BOARD OF DENTISTRY ANESTHESIA COMMITTEE AGENDA TELEPHONE CONFERENCE CALL

July 11, 2017 6:00 P.M. EST

Call In Number (888) 670-3525, Participant Code*: 4552635641

After entering the dial-in number, hold for a prompt to enter the public conference code. After entering the code, press the # sign to join the call.

I. CALL TO ORDER/ROLL CALL

MEMBERS PRESENT

Dr. Claudio Miro, Chair

Dr. T.J. Tejera

Dr. Naved Fatmi

Dr. Uday Mehta, Advisor

Dr. Charles Llano, Advisor

Dr. James Betancourt, Advisor

Dr. Nicholas White, Advisor

STAFF PRESENT

Jennifer Wenhold, Executive Director Jessica Sapp, Program Administrator

BOARD COUNSEL

David Flynn, Esq.

Assistant Attorney General

II. DISCUSSION ITEMS

- A. Permit Requirements for a Sedation Center
- B. Minimal Sedation, John Bitting, Esq., DOCS Education
- **III. OLD BUSINESS**
- **IV. NEW BUSINESS**
- V. ADJOURNMENT

Sapp, Jessica

From: Wenhold, Jennifer

Sent: Wednesday, June 28, 2017 1:01 PM

To: Sapp, Jessica

Subject: FW: Need for Conscious Sedation Permit

From: Klein, Eric [mailto:EKlein@dykema.com]

Sent: Friday, May 19, 2017 10:49 AM

To: Wenhold, Jennifer < Jennifer. Wenhold@flhealth.gov>

Subject: Need for Conscious Sedation Permit

Dear Ms. Wenhold:

Per my voicemail, I am writing to inquire as to whether dentists performing dental procedures at a sedation center would need to have a permit for conscious sedation. The sedation center will be a medical facility owned by a medical doctor. The dentists would be performing the dental procedures but not administering the conscious sedation. The conscious sedation would be performed by an anesthesiologist and/or CRNAs.

It is my understanding that Florida law generally requires dentists to have a sedation permit even when another health care practitioner administers and is responsible for the sedation of a dental patient in an outpatient dental office. In particular, the regulations state that 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." Fla. Admin. Code Ann. r. 64B5-14.005(1). However, the regulations do not define "dental office," so it is not clear to me whether a sedation center that is a medical facility owned by a medical doctor would constitute a dental office or not for purposes of the regulation. Any guidance regarding this would be greatly appreciated.

Please do not hesitate to contact me should you have any questions. In advance, thank you for your assistance.

Best regards, Eric



248-203-0700 Main

248-203-0891 Direct | 39577 Woodward Avenue, Suite 300 Bloomfield Hills, Michigan 48304 www.dykema.com

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Sapp, Jessica

From: John Bitting < John.Bitting@b2dmarketing.com>

Sent: Monday, January 30, 2017 12:40 AM

To: Sapp, Jessica

Cc: msilverman58@gmail.com; tony@tonyfeck.com

Subject: RE: November 18th meeting

Attachments: 2016 10 31 Florida minimal sedation draft rule change.pdf

Importance: High

Jessica,

For the Florida Board of Dentistry's consideration, my proposal for the February 17th meeting is simply this (rule language attached):

- 1. Change the substantive definitions of the Minimal and Moderate sedation to reflect those of the ASA and ADA quidelines.
- 2. Eliminate the dosage restrictions from Minimal sedation because they are arbitrary and not backed by any scientific evidence. The evidence to support this proposal can be reviewed here: www.getthescience.com
- 3. Require training (but not necessarily a permit) for Minimal sedation. The ADA guidelines recommend at least 16 hours. We would recommend 24 hours. ACLS for adults and PALS for peds (<13yo) would be optional, but we strongly recommend these certifications for any sedation. Right now, zero training is required for Minimal sedation in Florida.

The DOCS faculty is happy to host board members as our guests at any DOCS seminar. We would also be happy to bring our course(s) to Florida as we have in the past in Miami, Tampa, and Orlando. Please let me know and I will be sure it is arranged for the board members and faculty to at least connect. We acknowledge that Florida's ethics/sunshine rules may limit the board members' ability to audit...but consider that they need to have firsthand knowledge of the material on which they are ruling.

The faculty and I respectfully request the board consider this proposal. I have copied DOCS's Founder, Michael Silverman DMD, and our Dean of Faculty, Tony Feck DMD, on this as well.

Thank you and the board for your time.

--John

John P. Bitting, Esq.

Regulatory Counsel

DOCS Education
106 Lenora Street

Seattle, WA 98121
(206) 412-0089
(800) 727-4907 fax

John@DOCSeducation.com

admitted in Washington

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From: John Bitting

Sent: Friday, January 27, 2017 1:31 PM

To: Sapp, Jessica

Subject: RE: November 18th meeting

Jessica,

Thank you very much for letting me know this. I was literally about to resend it yesterday when your email came in. I think I'll send you an email with a concise explanation of three main points of my proposal. I should have that to you before Monday.

John P. Bitting, Esq.

Regulatory Counsel

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From: Sapp, Jessica [Jessica.Sapp@flhealth.gov]
Sent: Thursday, January 26, 2017 1:07 PM

To: John Bitting

Subject: RE: November 18th meeting

Mr. Bitting,

This is to let you know that your proposal was tabled from the November 18, 2016 board meeting and will now be discussed at the Board's February 17, 2017 meeting in Orlando.

Please let me know if you have any questions.

Jessica Sapp

Program Operations Administrator

Department of Health | Division of Medical Quality Assurance Bureau of Health Care Practitioner Regulation | Board of Dentistry 4052 Bald Cypress Way Bin C-08 Tallahassee, FL 32399-1708 Phone 850/245-4463 www.FloridasDentistry.gov



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Note: Florida has a very broad public records law. Most written communications to or from state officials regarding state business are public records available to the public and media upon request. Your email communication may therefore be subject to public disclosure.

From: John Bitting [mailto:John.Bitting@b2dmarketing.com]

Sent: Tuesday, November 1, 2016 4:08 PM

To: Wenhold, Jennifer < Jennifer. Wenhold@flhealth.gov>

Cc: Sapp, Jessica <Jessica.Sapp@flhealth.gov>

Subject: RE: November 18th meeting

Jennifer,

Please find draft sedation rule proposal attached (64B5-14 Anesthesia) for the Board's review for 11/18 meeting. See you then!

