental school; and

2. Is certified by the institution where the training was received to be competent in the administration of pediatric conscious sedation. This certification shall specify the type, the number of hours, the number of patients treated and the length of training. The minimum number of didactic hours shall be sixty. Clinical training shall include management of sedation for at least twenty patients including supervised training, clinical experience and demonstrated competence in airway management of the compromised airway; and

3. Is competent to handle all emergencies relating to pediatric conscious sedation. A dentist utilizing pediatric conscious sedation shall maintain a properly equipped facility for the administration of pediatric conscious sedation, staffed with supervised assistant/dental hygienist personnel, capable of reasonably handling procedures, problems, and emergencies incidental thereto. The facility must have the equipment capability of delivering positive pressure oxygen ventilation. Administration of pediatric conscious sedation requires at least two individuals: a dentist, and an auxiliary trained in basic cardiac life support. It shall be incumbent upon the operating dentist to insure that the patient is appropriately monitored.

(b) A dentist utilizing pediatric conscious sedation and his assistant/dental hygienist personnel shall be certified in an American Heart Association or American Red Cross or equivalent agency sponsored cardiopulmonary resuscitation course at the basic life support level to include one man CPR, two man CPR, infant resuscitation, and obstructed airway with a periodic update not to exceed two years. Starting with the licensure biennium commencing on March of 2000, a dentist and all assistant/dental hygienist personnel shall also be trained in the use of either an Automated External Defibrillator or a defibrillator and electrocardiograph as part of their cardiopulmonary resuscitation course at the basic life support level. In addition to CPR certification, a dentist utilizing pediatric conscious sedation must be currently trained in ACLS (Advanced Cardiac Life Support), PALS (Pediatric Advanced Life Support), or a course providing similar instruction which has been approved by the Board. An entity seeking approval of such a course shall appear before the Board and demonstrate that the content of such course and the hours of instruction are substantially equivalent to those in an ACLS or PALS course.

(c) Dentists permitted to administer pediatric conscious sedation may administer nitrous-oxide inhalation conscious sedation.

(d) Dentists permitted to administer conscious sedation may administer pediatric conscious sedation.

### (4) Nitrous-Oxide Inhalation Analgesia.

(a) A dentist may employ or use nitrous-oxide inhalation analgesia on an outpatient basis for dental patients provided such dentist:

1. Has completed no less than a two-day course of training as described in the American Dental Association's "Guidelines for Teaching and Comprehensive Control of Pain and Anxiety in Dentistry" or its equivalent; or

2. Has training equivalent to that described above while a student in an accredited school of dentistry; and

3. Has adequate equipment with fail-safe features and a 25% minimum oxygen flow.

(b) A dentist utilizing nitrous-oxide inhalation analgesia and such dentist's assistant/dental hygienist personnel shall be certified in an American Heart Association or American Red Cross or equivalent Agency sponsored cardiopulmonary resuscitation course at the basic life support level to include one man CPR, two man CPR, infant resuscitation and obstructed airway with a periodic update not to exceed two years. Starting with the licensure biennium commencing on March of 2000, a dentist and all assistant/dental hygienist personnel shall also be trained in the use of either an Automated External Defibrillator or a defibrillator and electrocardiograph as part of their cardiopulmonary resuscitation course at the basic life support level. In addition to CPR certification, a dentist utilizing pediatric conscious sedation must be currently trained in ACLS (Advanced Cardiac Life Support), ATLS (Advanced Trauma Life Support), or PALS (Pediatric Advanced Life Support).

(c) A dentist who regularly and routinely utilized nitrous-oxide inhalation analgesia on an outpatient basis in a competent and efficient manner for the three-year period preceding January 1, 1986, but has not had the benefit of formal training outlined in paragraphs 1. and 2. of subsection (3)(a) above, may continue such use provided the dentist fulfills the provisions set forth in paragraph 3. of subsection (3)(a) and the provisions of subsection (b) above.

(d) Nitrous oxide may be used in combination with a single dose enteral sedative or a single dose narcotic analgesic to achieve a minimally depressed level of consciousness so long as the manufacturer's maximum recommended dosage of the enteral agent is not exceeded. Nitrous oxide may not be used in combination with more than one (1) enteral agent, or by dosing a single enteral agent in excess of the manufacturer's maximum recommended dosage unless the administering dentist holds a conscious sedation permit issued in accordance with subsection 64B5-14.003(2), F.A.C., or a pediatric conscious sedation permit issued in accordance with Rule 64B5-14.010, F.A.C.

