

**BOARD OF DENTISTRY  
ANESTHESIA COMMITTEE AGENDA  
VIA TELEPHONE CONFERENCE CALL  
JUNE 18, 2013  
6:00 P.M. EDT**

**Call In Number (888) 670-3525, Participant Pass Code: 5805370981**

- I. CALL TO ORDER**
- II. REVIEW OF MINUTES**  
August 16, 2012 ..... **001**
- III. ITEMS FOR TOPIC DISCUSSION**
  - A. Letter from Florida Dental Association – Request to Clarify by Rule Florida Statutes Relating to the Administration of Local Anesthesia .. 008**
  - B. Rule Draft - 64B5-14.003(3), FAC, Training, Education, Certification, and Requirements for Issuance of Permits..... 009**
  - C. Concerns from the Florida Academy of Pediatric Dentistry and responses prepared by Dr. Gesek..... 010**
  - D. Drafts for Rules 64B5-14.008, 14.009 and 14.010, FAC..... 014**
- IV. FOR YOUR INFORMATION**  
Chapter 64B5-14, FAC, Anesthesia ..... **022**
- V. OLD BUSINESS**
- VI. NEW BUSINESS**
- VII. ADJOURNMENT**

**\*To connect to the conference call, dial the following number: 888-670-3525 a minute or two prior to the start time of the meeting. You will then be prompted to enter a "participant pass code", which is 5805370981, followed by the # sign.**

**Please mute your line. Press \*6 to mute/unmute the line.**

## REVISED DRAFT (8/31/12)

BOARD OF DENTISTRY  
ANESTHESIA COMMITTEE MINUTES  
PEABODY HOTEL  
9801 INTERNATIONAL DRIVE  
ORLANDO, FL 32819  
(407) 352-4000  
AUGUST 16, 2012  
4:00 P.M. EDT

### CALL TO ORDER

The meeting was called to order at 4:00 p.m. by Dr. Gesek, Chair. Those present for all or part of the meeting included the following:

#### Committee members present:

Dan Gesek, D.M.D., Chair  
Carol Stevens, D.D.S.  
Carl Melzer, D.D.S.  
Wade Winker, D.D.S.  
Dr. Barry Setzer, Advisor  
Dr. Clive Rayner, Advisor

#### Staff present:

David Flynn, Board Counsel  
Sue Foster, Board Director  
Cindy Ritter, Program Administrator  
American Court Reporting – Ms. Green (407)  
896-1813

#### Interested Parties Completing Speaker Cards:

Dr. Nick White, Florida Academy of Pediatric  
Dentistry  
Dr. Carlos Bertot  
Dr. Hector Vila, Pediatric Dental Anesthesia  
Association  
Dr. Charles Llano  
Dr. Lee Sheldon  
Glenn Thomas, Florida Association of Nurse  
Anesthetists  
Dr. Larry Nissen, Florida Dental Association  
Dr. Barry Setzer, Advisor  
Dr. Robert Churney, Florida Association of  
Periodontists  
Dr. Christopher Johnson

### REVIEW OF JULY 23, 2012 MINUTES

The minutes of the July 23, 2012 meeting were reviewed and following review, the following action was taken by the committee:

Motion: by Dr. Winker to approve the minutes

Second: by Dr. Stevens

Vote: unanimous

### BOARD COUNSEL REPORT

#### Rules Report

Mr. Flynn presented his August 2012 Rules Report including the rule number and title, date published in the Florida Administrative Weekly, when adopted and the effective date for the following:

- 64B5-2.0135 Dental Hygiene Examination, effective August 8, 2012
- 64B5-2.014 Licensure Requirements from Accredited Schools, effective August 5, 2012
- 64B5-14.001 Definitions, effective August 5, 2012
- 64B5-14.002 Prohibitions, effective August 5, 2012

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- 64B5-14.003 Training and Education, effective August 16, 2012
- 64B5-14.0032 Use of Physician Anesthesiologist, effective August 20, 2012
- 64B5-14.006 Reporting Adverse Occurrences, effective August 5, 2012
- 64B5-16.006 Remediable Tasks Delegable to a Dental Hygienist, effective August 5, 2012

### Annual Regulatory Plan Regarding Anesthesia

Mr. Flynn presented the annual regulatory plan for 2012 -2013 which is required by each state agency pursuant to s. 120.74(3), F.S. and in Compliance with Executive Order of the Governor.