Thank you for your time and consideration.

Best regards,

John P. Bitting, Esq. Regulatory Counsel **DOCS** Education 106 Lenora Street Seattle, WA 98121 (206) 412-0089 (800) 727-4907 fax

John@DOCSeducation.com

admitted in Washington

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From: John Bitting

Sent: Thursday, October 27, 2016 9:18 AM

To: Wenhold, Jennifer Cc: Sapp, Jessica

Subject: RE: November 18th meeting

Will do. I'll get them to you by EOB Tuesday. Thank you!

John P. Bitting, Esq. Regulatory Counsel **DOCS** Education 106 Lenora Street Seattle, WA 98121 (206) 412-0089 (800) 727-4907 fax

John@DOCSeducation.com

admitted in Washington

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From: Wenhold, Jennifer [Jennifer.Wenhold@flhealth.gov]

Sent: Thursday, October 27, 2016 9:16 AM

To: John Bitting **Cc:** Sapp, Jessica

Subject: RE: November 18th meeting

Good afternoon Mr. Bitting,

Thank you for contacting the Florida Board of Dentistry and requesting to appear before them at their November 18, 2016 board meeting in Miami, Florida. In order for us to properly place this on the board meeting agenda, can you please provide me with the specific topic for discussion and forward all presentation materials or material you would like the board to review in advance of the meeting to me no later than Tuesday, November 1, 2016. This deadline will ensure they are included in the board member's meeting material. If you have any questions, please feel free to contact me directly. Also, the board meeting details can be found at http://floridasdentistry.gov/meeting-information/.

Regards,

Jennifer L. Wenhold, MSW, Executive Director Florida Department of Health Florida Boards of Dentistry, Clinical Social Work, Marriage & Family Therapy and Mental Health Counseling, Opticianry, Hearing Aid Specialists and Athletic Training

850.245-4460 (office) 850.921.5389 (fax)

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From: John Bitting < John. Bitting @b2dmarketing.com>

Date: October 26, 2016 at 1:16:06 PM EDT

To: "info@floridasdentistry.gov" <info@floridasdentistry.gov>

Subject: November 18th meeting

Ms. Wenhold,

Would it be possible to add me to the agenda for the 11/18 meeting in Miami to make a brief presentation to the board regarding minimal sedation? It would be less than 20 minutes.

Thank you for your time and consideration.

John P. Bitting, Esq. Regulatory Counsel DOCS Education 106 Lenora Street Seattle, WA 98121 (206) 412-0089

(800) 727-4907 fax John@DOCSeducation.com

admitted in Washington

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CHAPTER 64B5-14 ANESTHESIA

| 64B5-14.001 | Definitions. |
|-------------|---|
| 64B5-14.002 | Prohibitions. |
| 64B5-14.003 | Training, Education, Certification, and Requirements for Issuance of Permits. |
| 64B5-14.004 | Additional Requirements. |
| 64B5-14.005 | Application for Permit. |
| 64B5-14.006 | Reporting Adverse Occurrences. |
| 64B5-14.007 | Inspection of Facilities. |
| 64B5-14.008 | Requirements for General Anesthesia or Deep Sedation. |
| 64B5-14.009 | Conscious Sedation Moderate sedation. |
| 64B5-14.010 | Pediatric Conscious Sedation. |

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.
- sedation Moderate sedation A drug-induced depression of consciousness during which natients Consciou respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. No intervention are required to maintain a patent airway, and spontaneous ventilation is adequate. A depressed level of consci 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 Formatted: Font: 10 pt, Font color: Red pharmacologic substances, that retains a child patient's ability to independently and continuously maintain an airwa 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, an Formatted: Font: 10 pt, Font color: Red all enteral routes; that is oral, rectal, or transmucosal. The drugs, doses, and techniques used should carry a margi Formatted: Font color: Red 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 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 an Formatted: Bullets and Numbering 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.
- (49)Office team approach A methodology employed by a dentist in the administration of general anesthesia, dee Formatted: Bullets and Numbering sedation, conscious sedationmoderate 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.

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(10) Minimal Sedation (anxiolysis) - A minimally depressed level of consciousness, produced by a pharmacological Formatted: Font color: Red method, that retains the patient's ability to independently and continuously maintain an airway and respond normal to tactile stimulation and verbal command. Although cognitive function and coordination may be modestly impaired, ventilatory and cardiovascular functions are unaffected. The perioperative use of medication to reli anxiety before or during a dental procedure which does not produce a depre verbal

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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 opiod 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 werethe level of consciousness and standard of care for minimal sedation were observed, this shall not automatically constitute a violation moderate sedation. A permit shall not be required for the perioperative use of medication for the purpose of providing anxiolysis minimal sedation. (11) Titration of Oral Medication - The administration of small incremental doses of an orally administer medication until an intended level of conscious minimal sedation is observed.

(12)(11) Physician anesthesiologist - Any physician licensed pursuant to Section 458 or Section 459 Florid Formatted: Bullets and Numbering Statutes, who is currently board certified or board eligible by the American Board of Anesthesiology or the Formatted: Font color: Red American Osteopathic Board of Anesthesiology, or is credentialed to administer anesthesia in a hospital of 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, Formerly59Q-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) Cons sedationModerate sedation. No dentists licensed in this State shall administer conscious sedation moderate 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 Formatted: Strikethrough 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 patien 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)(7) 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.

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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 moderate sedation and nitrous-oxide inhalation conscious sedation moderate 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) Co Sedation Moderate sedation Permit.
- (a) A permit shall be issued to a dentist authorizing the use of conscious sedationmoderate 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 moderate sedation; and
- 2. Is certified by the institution where the training was received to be competent in the administration of conscious sedation moderate sedation; and
- 3. Is competent to handle all emergencies relating to conscious sedation moderate 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 othe Formatted: Indent: Left: 0", First line: 0", Numbered + facility approved by the Board of Dentistry or part of the undergraduate curriculum of an accredited dental school.

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(d) A dentist utilizing conscious sedationmoderate sedation shall maintain a properly equipped facility for the conscious sedationmoderate 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 sedationmoderate 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 sedationmoderate sedation and his assistant/dental hygienist personnel shall b Formatted: Bullets and Numbering 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 sedationmoderate sedation must be currently trained in ACLS (Advanced Cardiac Life Support) or ATLS (Advanced Trauma Life Support).