*Specific Authority 466.004(4), 466.017(3) FS. Law Implemented 466.017(3) FS. History—New 1-31-80, Amended 4-20-81, 2-13-86, Formerly 21G-14.03, Amended 12-31-86, 11-8-90, 2-1-93, Formerly 21G-14.003, Amended 12-20-93, Formerly 61F5-14.003, Amended 8-8-96, 10-1-96, Formerly 59Q-14.003, Amended 2-17-98, 12-20-98, 5-31-00, 6-7-01, 11-4-03, 6-23-04, 6-11-07.*

#### **64B5-14.004 Additional Requirements.**

(1) Office Team – A dentist licensed by the Board and practicing dentistry in Florida and who is permitted by these rules to induce and administer general anesthesia, deep sedation, conscious sedation, pediatric conscious sedation or nitrous-oxide inhalation analgesia may employ the office team approach.

(2) Dental Assistants, Dental Hygienists – Dental assistants and dental hygienists may monitor nitrous-oxide inhalation analgesia under the direct supervision of a dentist who is permitted by rule to use general anesthesia, conscious sedation, pediatric conscious sedation, or nitrous-oxide inhalation analgesia, while rendering dental services allowed by Chapter 466, F.S., and under the following conditions:

(a) Satisfactory completion of no less than a two-day course of training as described in the American Dental Association's "Guidelines for Teaching and Comprehensive Control of Pain and Anxiety in Dentistry" or its equivalent; and

(b) Maintenance of competency in cardiopulmonary resuscitation evidenced by certification in an American Heart Association or American Red Cross or equivalent Agency sponsored cardiopulmonary resuscitation course at the basic life support level to include one man CPR, two man CPR, infant resuscitation and obstructed airway, with a periodic update not to exceed two years.

(3) After the dentist has induced a patient and established the maintenance level, the assistant or hygienist may monitor the administration of the nitrous-oxide oxygen making only adjustments during this administration and turning it off at the completion of the dental procedure.

(4) Nothing in this rule shall be construed to allow a dentist or dental hygienist or assistant to administer to himself or to any person any drug or agent used for anesthesia, analgesia or sedation other than in the course of the practice of dentistry.

(5) A dentist utilizing conscious sedation in the dental office may induce only one patient at a time. A second patient shall not be induced until the first patient is awake, alert, conscious, spontaneously

breathing, has stable vital signs, is ambulatory with assistance, is under the care of a responsible adult, and that portion of the procedure requiring the participation of the dentist is complete. In an office setting where two or more permit holders are present simultaneously, each may sedate one patient provided that the office has the necessary staff and equipment, as set forth in paragraph 64B5-14.003(2)(d), F.A.C., for each sedated patient.

(6) Each anesthesia permit holder must complete at least four (4) hours of continuing education relating to anesthesia each biennium the permit is held, to include two (2) hours dealing with the management of medical emergencies. These hours would be included in the 30 hours of continuing education required by Section 466.0135(1) Florida Statutes.

*Specific Authority 466.004(4), 466.017(3) FS. Law Implemented 466.017(3) FS. History—New 1-31-80, Amended 2-13-86, Formerly 21G-14.04, Amended 12-31-86, 12-28-92, Formerly 21G-14.004, Amended 12-20-93, Formerly 61F5-14.004, Amended 8-8-96, Formerly 59Q-14.004, Amended 11-4-03, 6-23-04, Amended 5-24-05.*

#### **64B5-14.005 Application for Permit.**

(1) No dentist shall administer, supervise or permit another health care practitioner, as defined in Section 456.001, F.S., to perform the administration of general anesthesia, deep sedation, conscious sedation or pediatric conscious sedation in a dental office for dental patients, unless such dentist possesses a permit issued by the Board. A permit is required even when another health care practitioner, as defined in Section 456.001, F.S., administers general anesthesia, deep sedation, conscious sedation, or pediatric conscious sedation in a dental office for a dental patient. The dentist holding such a permit shall be subject to review and such permit must be renewed biennially. Each dentist in a practice who performs the administration of general anesthesia, deep sedation, conscious sedation or pediatric conscious sedation shall each possess an individual permit. Nothing in this paragraph shall be construed to prohibit administration of anesthetics as part of a program authorized by Rule 64B5-14.003, F.A.C., any other educational program authorized by Board rule, for training in the anesthetic being administered, or pursuant to a demonstration for inspectors pursuant to Rule 64B5-14.007, F.A.C.