### ITEMS FOR TOPIC DISCUSSION

#### **Pediatric Conscious Sedation Permit Versus Conscious Sedation Permit, Changes to Rule 64B4-14.003, FAC**

Dr. Gesek stated that he wanted to hold this discussion concerning allowing anesthesiologists to administer sedation in pediatric dental offices as there was confusion concerning the regulations. It was noted that several pediatric dentists hold conscious sedation permits.

Motion: by Dr. Winker to move pediatric dentists to pediatric conscious sedation permit  
Second: by Dr. Stevens  
Vote: unanimous

#### **Necessity of Allowing Pediatric Dentists with Conscious Sedation Permits to be Granted a Pediatric Conscious Sedation Permit**

Effective August 20, 2012, Rule 64B5-14.0032, FAC, will become effective which prohibits conscious sedation permit holders from using the services of a physician anesthesiologist in the dental office. Discussion will be held later in the meeting to address changes to this language. Mr. Flynn presented language to allow a grandfather period for pediatric dentists who hold conscious sedation permits to be moved to a pediatric conscious sedation permit at the next renewal cycle. This change is necessary so that the pediatric dentists may continue to allow a physician anesthesiologist to administer sedation to their patients in the dental office.

Proposed language:

#### **64B5-14.0032 Use of Physician Anesthesiologist.**

- (1) No change.
- (a) No change.
- (b) No change.
- (2) Pediatric Conscious Sedation Permit Holders: Pursuant to this rule section and notwithstanding any other rule provisions to the contrary, a pediatric dentist, as recognized by the American Dental Association, who has an active pediatric conscious sedation permit may perform dental treatment on pediatric patients in their respective outpatient dental office under any level of sedation when the anesthesia is performed and administered by a physician anesthesiologist. Until the end of the next biennial renewal cycle, following the effective date of this rule, pediatric dentists who hold a pediatric sedation permit or a conscious sedation permit are deemed to have met the permit requirement of this subsection. Pediatric dentists who hold a conscious sedation permit only, may transfer their conscious sedation permit to a pediatric conscious sedation permit for no additional costs beyond the

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biennial renewal fee at the next biennial renewal cycle following the effective date of this rule. All of the following conditions shall be met:

- (a) –(e) No change.
- (3) – (4) No change.

The board staff will notify conscious permit holders of the procedure to change their permit to a pediatric conscious sedation permit.

Motion: by Dr. Stevens to accept the proposed language  
Second: by Dr. Winker  
Vote: unanimous

### **Dental General Anesthesia Permit Holders and Use by Other Dental Sedation Permit Holders (Itinerant Anesthesia)**

Deep Sedation, General Anesthesia permit holders - Dr. Gesek asked the committee to consider allowing General Anesthesia permit holders to go into a dental office of a permit holder to provide anesthesia services, as well as permit holders going into the general anesthesia permit holder's office.

There was a question regarding malpractice insurance. Mr. Flynn advised that each dental licensee should look into the extent of their patient coverage within their dental office and anesthesiologists should check with their attorney.

Motion: by Dr. Gesek to allow anesthesia services in an itinerant fashion to be provided by a licensee who has a general anesthesia permit in an anesthesia permitted dental office where all requirements have been met or in the general anesthesia permit holder's office  
Second: by Dr. Melzer  
Vote: unanimous

### **Non Permit Holders - Team Approach for Specialists**

Dr. Gesek asked for discussion on this issue. The concern was that the office may not be equipped and there would be no authority to inspect the office. Dr. Vila, Dr. Llano and Dr. Pierce also spoke against allowing this. After discussion the committee took the following action:

Motion: by Dr. Gesek that a non-permitted dentist cannot bring an anesthesia provider into the office to provide anesthesia services.  
Second: by Dr. Stevens  
Vote: unanimous

### **Allowing Specialists Without Sedation Permits to Perform Dental Work While Patient Sedated by Other Dental Permit Holder**

Motion: by Dr. Gesek that the committee not promulgate rules to allow specialists and/or other dentists without a sedation permit to perform dental treatment while patient sedated in another office by another anesthesia entity  
Second: by Dr. Stevens  
Motion dies

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Discussion was held regarding whether sedation permit holders must be present until patient is discharged and whether they would require additional airway management training. Dr. Thomas asked that the permit holder be totally responsible for the patient, not just present in the facility.