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

(2) Dentists permitted to administer conscious sedation may administer pediatric conscious Formatted: Bullets and Numbering 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 eonscious sedationanalgesia.
- (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 moderate 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) Minimal Sedation.

A permit shall not be required provided such dentist:

- 1. Has received formal training in the use of minimal sedation; and
- 2. Is certified by the institution where the training was received to be competent in the administration of minima sedation; and
- 3. Is competent to handle all emergencies relating to minimal sedation.
- 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 sixteen. Clinical training shall include observe administration of at least five patients and demonstrated competence in airway management of the compromise
- (b) This formal training may be part of a pre- or post-doctoral university program or a reputable continuing education provider.
- (1) Office Team A dentist licensed by the Board and practicing dentistry in Florida and who is permitted by thes rules to induce and administer general anesthesia, deep sedation, conscious sedationmoderate sedation, pediatri 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-oxid Not at 0.5" inhalation analgesia under the direct supervision of a dentist who is permitted by rule to use general anesthesia Formatted: Bullets and Numbering conscious sedation moderate 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
- (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

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- 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 eonscious sedation moderate 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 sedationmoderate 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 sedationmoderate 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 sedationmoderate 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 64B4-14.003, 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 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 sedationmoderate 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 sedationmoderate 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, <u>conscious sedation</u>, 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.

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_moderate sedation_ pediatric conscious 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 sedationmoderate 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, eonscious sedationmoderate 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. convulsions11. hypoglycemia
- 12. syncope
- 13. respiratory depression.
- (b) Demonstration of Conscious sedationModerate sedation. A dental procedure utilizing conscious sedationmoderate sedation must be observed and evaluated. Any conscious sedationmoderate sedation technique that is routinely employed may be demonstrated. The patient shall be monitored while sedated and during recovery. Futhermore, 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.
- (d) 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.
- (4) 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 sedationmoderate 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 sedationmoderate 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, eonscious sedationmoderate 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 and pulse oximeter to provide continuous monitoring of heart rhythm and rate of oxygen saturation of the blood. This equipment shall be used for each procedure; and
- (e) Defibrillator equipment appropriate for the patient population being treated.
- (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; (1) A muscle

relaxant;

(m) A narcotic and benzodiazepine antagonist; (n) An

appropriate antiarrhythmic medication; (o

Nitroglycerine;

- (p) Antiemetic;
- (q) Sodium bicarbonate; 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 administration, dosage, time and sequence 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.

64B5-14.009 Conscious sedation Moderate sedation and Minimal Sedation.

Conscious sedation Moderate sedation Permit applicants or permit holders and dentists providing Minimal Sedation 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; and
- (h) Defibrillator equipment appropriate for the patient population being treated.
- (4) The following emergency equipment must be present for Moderate Sedation, and for Minimal Sedation where indicated:
- (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 operatory and recovery room:
- (a) Epinephrine (also for

Minimal Sedation);

- (b) Atropine;
- (c) Lidocaine;
- (d) Narcotic (e.g., Naloxone HCI) and benzodiazepine (e.g., Flumazenil) antagonists, if these agents are used <u>(also for Minimal Sedation)</u>;
- (e) An antihistamine (e.g., Diphenhydramine HCI) (also for

Minimal Sedation);

- (f) A corticosteroid (e.g., Hydrocortisone);
- (g) Nitroglycerine (also for Minimal Sedation);
- (h) A bronchodilator (e.g., Albuterol inhaler) (also for

Minimal Sedation);

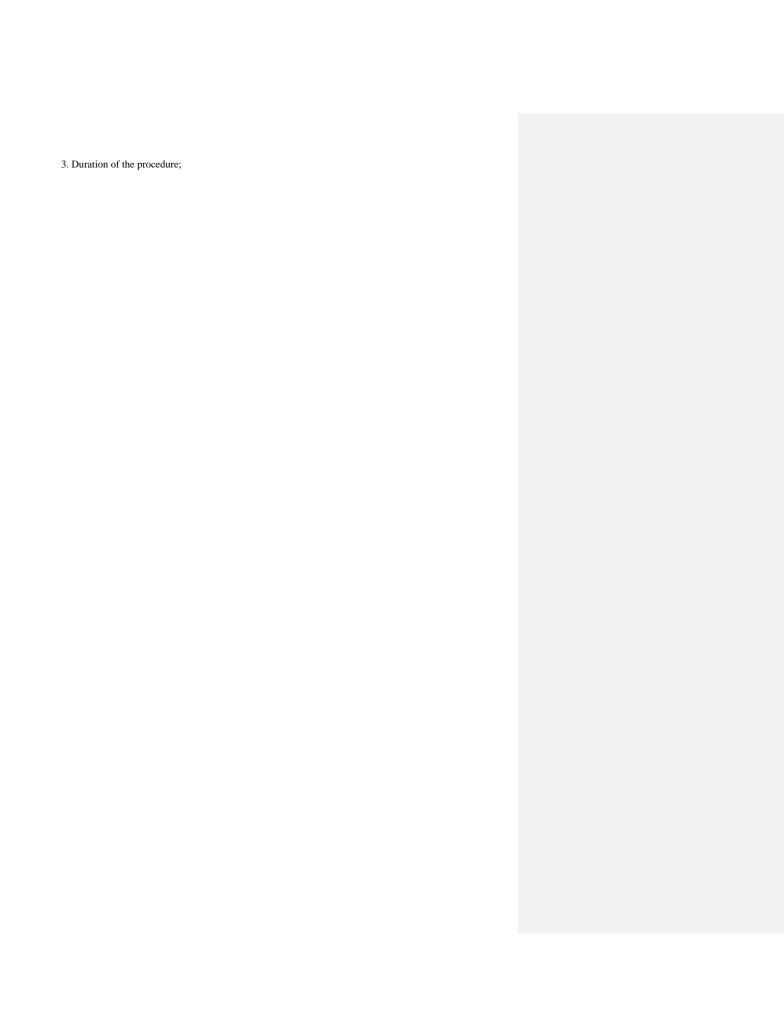
(i) An antihypoglycemic (e.g., 50% glucose) (also for

Minimal Sedation);

- (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 minimal or moderate 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;



- 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 sedationmoderate 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.