(2) An applicant for any type of anesthesia permit must demonstrate both:

- (a) Training in the particular type of anesthesia listed in Rule 64B5-14.003, F.A.C.; and
- (b) Documentation of actual clinical administration of anesthetics to 20 dental or oral and maxillofacial patients within two (2) years prior to application of the particular type of anesthetics for the permit applied for.

(3) Prior to the issuance of such permit, an on-site inspection of the facility, equipment and personnel will be conducted pursuant to Rule 64B5-14.007, F.A.C., to determine if the requirements of this chapter have been met.

(4) An application for a general anesthesia permit must include the application fee specified in Rule 64B5-15.017, F.A.C., which is non-refundable; the permit fee specified in Rule 64B5-15.018, F.A.C., which may be refunded if the application is denied without inspection of the applicant's facilities; evidence indicating compliance with all the provisions of this chapter; and identification of the location or locations at which the licensee desires to be authorized to use or employ general anesthesia or deep sedation.

(5) An application for a conscious sedation permit must include the application fee specified in Rule 64B5-15.017, F.A.C., which is non-refundable; the permit fee specified in Rule 64B5-15.018, F.A.C., which may be refunded if the application is denied without inspection of the applicant's facilities; evidence indicating compliance with all the provisions of this chapter; and identification of the location or locations at which the licensee desires to be authorized to use or employ conscious sedation.

(6) An application for a pediatric conscious sedation permit must include the application fee specified in Rule 64B5-15.017, F.A.C., which is non-refundable; the permit fee specified in Rule 64B5-15.018, F.A.C., which may be refunded if the application is denied without inspection of the applicant's facilities; evidence indicating compliance with all the provisions of this chapter; and identification of the location or locations at which the licensee desires to be authorized to use or employ pediatric conscious sedation.

(7) The Board shall renew the permit biennially upon application by the permit holder, proof of continuing education required by subsection 64B5-14.004(6), F.A.C., and payment of the renewal fee specified by Rule 64B5-15.019, F.A.C., unless the holder is informed in writing that a re-evaluation of his credentials and facility is to be required. In determining whether such re-evaluation is necessary, the Board shall consider such factors as it deems pertinent including, but not limited to, patient complaints, reports of

adverse occurrences and the results of inspections conducted pursuant to Rule 64B5-14.007, F.A.C. Such re-evaluation shall be carried out in the manner described in subsection (2) set forth above. A renewal fee of \$25.00 must accompany the biennial application.

(8) The holder of any general anesthesia, conscious sedation, or pediatric conscious sedation permit is authorized to practice pursuant to such permit only at the location or locations previously reported to the Board office.

*Specific Authority 466.004, 466.017 FS. Law Implemented 466.017 FS. History—New 4-7-86, Amended 1-29-89, 11-16-89, 11-8-90, 4-24-91, Formerly 21G-14.005, Amended 12-20-93, Formerly 61F5-14.005, Amended 8-8-96, Formerly 59Q-14.005, Amended 12-12-00, 11-4-03, 6-23-04, 2-22-06, 6-28-07, 7-5-10.*

#### **64B5-14.006 Reporting Adverse Occurrences.**

(1) Any dentist practicing in the State of Florida must notify the Board in writing by registered mail, postmarked within 48 hours of any mortality or other incident occurring in the dentist's outpatient facilities. A complete written report shall be filed with the Board within 30 days of the mortality or other incident. Incidents which shall be reported are those which result in temporary or permanent physical or mental injury requiring hospital emergency room treatment and/or hospitalization of a patient during, or as a direct result of the use of general anesthesia, deep sedation, conscious sedation, pediatric conscious sedation, oral sedation, nitrous oxide, or local anesthesia during or related to a dental procedure. The report shall include at minimum, responses to the following:

(a) Description of dental procedure.

(b) Description of preoperative physical condition of the patient.

(c) List of drugs and dosage administered.

(d) Description in detail, of techniques utilized in administering the drugs utilized.

(e) Description of adverse occurrence.

1. Describe in detail symptoms of any complications to include but not limited to onset, and type of symptoms in patient.

2. Treatment instituted on patient.

3. Response of the patient to treatment.

(f) Describe the patient's condition on termination of any procedure undertaken.

(g) Provide the name and address of the patient.

(h) Provide the names and addresses of all witnesses.

(2) Failure to comply with subsection 64B5-14.006(1), F.A.C., will be the basis for disciplinary action by the Board.