Dr. Russin expressed concern that the non-sedation permitted dentist is experienced in performing dentistry on non-sedated patients, however, there are tasks that affect the airway that may be performed that can cause a danger to the sedated patient such as rinsing the mouth, etc.

Motion: by Dr. Winker to allow Florida licensed dentists without anesthesia permits to perform dental treatment while the patient is sedated by an anesthesia permit holder in the anesthesia permit holder's office, with the anesthesia permit holder present during the treatment until discharge

Second: by Dr. Melzer

Vote: motion passes with Dr. Gesek opposed

Mr. Flynn will review patient record requirements.

The committee discussed the possibility of requiring dentists treating dental patients who are sedated beyond minimal sedation to complete airway management training in the form of Advanced Cardiac Life Support (ACLS) or Pediatric Advanced Life Support (PALS). Mr. Flynn advised that the board had rulemaking authority to require dentists to have some airway management training if they were going to be involved in treating sedated patients. Concerning enforcement, it was suggested that the sedation permit holder should ask the non-permitted dentist if their ACLS or PALS training is up to date before agreeing to perform the sedation.

Dr. Bertot asked the board to consider the costs and access to care issues when a pediatric dentist needs the treatment provided by a specialist when that additional treatment cannot be provided if the licensed dentist has not completed an ACLS or PALS course.

Dr. Melzer stated he is aware of a good 8 hour airway management course and thought the board had previously agreed to require all sedation permit holders to complete an airway management course as part of their continuing education hours. Dr. Rayner indicated the Florida Dental Society of Anesthesiology is preparing to offer a variety of airway management courses in the near future.

Dr. Gesek asked the committee to consider airway management training in the future and not pursue ACLS or PALS training.

### **Prohibition of Rule 64B5-14.005, FAC**

This was included for information only.

### **Role of Nurse Anesthetists in the Dental Outpatient Office**

**References - s. 466.002(2), F.S., s. 466.003(8), F.S. regarding supervision and Rule 64B5-14.005, FAC**

#### **1) Dentists Who Do Not Hold an Anesthesia Permit**

Dentists cannot use the services of a CRNA to sedate patients if the dentist does not hold an anesthesia permit.

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Motion: by Dr. Melzer that CRNA's are not permitted to provide anesthesia in the office of a dental licensee who does not hold an anesthesia permit  
Second: by Dr. Stevens  
Vote: unanimous

Mr. Flynn briefed the board about a case that was heard in the 1980s and he stated that s. 466.002(2), F.S., exempts the following from operation of Chapter – a qualified anesthetist giving an anesthetic for a dental operation under the direct supervision of a licensed dentist. The definition of direct supervision as stated in chapter 466.003, F.S., prevails. The dentist must be competent to approve procedures to be performed by CRNA, meaning the level of sedation cannot be general when the dentist is a conscious sedation permit holder.

- 2) conscious sedation permit holders
- 3) pediatric conscious sedation permit holder
- 4) deep/general sedation permit holder

Motion: by Dr. Stevens to allow CRNA to administer anesthesia in the dental office of an anesthesia permit holder to the level of the dentist's permit  
Second: by Dr. Winker  
Vote: unanimous

### **Anesthesiologists**

Dr. Vila asked the board to consider rulemaking to allow anesthesia assistants to perform duties under the supervision of an anesthesiologist. Mr. Flynn advised this was not an issue as the anesthesiologist would be responsible for the equipment and personnel he brings with him.

### **Conscious Sedation Permit Holders**

Rule 64B5-14.0032, FAC, effective August 20, 2012, prohibits conscious sedation permit holders from bringing in physician anesthesiologists. Dr. Gesek stated the rule should be amended to allow conscious sedation permit holders to bring in physician anesthesiologists as well and that the office should be equipped and inspected to the level of the anesthesia provided. Mr. Flynn will prepare the amended language for review. The language should include treatment of special needs patients for pediatric conscious sedation and conscious sedation permit holders.

Dr. Stevens stated that many conscious sedation permit holders also use certified registered nurse anesthetists (CRNA) however all of the discussion seems to address physician anesthesiologists only. Mr. Flynn indicated he has included provision to develop a rule relating to the use of a CRNA.