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; and
- (f) A scale for weighing pediatric patients.
- (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 HCI) and benzodiazepine (e.g., Flumazenil) antagonists, if these agents are used;
- (e) An antihistamine (e.g., Diphenhydramine HCI);
- (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 sedationmoderate 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 sedationmoderate 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.

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 opiod 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 Chapter 458 or 459, F.S., 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.
- (13) Qualified Anesthetist: means an Advanced Registered Nurse Practitioner who is licensed in this state to practice professional nursing and who is certified in the advanced or specialized nursing practice as a certified registered nurse anesthetist pursuant to Chapter 464, Part I, F.S.
- (14) Certified Registered Dental Hygienist: means any Florida licensed dental hygienist who is certified by the Board and has received a certificate from the Department of Health that allows the administration of local anesthesia while the CRDH is appropriately supervised by a Florida licensed dentist.

Rulemaking Authority 466.004(4), 466.017(3), 466.17(6) FS. Law Implemented 466.002(3), 466.017(3), 466.017(5) 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, 7-3-06, 6-11-07, 8-5-12.

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) Pediatric Conscious Sedation: 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. Certified Registered Dental Hygienists are the only hygienists allowed to adminster local anesthesia.
- (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, etomidate, ketamine, or volatile gases (i.e., sevoflurane, isoflurane).
- (9) A hygienist certified by the board to administer local anesthesia shall not administer local anesthesia to a patient sedated by general anesthesia, deep sedation, conscious sedation, or pediatric conscious sedation. If a dentist has administered nitrous-oxide to the patient, the certified dental hygienist may administer local anesthesia under the direct supervision of the supervising dentist. A patient who has been prescribed a medical drug by their licensed health care provider for the purposes of life functions may be administered local anesthesia by the certified dental hygienist under the direct supervision of the supervising dentist. If, however, the medical drug is prescribed or administered for the purposes of a dental procedure which is intended to induce minimal sedation (anxiolysis), the hygienist may not administer local anesthesia to the patient.

Rulemaking Authority 466.004(4), 466.017(3), 466.017(6) FS. Law Implemented 466.017(3), 466.017(5) 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, 12-11-11, 8-5-12, 12-15-14, 7-14-16.

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 a two year residency program accredited by the Commission on Dental Accreditation in dental anesthesiology or has completed an oral and maxillofacial surgical residency program accredited by the Commission on Dental Accreditation beyond the undergraduate dental school level; 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.
- (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.
 - (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, which must include four (4) hours of airway management. Airway management

must include emergency airway management protocols. 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. The program must certify that a total of three (3) hours of clinical training was dedicated to hands-on simulated competence in airway management of the compromised airway.

- (c) Personal Administration of Conscious Sedation: The board shall award credit towards the required 20 dental patients, if and only if, the applicant is responsible for and remains with the patient from pre-anesthetic evaluation through discharge. The evaluation and responsibilities include the following: pre-anesthetic evaluation, induction, maintenance, emergence, recovery, and approval for discharge. The board will not award credit for dental anesthetic procedures performed that are greater than or less than the administration of conscious sedation.
- (d) This formal training program shall be offered through an accredited dental school or program; or through an accredited, teaching hospital.
- (e) 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.
- (f) 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 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 conscious sedation must be currently trained in ACLS (Advanced Cardiac Life Support) or ATLS (Advanced Trauma Life Support).
 - (g) Dentists permitted to administer conscious sedation may administer nitrous-oxide inhalation conscious sedation.
- (h) 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 offered through an accredited dental school or program; or through an accredited teaching program; 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, which must include four (4) hours of airway management. Clinical training shall include personal administration for at least twenty patients including supervised training, management of sedation, clinical experience and demonstrated competence in airway management of the compromised airway. The program must certify that three (3) hours of clinical training was dedicated to hands-on simulated competence in airway management of the compromised airway; and
- 3. Personal Administration of Pediatric Conscious Sedation: The board shall award credit towards the required 20 dental patients, if and only if, the applicant is responsible for and remains with the patient from pre-anesthetic evaluation through discharge. The evaluation and responsibilities include the following: pre-anesthetic evaluation, induction, maintenance, emergency, recovery, and approval for discharge. The board will not award credit for dental anesthetic procedures performed that are greater than or less than the administration of pediatric conscious sedation; or
- 4. The applicant demonstrates that the applicant graduated, within 24 months prior to application for the permit, from an accredited post-doctoral pediatric residency. The pediatric residency anesthesia requirements must meet the minimum number of sedation cases as required in subsection (2).
- 5. 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 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 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 analysis 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 subparagraphs 1. and 2. of paragraph (4)(a) above, may continue such use provided the dentist fulfills the provisions set forth in paragraph 3. of paragraph (4)(a) and the provisions of paragraph (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.
- (5) Local Anesthesia Certificate or Permit: A permit or certificate to administer local anesthesia under the direct supervision of a Florida licensed dentist to non-sedated patients eighteen (18) years of age or older shall be issued by the Department of Health to a Florida licensed dental hygienist who has completed the appropriate didactic and clinical education and experience as required by Section 466.017(5), F.S., and who has been certified by the Board as having met all the requirements of Section 466.017, F.S.
- (a) A registered dental hygienist who is seeking a permit or certificate for administering local anesthesia must apply to the department on form DH-MQA 1261 (May 2012), Application for Dental Hygiene Certification Administration of Local Anesthesia, herein incorporated by reference and available at http://www.flrules.org/Gateway/reference.asp?No=Ref-01469, or available on the Florida Board of Dentistry website at http://www.doh.state.fl.us/mqa/dentistry.
 - (b) An applicant shall submit the following with the application:

- 1. A thirty-five dollar (\$35) non refundable certificate or permit fee;
- 2. A certified copy of the applicant's transcripts that reflect the required didactic and clinical education and experience;
- 3. A certified copy of the diploma or certificate issued by the applicant's institution, program, or school; and
- 4. Proof of acceptable certification in Cardiopulmonary Resuscitation for health professionals or Advanced Cardiac Life Support as defined in Section 466.017, F.S.

Rulemaking Authority 466.004(4), 466.017(3), (6) FS. Law Implemented 466.017(3), (4), (5), (6) 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, 2-8-12, 8-16-12 (1)(a)-(f), 8-16-12 (5), 8-19-13, 12-16-13, 3-9-14, 7-14-16.

64B5-14.0032 Itinerate/Mobile Anesthesia – Physician Anesthesiologist.