*Specific Authority 466.004(4), 466.017(3) FS. Law Implemented 466.017(3) FS. History—New 2-12-86, Amended 3-27-90, Formerly 21G-14.006, Amended 12-20-93, Formerly 61F5-14.006, Amended 8-8-96, Formerly 59Q-14.006, Amended 11-4-03, 12-25-06.*

#### **64B5-14.007 Inspection of Facilities and Demonstration of Sedation Technique**

(1) The Chairman of the Board or the Board by majority vote shall appoint consultants who are Florida licensed dentists to inspect facilities where general anesthesia, deep sedation, conscious sedation, or pediatric conscious sedation is performed. Consultants shall receive instruction in inspection procedures from the Board prior to initiating an inspection.

(2) Prior to issuance of a general anesthesia permit, conscious sedation permit, or pediatric conscious sedation permit, the applicant must demonstrate that he or she has knowledge of the use of the required equipment and drugs as follows:

(a) Demonstration of General Anesthesia/Deep Sedation. A dental procedure utilizing general anesthesia/deep sedation must be observed and evaluated. Any general anesthesia/deep sedation technique that is routinely employed may be demonstrated. The patient shall be monitored while sedated and during recovery. Furthermore, the dentist and his or her team must physically demonstrate by simulation an appropriate response to the following emergencies:

1. airway obstruction

2. bronchospasm

3. aspiration of foreign object

4. angina pectoris

5. myocardial infarction
6. hypotension
7. hypertension
8. cardiac arrest
9. allergic reaction
10. convulsions
11. hypoglycemia
12. syncope
13. respiratory depression.

(b) Demonstration of Conscious Sedation. A dental procedure utilizing conscious sedation must be observed and evaluated. Any conscious sedation technique that is routinely employed may be demonstrated. The patient shall be monitored while sedated and during recovery. Furthermore, the dentist and his or her team must physically demonstrate by simulation an appropriate response to the following emergencies:

1. airway obstruction
2. bronchospasm
3. aspiration of foreign object
4. angina pectoris
5. myocardial infarction
6. hypotension
7. hypertension
8. cardiac arrest
9. allergic reaction
10. convulsions
11. hypoglycemia
12. syncope
13. respiratory depression.

(c) Demonstration of Pediatric Conscious Sedation. A dental procedure utilizing pediatric conscious sedation must be observed and evaluated. Any pediatric conscious sedation technique that is routinely employed may be demonstrated. The patient shall be monitored while sedated and during recovery. Furthermore, the dentist and his or her team must physically demonstrate by simulation an appropriate response to the following emergencies:

1. airway obstruction
2. bronchospasm
3. aspiration of foreign object
4. angina pectoris
5. myocardial infarction
6. hypotension
7. hypertension
8. cardiac arrest
9. allergic reaction
10. convulsions
11. hypoglycemia
12. syncope
13. respiratory depression.

(3) Any dentist who has applied for or received a general anesthesia permit, conscious sedation permit, or pediatric conscious sedation permit shall be subject to announced or unannounced on-site inspection and evaluation by an inspection consultant. This inspection and evaluation shall be required prior to issuance of an anesthesia permit. However, if the Department cannot complete the required inspection prior to licensure, such inspection shall be waived until such time that it can be completed following licensure.

(4) The inspection consultant shall determine compliance with the requirements of Rules 64B5-14.008, 64B5-14.009 and 64B5-14.010, F.A.C., as applicable, by assigning a grade of pass or fail.

(5) Any applicant who receives a failing grade as a result of the on-site inspection shall be denied a permit for general anesthesia and conscious sedation.

(6) Any permit holder who fails the inspection shall be so notified by the anesthesia inspection consultant and shall be given a written statement at the time of inspection which specifies the deficiencies which

resulted in a failing grade. The inspection team shall give the permit holder 20 days from the date of inspection to correct any documented deficiencies. Upon notification by the permit holder to the inspection consultant that the deficiencies have been corrected, the inspector shall reinspect to insure that the deficiencies have been corrected. If the deficiencies have been corrected, a passing grade shall be assigned. No permit holder who has received a failing grade shall be permitted 20 days to correct deficiencies unless he voluntarily agrees in writing that no general anesthesia or deep sedation or conscious sedation will be performed until such deficiencies have been corrected and such corrections are verified by the anesthesia inspection consultant and a passing grade has been assigned.