The committee discussed the equipment and whether the office should be equipped or if the physician anesthesiologist should bring in the equipment. The jurisdiction the board has is to regulate the dentist and in the interest of safety, to ensure that dentists maintain their office to the level of sedation administered, regardless of whether the anesthesiologist brings in equipment.

Dr. Thomas suggested that permit holders be allowed to submit an affidavit that their office is properly equipped and then inspections would occur on a random basis.

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Ms. Gainey asked for an explanation of the regulation of the physician anesthesiologists. Dr. Vila stated the Board of Medicine regulates and performs office inspections of the permitted office while the physician anesthesiologist is present with his equipment. Current rule is an effective model, coordinating inspections when highest form of anesthesia is being delivered.

Motion: by Dr. Melzer to allow anesthesiologists to administer sedation in the conscious sedation permit holder's office

Second: by Dr. Gesek

Vote: unanimous

Mr. Flynn stated patients are scheduled to be treated in a dental office with a conscious sedation permit. This poses a problem based on rule change to become effective Monday, August 20, 2012. Mr. Flynn asked that the committee allow conscious sedation permit holders to bring in the physician anesthesiologists because patients have been scheduled and he encouraged all dentists to read the anesthesia chapter, which already requires offices to be equipped to the level of general anesthesia when bringing in physician anesthesiologists. Mr. Flynn asked for an allowance of 180 days to educate practitioners, and not issue citations on this rule while he promulgates the change.

Motion: by Dr. Gesek to allow a 180 day grace period to allow time for rule promulgation concerning conscious sedation permit holders using physician anesthesiologists in their office

Second: by Dr. Winker

Vote: unanimous

There was also discussion of levels of anesthesia. When a physician anesthesiologist is present, the anesthesia should be administered to the level required to treat the patient as determined by the physician anesthesiologist.

### FOR YOUR INFORMATION

#### **Correspondence regarding proposed rule 64B5-14.0032, Use of Physician Anesthesiologists**

Correspondence was received from the following: Hector Vila, Jr., M.D., Dennis Stone, M.D., Gary Myers, D.M.D., President, Florida Academy of Pediatric Dentistry, J. Tim Russin, D.D.S., John Cherry, D.M.D., Rick Kernagis, Joseph C. Spoto, III, D.M.D., Pediatric Dental Anesthesia Associates, Barry Setzer, D.D.S., Committee Advisor, Victor Spiro, D.D.S., Clive Rayner, D.M.D., Director & Past President, Florida Dental Society of Anesthesiology, Florida Association of Nurse Anesthetists, Florida Society of Oral and Maxillofacial Surgeons, James Tom, D.D.S., University of Southern California, Ostrow School of Dentistry, Michael Mashni, D.D.S., President, American Society of Dentist Anesthesiologists, Letters from Family Members of Special Needs Patients

The following documents were provided for reference - Current Rules - Chapter 64B5-14, FAC, Anesthesia, Rule Drafts Approved at May 18, 2012 Board of Dentistry meeting, 64B5-14.003 Training, Education, Certification, and Requirements For Issuance of Permits, 64B5-14.0032 Use of Physician Anesthesiologists, Chapter 466.002, F.S., Persons Exempt from Operation of Chapter, Chapter 466.003, F.S., Definition of Direct Supervision, Chapter 464.012, F.S., Certification of Advanced Registered Nurse Practitioners; fees, Chapter 64B9-4, FAC, Administrative Policies Pertaining to Certification of Advanced Registered Nurse Practitioners,

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Chapter 64B8-9.009, FAC, Standard of Care for Office Surgery, Chapter 59A-5.019, FAC, Quality Assessment and Improvement, Chapter 64B8-9.0091, FAC, Requirement for Physician Office Registration; Inspection or Accreditation, Inspection Forms - General Anesthesia, Conscious Sedation, Pediatric Conscious Sedation, Application Forms - General Anesthesia, Conscious Sedation, Pediatric Conscious Sedation

### **OLD BUSINESS**

None

### **NEW BUSINESS**

None

### **ADJOURNMENT**

The meeting was adjourned at 7:00 p.m.