The provisions of this rule control the treatment of dental patients in an outpatient dental office setting where a physician anesthesiologist has performed the sedation services. This rule shall control notwithstanding any rule provision in this Chapter that prohibits such conduct. The level of sedation is not restricted to the level of the permit held by the treating dentist. The level of sedation may be any level necessary for the safe and effective treatment of the patient.

(1) General Anesthesia Permit Holders:

A dentist who holds a general anesthesia permit may treat their adult, pediatric, or special needs patients when a physician anesthesiologist performs the sedation services. The following conditions shall apply:

- (a) The physician anesthesiologist performs the administration of the anesthesia and the physician anesthesiologist is responsible for the anesthesia procedure;
 - (b) The dental treatment takes place in the general anesthesia permit holder's board-inspected and board-registered dental office.
 - (2) Pediatric Conscious Sedation Permit Holders:

A pediatric dentist, as recognized by the American Dental Association, who holds a pediatric conscious sedation permit may treat their pediatric or special needs dental patients when a physician anesthesiologist performs the sedation services. The following conditions shall apply:

- (a) The physician anesthesiologist performs the administration of the anesthesia, and the physician anesthesiologist is responsible for the anesthesia procedure;
 - (b) The treatment takes place in the permit holder's board-inspected and board-registered dental office;
 - (c) The dental office meets the supply, equipment, and facility requirements as mandated in Rule 64B5-14.008, F.A.C.;
- (d) A board-approved inspector performs an inspection of the dental office and the inspector reports the office to be in full compliance with the minimum supply, equipment, and facility requirements.

A pediatric dentist who holds an active conscious sedation permit and not a pediatric conscious sedation permit shall meet the sedation permit requirement of this rule until the next biennial license renewal cycle that follows the effective date of this rule. At the next biennial license renewal cycle that follows the effective date of this rule, a pediatric dentist who hold a conscious sedation permit may transfer the permit to a pediatric conscious sedation permit without any additional cost besides the renewal fee.

(3) Conscious Sedation Permit Holders:

A dentist who holds a conscious sedation permit may treat their adult or adult special needs dental patients when a physician anesthesiologist performs the sedation services. The following conditions shall apply:

- (a) The physician anesthesiologist performs the administration of the anesthesia, and the physician anesthesiologist is responsible for the anesthesia procedure;
 - (b) The treatment takes place in the permit holder's properly board-inspected and board-registered dental office;
 - (c) The dental office meets the supply, equipment, and facility requirements as mandated in Rule 64B5-14.008, F.A.C.;
- (d) A board-approved inspector performs an inspection of the dental office and the inspector reports the office to be in full compliance with the minimum supply, equipment, and facility requirements.
 - (4) Non-Sedation Permit Holders:

All provisions of this Chapter relating to the administration of any type of anesthesia or sedation and treatment to sedated patients shall remain in full force and effect. Nothing in this section supersedes, alters, or creates a variance to any prohibitions and mandates applicable to non-sedation permit holding dentists.

(5) Staff or Assistants:

A dentist treating a patient pursuant to this rule must have at least three (3) properly credentialed individuals present as mandated in Rule 64B5-14.003, F.A.C. To fulfill the mandatory minimum required personnel requirements of Rule 64B5-14.003, F.A.C., a physician anesthesiologist assistant or a certified registered nurse anesthetist in addition to, or in lieu of a dental assistant or dental hygienist may be utilized. However, the dentist must have a dedicated member of the team to assist in the dental procedure or during dental emergencies.

(6) Equipment:

A dentist may comply with the electrocardiograph and end tidal carbon dioxide monitor equipment standards set by Rule 64B5-14.008, F.A.C., by utilizing mobile or non-fixed equipment if the dentist meets the following conditions:

- (a) During the required board inspection, the equipment is available for inspection, or the dentist supplies an inspection of the equipment, which a licensed health care risk manager performed. A licensed health care risk manager inspection is valid for a period of twelve months; and
- (b) The dentist shall make the inspected equipment available during all required inspections, if specifically requested within 48 hours in advance of the inspection, and the equipment must be immediately available for an adverse incident inspection.
 - (7) Records:

The treating dentist shall maintain a complete copy of the anesthesia records in the patient's dental chart. The dentist shall make certain that name and license numbers identify the treating dentist, the physician anesthesiologist, and all personnel utilized during the procedure.

Rulemaking Authority 466.004(4), 466.017(3) FS. Law Implemented 466.017(3) FS. History-New 8-20-12, Amended 11-19-12, 2-21-13, 12-16-13.

64B5-14.0034 Itinerate/Mobile Anesthesia – General Anesthesia Permit Holders.

The provisions of this rule control the treatment of dental patients in an outpatient dental office where a dentist with a general anesthesia permit performs the sedation services for a treating dentist. The treating dentist must possess a general anesthesia permit, conscious sedation permit, or pediatric conscious sedation permit. The level of anesthesia administered shall be to any level necessary to safely and effectively treat the dental patient. This rule shall control notwithstanding any rule provision in this Chapter that prohibits such conduct.

(1) General Anesthesia Permit Holder's Office:

A general anesthesia permit holder may perform sedation services for a dental patient of another general anesthesia permit holder or conscious or pediatric conscious sedation permit holder in his or her office or in another general anesthesia permit holder's office. In this setting, the following shall apply:

- (a) The dental treatment may only be performed by a treating dentist who holds a valid anesthesia permit of any level;
- (b). The treating dentist and the anesthesia provider are both responsible for the adverse incident reporting under Rule 64B5-14.006, F.A.C.
 - (2) Conscious and Pediatric Conscious Sedation Permit Holder's Office:

A general anesthesia permit holder may perform sedation services for a dental patient of another dentist who holds a conscious sedation permit or a pediatric conscious sedation permit at the office of the treating dentist. In this setting, the following shall apply:

- (a) The dental treatment may only be performed by the conscious sedation or pediatric conscious sedation permit holder;
- (b) The general anesthesia permit holder may perform general anesthesia services once an additional board-inspection establishes that the office complies with the facility, equipment and supply requirements of Rule 64B5-14.008, F.A.C.;
- (c) The treating dentist and the anesthesia provider are both responsible for the adverse incident reporting requirements under Rule 64B5-14.006, F.A.C.
 - (3) Equipment:

When the general anesthesia permit holder performs the anesthesia services in a dental office of a conscious or pediatric conscious sedation permit holder's office, the electrocardiograph and end tidal carbon dioxide monitor equipment mandates may be met as follows:

- (a) The general anesthesia permit holder provides the equipment which has already been inspected during the general anesthesia permit holder's required inspection;
 - (b) The equipment is available for inspection during the office's mandated inspection; and
 - (c) The equipment is immediately available for an adverse incident report inspection.
 - (4) Staff or Personnel:

An anesthesia provider and the treating dentist are both responsible for ensuring that a minimum number of three (3) personnel are present during the procedure. The personnel must meet the minimum credentialing requirements of Rule 64B5-14.003, F.A.C.