(7) Upon a determination of the inspection consultant that a permit holder has received a failing grade and that the permit holder has not chosen to exercise his option by taking immediate remedial action and submitting to reinspection, or reinspection has established that remedial action has not been accomplished, the Inspection Consultant shall determine whether the deficiencies constitute an imminent danger to the public. Should an imminent danger exist, the consultant shall report his findings to the Executive Director of the Board. The Executive Director shall immediately request an emergency meeting of the Probable Cause Panel. The Probable Cause Panel shall determine whether an imminent danger exists and upon this determination of imminent danger request the Secretary of the Department to enter an emergency suspension of the anesthesia permit. If no imminent danger exists, the consultant shall report his findings to the Probable Cause Panel for further action against the permit holder. Nothing herein is intended to affect the authority of the Secretary of the Department to exercise his emergency suspension authority independent of the Board or the Probable Cause Panel.

(8) When a patient death or other adverse occurrence as described in subsection 64B5-14.006(1), F.A.C., is reported to the Department pursuant to Rule 64B5-14.006, F.A.C., the initial report shall be faxed or otherwise telephonically transmitted to the Chairman of the Board's Probable Cause Panel or another designated member of the Probable Cause Panel to determine if an emergency suspension order is necessary. If so, the Department shall be requested to promptly conduct an investigation which shall include an inspection of the office involved in the patient death.

(a) If the results of the investigation substantiate the previous determination, an emergency suspension order shall be drafted and presented to the Secretary of the Department for consideration and execution. Thereafter, a conference call meeting of the Probable Cause Panel shall be held to determine the necessity of further administrative action.

(b) If the determination is made that an emergency does not exist, the office involved with the patient death shall be inspected as soon as practicable following receipt of the notice required by Rule 64B5-14.006, F.A.C. However, in the event that the office has previously been inspected with a passing result, upon review of the inspection results, the Chairman of the Probable Cause Panel or other designated member of the Probable Cause Panel shall determine whether or not a reinspection is necessary. The complete written report of the adverse occurrence as required in Rule 64B5-14.006, F.A.C., shall be provided to the Probable Cause Panel of the Board to determine if further action is appropriate.

(c) If a routine inspection reveals a failure to comply with Rule 64B5-14.006, F.A.C., the Inspection Consultant shall obtain the information which was required to be reported and shall determine whether the failure to report the death or incident reveals that an imminent danger to the public exists and report to the Executive Director or Probable Cause Panel as set forth in subsection 64B5-14.007(6), F.A.C.

(9) The holder of any general anesthesia, conscious sedation, or pediatric conscious sedation permit shall inform the Board office in writing of any change in authorized locations for the use of such permits prior to accomplishing such changes. Written notice shall be required prior to the addition of any location or the closure of any previously identified location.

(10) Failure to provide access to an inspection team on two successive occasions shall be grounds for the issuance of an emergency suspension of the licensee's permit pursuant to the provisions of Section 120.60(8), Florida Statutes.

*Specific Authority 466.017(3) FS. Law Implemented 120.60(8), 466.017(3) FS. History—New 10-24-88, Amended 3-27-90, 11-8-90, 4-24-91, 2-1-93, Formerly 21G-14.007, Amended 12-20-93, Formerly 61F5-14.007, Amended 8-8-96, Formerly 59Q-14.007, Amended 11-4-03, 6-11-07.*

#### **64B5-14.008 Requirements for General Anesthesia or Deep Sedation.**

General Anesthesia Permit applicants and permit holders shall comply with the following requirements at each location where anesthesia procedures are performed. The requirements shall be met and equipment permanently maintained and available at each location.

(1) The operatory where anesthesia is to be administered must:

- (a) Be of adequate size and design to permit physical access of emergency equipment and personnel and to permit effective emergency management;
- (b) Be equipped with a chair or table adequate for emergency treatment, including a chair or cardiopulmonary resuscitation (CPR) board suitable for CPR;
- (c) Be equipped with suction and backup suction equipment, also including suction catheters and tonsil suction.

(2) If a recovery room is present it shall be equipped with suction and backup suction equipment, positive pressure oxygen and sufficient light to provide emergency treatment. The recovery room shall also be of adequate size and design to allow emergency access and management. The recovery room shall be situated to allow the patient to be observed by the Dentist or an office team member at all times.