(5) Records: The treating dentist shall maintain a complete copy of the anesthesia records in the patient's dental chart. The dentist performing the anesthesia must maintain the original anesthesia records. The treating dentist must identify by name and license number all personnel utilized during the procedure.

Rulemaking Authority 466.004(4), 466.017 FS. Law Implemented 466.017 FS. History-New 3-14-13.

64B5-14.0036 Treatment of Sedated Patients by Dentists Without an Anesthesia Permit.

The provisions of this rule control the treatment of patients where an anesthesia permitted dentist sedates the dental patient in his or her board-inspected and board-registered dental office and a Florida licensed dentist without an anesthesia permit performs the dental treatment. This rule shall control notwithstanding any rule provision in this Chapter to the contrary, which prohibits such conduct.

- (1) The permitted dentist shall perform the sedation in his or her out-patient dental office where the permitted dentist is registered to perform the anesthesia services;
- (2) The permitted dentist shall remain with the patient from the onset of the performance of the anesthesia until discharge of the patient;
- (3) The permitted dentist shall have no other patient induced with anesthesia or begin the performance of any other anesthesia services until the patient is discharged;
- (4) The treating dentist shall have taken a minimum of four hours of continuing education in airway management prior to treating any sedated patient. Two hours must be in didactic training in providing dentistry on sedated patients with compromised airways and two hours must include hands-on training in airway management of sedated patients. After the initial airway management course, the treating dentist shall continue to repeat a minimum of four hours in airway management every four years from the date the course was last taken by the dentist. The continuing education courses taken may be credited toward the mandatory thirty hours of continuing education required for licensure renewal. The requirement that a dentist must first have taken an initial airway management course before treating a sedated patient shall not take effect until March 1, 2014.

Rulemaking Authority 466.004(4), 466.017 FS. Law Implemented 466.017 FS. History-New 3-14-13, Amended 8-19-13.

64B5-14.0038 Use of a Qualified Anesthetist.

In an outpatient dental office, and pursuant to Section 466.002(2), F.S., a dentist may supervise a qualified anesthetist who is administering anesthetic for a dental procedure on a patient of the supervising dentist. The type of supervision required is direct supervision as defined in Section 466.003(8), F.S. In an outpatient dental office, the supervising dentist must have a valid permit for administering sedation to the level of sedation that the qualified anesthetist will be administering to the dental patient during the dental procedure. The dentist must maintain all office equipment and medical supplies required by this chapter to the level of the sedation that the qualified anesthetist will administer to the dental patient.

Rulemaking Authority 466.004(4), 466.017 FS. Law Implemented 466.002(2), 466.017, 466.003(8) FS. History-New 11-11-13.

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) All dentists who hold an active sedation permit of any level must complete four (4) hours of continuing education in airway management and four (4) hours of continuing education in medical emergencies, every four (4) years from the last date the dentist took the continuing education course. The four (4) hours in airway management must include two hours didactic training in providing dentistry on sedated patients with compromised airways and two hours must include hands-on training in airway management of sedated patients. The continuing education must be taken through a board approved continuing education provider. The continuing education required by this subsection will take effect on March 1, 2014. The continuing education required by this subsection may be included in the thirty (30) hours required by Section 466.0135, F.S.

Rulemaking 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, 5-24-05, 8-19-13.

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.

Rulemaking Authority 466.004, 466.017(3), 466.017(6) FS. Law Implemented 466.017, 466.017(5) 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, 8-5-12.

64B5-14.006 Reporting Adverse Occurrences.

- (1) Definitions:
- (a) Adverse occurrence means any mortality that occurs during or as the result of a dental procedure, or an incident that results in the temporary or permanent physical or mental injury that requires hospitalization or emergency room treatment of a dental patient that occurred during or as a direct result of the use of general anesthesia, deep sedation, conscious sedation, pediatric conscious sedation, oral sedation, minimal sedation (anxiolysis), nitrous oxide, or local anesthesia.
- (b) Supervising Dentist means the dentist that was directly responsible for supervising the Certified Registered Dental Hygienist (CRDH) who is authorized by proper credentials to administer local anesthesia.
- (2) Dentists: Any dentist practicing in the State of Florida must notify the Board in writing by registered mail within forty-eight hours (48 hrs.) of any mortality or other adverse occurrence that occurs in the dentist's outpatient facility. A complete written report shall be filed with the Board within thirty (30) days of the mortality or other adverse occurrence. The complete written report shall, at a minimum, include the following:
 - (a) The name, address, and telephone number of the patient;
 - (b) A detailed description of the dental procedure;
 - (c) A detailed description of the preoperative physical condition of the patient;
 - (d) A detailed list of the drugs administered and the dosage administered;
 - (e) A detailed description of the techniques utilized in administering the drugs;
- (f) A detailed description of the adverse occurrence, to include 1) the onset and type of complications and the onset and type of symptoms experienced by the patient; 2) the onset and type of treatment rendered to the patient; and 3) the onset and type of response of the patient to the treatment rendered; and
 - (g) A list of all witnesses and their contact information to include their address.
- (3) A failure by the dentist to timely and completely comply with all the reporting requirements mandated by this rule is a basis for disciplinary action by the Board, pursuant to Section 466.028(1), F.S.
- (4) Certified Registered Dental Hygienists: Any CRDH administering local anesthesia must notify the Board, in writing by registered mail within forty-eight hours (48 hrs.) of any adverse occurrence that was related to or the result of the administration of local anesthesia. A complete written report shall be filed with the Board within thirty (30) days of the mortality or other adverse occurrence. The complete written report shall, at a minimum, include the following:
 - (a) The name, address, and telephone number of the supervising dentist;
 - (b) The name, address, and telephone number of the patient;
 - (c) A detailed description of the dental procedure;
 - (d) A detailed description of the preoperative physical condition of the patient;
 - (e) A detailed list of the local anesthesia administered and the dosage of the local anesthesia administered;

- (f) A detailed description of the techniques utilized in administering the drugs;
- (g) A detailed description of any other drugs the patient had taken or was administered;
- (h) A detailed description of the adverse occurrence, to include 1) the onset and type of complications and the onset and type of symptoms experienced by the patient; 2) the onset and type of treatment rendered to the patient; and 3) the onset and type of response of the patient to the treatment rendered; and
 - (i) A list of all witnesses and their contact information to include their address.
- (5) A failure by the hygienist to timely and completely comply with all the reporting requirements mandated by this rule is a basis for disciplinary action by the Board pursuant to Section 466.028(1), F.S.
 - (6) Supervising Dentist:

If a Certified Registered Dental Hygienist is required to file a report under the provisions of this rule, the supervising dentist shall also file a contemporaneous report in accordance with subsection (2).

(7) The initial and complete reports required by this rule shall be mailed to: The Florida Board of Dentistry, 4052 Bald Cypress Way, Bin #C08, Tallahassee, Florida 32399-3258.

Rulemaking Authority 466.004(4), 466.017(3), (6) FS. Law Implemented 466.017(3), (5) 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, 8-5-12.

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; and
 - 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; and
- 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; and
 - 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), F.S.

Rulemaking 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: Operatory, Recovery Room, Equipment, Medicinal Drugs, Emergency Protocols, Records, and Continuous Monitoring.

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) Operatory: 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) Recovery Room: If a recovery room is present, it shall be equipped with suction and back up 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) Standard Equipment: 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) Cardioscope electrocardiograph (EKG) machine, pulse oximeter, and capnograph;
- (e) Precordial stethoscope;
- (f) Suction with backup suction, including suction catheters and tonsil suction;
- (g) Thermometer (Continuous temperature monitoring device, if volatile gases are used);
- (h) A backup lighting system; and
- (i) A scale to weigh patients.
- (4) Emergency Equipment: The following emergency equipment must be present, readily available and maintained in good working order:
 - (a) Appropriate I.V. set-up, including appropriate supplies and fluids;
 - (b) Laryngoscope with spare batteries and spare bulbs;
 - (c) McGill forceps, endotracheal tubes, and stylet;
 - (d) Appropriate syringes;
 - (e) Tourniquet and tape;
 - (f) CPR board or chair suitable for CPR;
 - (g) Defibrillator equipment appropriate for the patient population being treated;
 - (h) Cricothyrotomy equipment; and
 - (i) A Supraglottic Airway Device (SAD) or a Laryngeal Mask Airway (LMA).
- (5) Medicinal Drugs: 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) A narcotic (e.g., Naloxone) and benzodiazepine (e.g., Flumazenil) antagonist, if these agents are used;
 - (c) An antihistamine (e.g., Diphenhydramine);
 - (d) A corticosteroid (e.g., Dexamethasone);
 - (e) Nitroglycerin;
 - (f) A bronchodilator (e.g., Albuterol inhaler);
 - (g) An antihypoglycemic agent (e.g., D50W IV solution);
 - (h) Amiodarone;
 - (i) A vasopressor (e.g., Ephedrine);
 - (j) An anticonvulsant (e.g., Valium or Versed);
 - (k) Antihypertensive (e.g., Labetalol);
 - (l) Anticholinergic (e.g., atropine);
 - (m) Antiemetic;
 - (n) A muscle relaxant (e.g., Succinylcholine);
 - (o) An appropriate antiarrhythmic medication (e.g., Lidocaine);
 - (p) Adenosine; and
 - (q) Dantrolene, if volatile gases are used.
- (6) Emergency Protocols: 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;
 - (i) Seizures;
 - (k) Syncope;

- (1) Phlebitis;
- (m) Intra-arterial injection;
- (n) Hyperventilation/Hypoventilation;
- (o) Cardiac arrest; and
- (p) Cardiac arrhythmias.

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) Records: The following records are required when general anesthesia or deep sedation is administered:
- (a) The patient's current written medical history, including known allergies and previous surgery;
- (b) Physical examination including airway evaluation and risk assessment (e.g., Mallampati Classification, Body Mass Index, and ASA Classification);
 - (c) Base line vital signs, including blood pressure, and pulse; and
 - (d) An anesthesia record which shall include:
- 1. Continuous monitoring of vital signs, which are taken and recorded at a minimum of every 5 minute 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 (See Rule 64B5-14.006, F.A.C., for Adverse Incident Reporting Requirements);
 - 5. Status of patient upon discharge, and to whom the patient is discharged; and
 - 6. Names of participating personnel.
- (8) Continuous Monitoring: The patient who is administered drug(s) for general anesthesia or deep sedation must be continuously monitored intra-operatively by electrocardiograph (EKG), pulse oximeter, and capnograph to provide heart rhythm and rate, oxygen saturation of the blood, and ventilations (end-tidal carbon dioxide). This equipment shall be used for each procedure.

Rulemaking 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, 3-9-14.

64B5-14.009 Conscious Sedation Requirements: Operatory, Recovery Room, Equipment, Medicinal Drugs, Emergency Protocols, Records, and Continuous Monitoring.