(3) The following equipment must be readily available to the operatory and recovery room and maintained in good working order:

- (a) A positive pressure oxygen delivery system and backup system, including full face mask for adults and for pediatric patients, if pediatric patients are treated;
- (b) Oral and nasal airways of various sizes;
- (c) Blood pressure cuff and stethoscope; and
- (d) Cardioscope – electrocardiograph (EKG) machine, pulse oximeter, and end tidal carbon dioxide to provide continuous monitoring of heart rhythm and rate, oxygen saturation of the blood, and ventilation. This equipment shall be used for each procedure;
- (e) Defibrillator equipment appropriate for the patient population being treated; and
- (f) Thermometer.

(4) The following emergency equipment must be present:

- (a) Appropriate I.V. set-up, including appropriate hardware and fluids;
- (b) Laryngoscope with current batteries;
- (c) McGill forceps and endotracheal tubes;
- (d) Suction with backup suction;
- (e) Appropriate syringes;
- (f) Tourniquet and tape;
- (g) CPR board or chair suitable for CPR;
- (h) Stylet;
- (i) Spare bulbs and batteries;
- (j) Cricothyrotomy equipment;
- (k) Precordial stethoscope or capnometer; and
- (l) Blood pressure cuff and stethoscope.

(5) The following drugs or type of drugs with a current shelf life must be maintained and easily accessible from the operatory and recovery room:

- (a) Epinephrine;
- (b) Atropine;
- (c) Lidocaine;
- (d) Amiodarone;
- (e) An antihistamine;
- (f) A vasodilator;
- (g) A bronchodilator;
- (h) An antihypoglycemic agent;
- (i) A vasopressor;
- (j) A corticosteroid;
- (k) An anticonvulsant;
- (l) A muscle relaxant;
- (m) A narcotic and benzodiazepine antagonist;
- (n) An appropriate antiarrhythmic medication;
- (o) Nitroglycerine;
- (p) Antiemetic;

- (q) Adenosine; and
  - (r) Dantrolene, when used with volatile gases.
- (6) The applicant or permit holder shall provide written emergency protocols, and shall provide training to familiarize office personnel in the treatment of the following clinical emergencies:
- (a) Laryngospasm;
  - (b) Bronchospasm;
  - (c) Emesis and aspiration;
  - (d) Airway blockage by foreign body;
  - (e) Angina pectoris;
  - (f) Myocardial infarction;
  - (g) Hypertension/Hypotension;
  - (h) Hypertensive crisis;
  - (i) Allergic and toxicity reactions;
  - (j) Convulsions;
  - (k) Seizures;
  - (l) Syncope;
  - (m) Phlebitis;
  - (n) Intra-arterial injection; and
  - (o) Hyperventilation/Hypoventilation.

The applicant or permit holder shall maintain for inspection a permanent record which reflects the date, time, duration and type of training provided to named personnel.

- (7) The following records are required when general anesthesia is administered:
- (a) The patient's current written medical history, including known allergies and previous surgery; and
  - (b) Base line vital signs, including blood pressure, and pulse; and
  - (c) An anesthesia record which shall include:
    1. Continuous monitoring of vital signs taken at appropriate intervals during the procedure;
    2. Drugs administered during the procedure, including route of administration, dosage, time and sequence of administration;
    3. Duration of the procedure;
    4. Documentation of complications or morbidity;
    5. Status of patient upon discharge, and to whom the patient is discharged;
  - (d) Names of participating personnel.

*Specific Authority 466.004, 466.017 FS. Law Implemented 466.017 FS. History—New 10-24-88, Amended 11-16-89, Formerly 21G-14.008, Amended 12-20-93, Formerly 61F5-14.008, Amended 8-8-96, Formerly 59Q-14.008, Amended 5-31-00, 6-23-04, 9-14-05, 3-23-06, 10-24-11.*

#### **64B5-14.009 Conscious Sedation.**

Conscious Sedation Permit applicants or permit holders shall comply with the following requirements at each location where anesthesia procedures are performed. The requirements shall be met and equipment permanently maintained and available at each location.