Conscious Sedation 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) Operatory: 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) Recovery Room: 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) Standard Equipment: The following standard equipment must be readily available to the operatory and recovery room and must be 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) A pulse oximeter which provides continuous monitoring of pulse and rate of oxygen saturation of the blood shall be used during each procedure;
 - (e) A Precordial stethoscope;
 - (f) Capnograph;
 - (g) Suction with backup suction, also including suction catheters and tonsil suction;
 - (h) Thermometer;
 - (i) A backup lighting system; and,
 - (j) A scale to weigh patients.
- (4) Emergency Equipment: The following emergency equipment must be present, readily available and must be maintained in good working order:
 - (a) Appropriate I.V. set-up, including appropriate supplies and fluids;
 - (b) Laryngoscope with spare batteries and spare bulbs;
 - (c) McGill forceps, endotracheal tubes, and stylet;
 - (d) Appropriate syringes;
 - (e) Tourniquet and tape;
 - (f) CPR board or chair suitable for CPR;
 - (g) Defibrillator equipment appropriate for the patient population being treated;
 - (h) Cricothyrotomy equipment; and,
 - (i) A Supraglottic Airway Device (SAD) or a Lyryngeal Mask Airway (LMA).
- (5) Medicinal Drugs: 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) A narcotic (e.g., Naloxone) and benzodiazepine (e.g., Flumazenil) antagonists, if these agents are used;
 - (c) An antihistamine (e.g., Diphenhydramine);
 - (d) A corticosteroid (e.g., Dexamethasone);
 - (e) Nitroglycerin;
 - (f) A bronchodilator (e.g., Albuterol inhaler);
 - (g) An antihypoglycemic agent (e.g., D50W IV solution);
 - (h) Amiodarone;
 - (i) A vasopressor (e.g., Ephedrine);
 - (j) An anticonvulsant (e.g., Valium or Versed);
 - (k) Antihypertensive (e.g., Labetalol);
 - (l) Anticholinergic (e.g, atropine);
 - (m) Antiemetic;
 - (n) A muscle relaxant (e.g., Succinylcholine);
 - (o) An appropriate antiarrhythmic medication (e.g., Lidocaine); and,
 - (p) Adenosine.
- (6) Emergency Protocols: 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) Seizures;

- (k) Syncope;
- (1) Phlebitis;
- (m) Intra-arterial injection;
- (n) Hyperventilation/Hypoventilation;
- (o) Cardiac arrest; and
- (p) Cardiac arrhythmias.

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) Records: The following records are required when conscious sedation is administered:
- (a) The patient's current written medical history, including known allergies and previous surgery;
- (b) Physical examination including airway evaluation and risk assessment (e.g., Mallampati Classification, Body Mass Index, and ASA Classification);
 - (c) Base line vital signs, including blood pressure, and pulse; and,
 - (d) A sedation or anesthesia record which shall include:
- 1. Continuous monitoring of vital signs, which are taken and recorded at a minimum of every 5 minute 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 (See Rule 64B5-14.006, F.A.C., for Adverse Incident Reporting requirements);
 - 5. Status of patient upon discharge, and to whom the patient is discharged; and
 - 6. Names of participating personnel.
- (8) Continuous Monitoring: The patient who is administered a drug(s) for conscious sedation must be continuously monitored intraoperatively by pulse oximetry, and capnograph to provide pulse rate, oxygen saturation of the blood, and ventilations (end-tidal carbon dioxide). A precordial/pretracheal stethoscope must be available to assist in the monitoring of the heart rate and ventilations.

Rulemaking 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, 3-9-14, 4-17-16.

64B5-14.010 Pediatric Conscious Sedation Requirements: Operatory; Recovery Room, Equipment, Medicinal Drugs, Emergency Protocols, Records, and Continuous Monitoring.

Pediatric Conscious Sedation 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) Operatory: 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 cardiopulmonary resuscitation (CPR) board of chair suitable for CPR:
 - (c) Be equipped with suction and backup suction equipment, also including suction catheters and tonsil suction.
- (2) Recovery Room: 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) Standard Equipment: 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) Oral and Nasal Airways of appropriate size for the pediatric patient;
 - (c) Blood pressure cuff and stethoscope or automated unit;
- (d) A pulse oximeter which provides continuous monitoring of pulse and rate of oxygen saturation of the blood shall be used during each procedure;

- (e) A Precordial stethoscope;
- (f) Capnograph;
- (g) Suction with backup suction, also including suction catheters and tonsil suction;
- (h) Thermometer;
- (i) A backup lighting system; and,
- (j) A scale for weighing pediatric patients.
- (4) Emergency Equipment: The following emergency equipment must be present, readily available and maintained in good working order:
 - (a) Appropriate I.V. set-up, including appropriate supplies and fluids;
 - (b) Laryngoscope with spare batteries and spare bulbs;
 - (c) McGill forceps, endotracheal tubes, and stylet;
 - (d) Suction with backup suction, also including suction catheters and tonsil suction;
 - (e) Appropriate syringes;
 - (f) Tourniquet and tape;
 - (g) CPR board or chair suitable for CPR;
 - (h) Defibrillator equipment appropriate for the patient population being treated; and,
 - (i) Cricothyrotomy equipment.
 - (j) A Supraglottic Airway Device (SAD) or a Lyryngeal Mask Airway (LMA).
- (5) Medicinal Drugs: 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) A narcotic (e.g., Naloxone) and benzodiazepine (e.g., Flumazenil) antagonists, if these agents are used;
 - (c) An antihistamine (e.g., Diphenhydramine HCl);
 - (d) A corticosteroid (e.g., Dexamethasone);
 - (e) Nitroglycerin;
 - (f) A bronchodilator (e.g., Albuterol inhaler);
 - (g) An antihypoglycemic agent (e.g., D50W IV solution);
 - (h) Amiodarone;
 - (i) A vasopressor (e.g., Ephedrine);
 - (i) An anticonvulsant (e.g., Valium or Versed);
 - (k) Antihypertensive (e.g., Labetalol);
 - (1) Anticholinergic (e.g., atropine);
 - (m) Antimetic;
 - (n) A muscle relaxant (e.g., Succinylcholine);
 - (o) An appropriate antiarrhythmic medication (e.g., Lidcaine); and
 - (p) Adenosine.
- (6) Emergency Protocols: 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;
 - (i) Seizures;
 - (k) Syncope;

- (1) Phlebitis;
- (m) Intra-arterial injection;
- (n) Hyperventilation/Hypoventilation;
- (o) Cardiac arrest; and
- (p) Cardiac arrhythmias.

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) Records: 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 examination including airway evaluation and risk assessment (e.g., Mallampati Classification, Body Mass Index, and ASA Classification);
 - (c) Base line vital signs, including pulse, percent hemoglobin oxygen saturation, and when possible, blood pressure; and,
 - (d) An anesthesia or sedation record which shall include:
 - 1. Periodic vital signs recorded a minimum of every 5 minute 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 (See Rule 64B5-14.0006, F.A.C., for Adverse Incident Reporting Requirements);
 - 5. Status of patient upon discharge, and to whom the patient is discharged; and,
 - 6. Names of participating personnel.
- (8) Continuous Monitoring: The patient who is administered a drug(s) for conscious sedation must be continuously monitored intra-operatively by pulse oximetry and capnograph to provide pulse rate, oxygen saturation of the blood, and ventilations (end-tidal carbon dioxide).

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