- (1) The operatory where sedation is to be administered must:
- (a) Be of adequate size and design to permit physical access of emergency equipment and personnel and to permit effective emergency management;
  - (b) Be equipped with a chair or table adequate for emergency treatment, including a CPR board or chair suitable for CPR;
  - (c) Be equipped with suction and backup suction equipment, also including tonsil suction and suction catheters.
- (2) If a recovery room is present it shall be equipped with suction and backup suction equipment, positive pressure oxygen and sufficient light to provide emergency treatment. The recovery room shall also be of adequate size and design to allow emergency access and management. The recovery room shall be situated so that the patient can be observed by the dentist or an office team member at all times.
- (3) The following equipment must be readily available to the operatory and recovery room and maintained in good working order:
- (a) A positive pressure oxygen delivery system and backup system, including full face mask for adults and for pediatric patients, if pediatric patients are treated;

- (b) Oral and nasal airways of various sizes;
  - (c) Blood pressure cuff and stethoscope;
  - (d) Suction and backup suction equipment, also including suction catheters and tonsil suction;
  - (e) A pulse oximeter which provides continuous monitoring of pulse and rate of oxygen saturation of the blood shall be used during each procedure;
  - (f) A backup lighting system;
  - (g) A Precordial stethoscope or capnometer;
  - (h) Defibrillator equipment appropriate for the patient population being treated; and
  - (i) Thermometer.
- (4) The following emergency equipment must be present:
- (a) Appropriate intravenous set-up, including appropriate hardware and fluids;
  - (b) Appropriate syringes;
  - (c) Tourniquet and tape.
- (5) The following drugs or type of drugs with a current shelf life must be maintained and easily accessible from the operator and recovery room:
- (a) Epinephrine;
  - (b) Atropine;
  - (c) Lidocaine;
  - (d) Narcotic (e.g., Naloxone HCl) and benzodiazepine (e.g., Flumazenil) antagonists, if these agents are used;
  - (e) An antihistamine (e.g., Diphenhydramine HCl);
  - (f) A corticosteroid (e.g., Hydrocortisone);
  - (g) Nitroglycerine;
  - (h) A bronchodilator (e.g., Albuterol inhaler);
  - (i) An antihypoglycemic (e.g., 50% glucose);
  - (j) Amiodarone;
  - (k) Vasopressor;
  - (l) Anticonvulsant;
  - (m) Antihypertensive;
  - (n) Anticholinergic; and
  - (o) Antiemetic.
- (6) The applicant or permit holder shall provide written emergency protocols, and shall provide training to familiarize office personnel in the treatment of the following clinical emergencies:
- (a) Laryngospasm;
  - (b) Bronchospasm;
  - (c) Emesis and aspiration;
  - (d) Airway blockage by foreign body;
  - (e) Angina pectoris;
  - (f) Myocardial infarction;
  - (g) Hypertension/Hypotension;
  - (h) Hypertensive crisis;
  - (i) Allergic and toxicity reactions;
  - (j) Convulsions;
  - (k) Seizures;
  - (l) Cardiac arrest;
  - (m) Intra-arterial injection;
  - (n) Syncope; and
  - (o) Hyperventilation/Hypoventilation.
- The applicant or permit holder shall maintain for inspection a permanent record which reflects the date, time, duration and type of training provided to named personnel.
- (7) The following records are required when conscious sedation is administered:
- (a) The patient's current written medical history, including known allergies and history of previous surgery and anesthesia history;
  - (b) Physical and risk assessment (e.g., ASA classification);
  - (c) Base line vital signs, including blood pressure, and pulse; and
  - (d) A sedation record which shall include:

1. Periodic vital signs recorded at appropriate intervals during the procedure;
  2. Drugs administered during the procedure, including route of administration, dosage, time and sequence of administration;
  3. Duration of the procedure;
  4. Documentation of complications or morbidity;
  5. Status of patient upon discharge and to whom discharged;
  6. The patient who is administered a drug(s) for conscious sedation, must be continuously monitored intraoperatively by pulse oximetry. A precordial/pretracheal stethoscope must be available to assist in the monitoring of heart and respiratory rates. A sphygmomanometer shall be immediately available.
- (e) Names of participating personnel.

*Specific Authority 466.004, 466.017 FS. Law Implemented 466.017 FS. History--New 10-24-88, Amended 11-16-89, 4-24-91, Formerly 21G-14.009, 61F5-14.009, Amended 8-8-96, 10-1-96, Formerly 59Q-14.009, Amended 8-2-00, 11-4-03, 6-23-04, 3-23-06, 10-26-11.*

**64B5-14.010 Pediatric Conscious Sedation.**

Pediatric Conscious Sedation Permit applicants or permit holders shall comply with the following requirements at each location where anesthesia procedures are performed. The requirements shall be met and equipment permanently maintained and available at each location.

- (1) The operatory where the sedated child patient is to be treated must:
  - (a) Be of adequate size and design to permit physical access of emergency equipment and personnel and to permit effective emergency management;
  - (b) Be equipped with a chair or table adequate for emergency treatment, including a CPR board or chair suitable for CPR;
  - (c) Be equipped with suction and backup suction equipment, also including tonsil suction and suction catheters.
- (2) If a recovery room is present, it shall be equipped with suction and backup suction equipment, positive pressure oxygen and sufficient light to provide emergency treatment. The recovery room shall also be of adequate size and design to allow emergency access and management. The recovery room shall be situated so that the patient can be observed by the dentist or an office team member at all times.
- (3) The following equipment must be readily available to the operatory and recovery room and maintained in good working order:
  - (a) A positive pressure oxygen delivery system and backup system, including full face mask for pediatric patients;
  - (b) Airways of appropriate size for the pediatric patient;
  - (c) Blood pressure cuff and stethoscope;
  - (d) Suction and backup suction equipment, also including tonsil suction and suction catheters;
  - (e) A pulse oximeter which provides continuous monitoring of pulse and rate of oxygen saturation of the blood shall be used during each procedure;
  - (f) A scale for weighing pediatric patients; and
  - (g) Thermometer.
- (4) The following emergency equipment must be present:
  - (a) Appropriate intravenous set-up, including appropriate hardware and fluids;
  - (b) Appropriate syringes;
  - (c) Tourniquet and tape; and
  - (d) Defibrillator equipment appropriate for the patient population being treated.
- (5) The following drugs or type of drugs with a current shelf life must be maintained and easily accessible from the operatory and recovery room:
  - (a) Epinephrine;
  - (b) Atropine;
  - (c) Lidocaine;
  - (d) Narcotic (e.g., Naloxone HCl) and benzodiazepine (e.g., Flumazenil) antagonists, if these agents are used;
  - (e) An antihistamine (e.g., Diphenhydramine HCl);
  - (f) A corticosteroid (e.g., Hydrocortisone);
  - (g) Nitroglycerine;

- (h) A bronchodilator (e.g., Albuterol inhaler);
- (i) An antihypoglycemic (e.g., 50% glucose);
- (j) A vasopressor;
- (k) An anticonvulsant;
- (l) An antihypertensive;
- (m) Nitroglycerin;
- (n) An anticholinergic;
- (o) An antiemetic; and
- (p) Amiodarone.

(6) The applicant or permit holder shall provide written emergency protocols, and shall provide training to familiarize office personnel in the treatment of the following clinical emergencies:

- (a) Laryngospasm;
- (b) Bronchospasm;
- (c) Emesis and aspiration;
- (d) Airway blockage by foreign body;
- (e) Cardiac arrhythmias;
- (f) Hypertension/Hypotension;
- (g) Hypertensive crisis;
- (h) Allergic and toxicity reactions;
- (i) Convulsions;
- (j) Hyperventilation/Hypoventilation;
- (k) Syncope;
- (l) Seizures;
- (m) Cardiac arrest;
- (n) Intra-arterial injection;
- (o) Angina pectoris; and
- (p) Myocardial infarction.

The applicant or permit holder shall maintain for inspection a permanent record which reflects the date, time, duration and type of training provided to named personnel.

(7) The following records are required when pediatric conscious sedation is administered:

- (a) The patient's current written medical history, including known allergies, history of previous surgery and anesthesia, and the patient's age, weight, and calculation of maximum allowable local anesthesia.
- (b) Physical and risk assessment (e.g., ASA classification);
- (c) Base line vital signs, including pulse, percent hemoglobin oxygen saturation, and when possible, blood pressure;
- (d) A sedation record which shall include:
  1. Periodic vital signs recorded at appropriate intervals during the procedure;
  2. Drugs, including local anesthetics, administered during the procedure, including route of administration, dosage, time and sequence of administration;
  3. Duration of the procedure;
  4. Documentation of complications or morbidity; and
  5. Status of patient upon discharge and to whom discharged.
- (e) Names of participating personnel.

(8) Drugs for conscious sedation must be administered in a dental office and the patient must be observed by a qualified office staff member. Continuous monitoring with pulse oxymetry must be initiated with early signs of conscious sedation and continued until the patient is alert. A precordial, pretracheal stethoscope or capnometer must be available to assist interoperatively in the monitoring of heart and respiratory rates. A sphygmomanometer shall be immediately available.

*Specific Authority 466.004, 466.017 FS. Law Implemented 466.017 FS. History--New 8-8-96, Formerly 59Q-14.010, Amended 8-2-00, 5-20-01, 3-23-06, 10-26-11.*