HEADQUARTERS  
 1111 E. Tennessee St.  
 Tallahassee, FL 32308-6914  
 Phone: (800) 877-9922 • (850) 681-3629  
 Fax: (850) 561-0504  
 E-mail: fda@floridadental.org

GOVERNMENTAL AFFAIRS OFFICE  
 118 E. Jefferson St.  
 Tallahassee, FL 32301  
 Phone: (850) 224-1089  
 Fax: (850) 224-7058  
 E-mail: gao@floridadental.org

FLORIDA DENTAL ASSOCIATION

FOUNDED 1884

April 19, 2013

Florida Board of Dentistry  
 4052 Bald Cypress Way, Bin # C08  
 Tallahassee, FL 32399

Florida Board of Dentistry Members:

The Florida Dental Association (FDA) is asking the Board to clarify by rule Florida Statutes relating to the administration of local anesthesia by an anesthesia certified hygienist (s. 466.017(5), F.S.).

There appears to be some misunderstanding by Florida dentists and hygienists as to the definition of a sedated patient. The statute is emphatic that a hygienist may administer local anesthesia to ONLY non-sedated patients. The FDA strongly feels that both nitrous-oxide inhalation analgesia and anti-anxiety medications (anxiolysis) are forms of sedation. Therefore, patients under the effects of these two modalities can not be administered local anesthesia by a hygienist.

Proposed Rule 64B5-14.002(9) Prohibitions

- A hygienist certified by the board to administer local anesthesia shall not administer local anesthesia to patients sedated by nitrous-oxide analgesia or anti-anxiety medications (anxiolysis). This includes those patients prescribed anti-anxiety medications by a physician or the treating dentist.

Respectfully Submitted,

Kim Jernigan, D.M.D.  
 FDA President

cc: FDA Board of Trustees  
 FDA Governmental Affairs Committee  
 Dan Buker, FDA Executive Director  
 Joe Anne Hart, Director of Governmental Affairs

Received by email  
 4-19-13 @

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

(1) General Anesthesia Permit.

(a) through (e) No Change

(2) Conscious Sedation Permit.

(a) through (f) No Change

(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, which must include four (4) hours of airway management. Clinical training shall include personal administration management of sedation 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 a total of three (3) hours of clinical training was dedicated to hands-on simulated 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 person ~~man~~ CPR, two person ~~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) through (d) No Change.

(4) Through (5) No. Change.

*Rulemaking Authority 466.004(4), 466.017(3), (6) FS. Law Implemented 466.017(3), (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).*

Ritter, Cynthia

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**From:** Barry Setzer [barry.setzer@me.com]  
**Sent:** Thursday, May 02, 2013 2:27 PM  
**To:** Dan Gesek; Ritter, Cynthia  
**Cc:** Nick White; Gary Myers; Robert Eliot Primosch  
**Subject:** New Anesthesia Rules

**Attachments:** FAPD Comments on new sedation rules-1.docx



FAPD Comments on  
new sedation ...

Dear Dan,  
I have been asked by the leadership of the Florida Academy of Pediatric Dentistry (FAPD) to have you, Dr. Melzer and the BOD clarify several questions that we have about the new Anesthesia Rules. Would you please review our comments and questions and help us answer our member's questions.

Would you please forward to Dr. Melzer as I don't have his e-mail address.

Thank you very much for your help.

Sincerely,

Barry Setzer  
Pediatric Dentist  
Consultant on the BOD Anesthesia Committee

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BEGIN-ANTISPAM-VOTING-LINKS

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Teach CanIt if this mail (ID 0eJv6r44S) is spam:  
Spam: <https://antispam.doh.ad.state.fl.us/canit/b.php?i=0eJv6r44S&m=4bda3f37e52c&t=20130502&c=s>  
Not spam: <https://antispam.doh.ad.state.fl.us/canit/b.php?i=0eJv6r44S&m=4bda3f37e52c&t=20130502&c=n>  
Forget vote: <https://antispam.doh.ad.state.fl.us/canit/b.php?i=0eJv6r44S&m=4bda3f37e52c&t=20130502&c=f>

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END-ANTISPAM-VOTING-LINKS

The following are comments regarding the recent Florida BOD sedation rule changes that may need clarification and direction from the BOD.

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

**(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.*

~~comment: Can only pediatric dentists with pediatric conscious sedation permits use itinerate anesthesia services for children? What happens to any other non-pediatric dentist permit holders who have pediatric conscious sedation permits, if they exist?~~

*(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.*

**(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, and (should this be or) the dentist supplies an inspection of the equipment, which a licensed health care risk manager performed.*

*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.*

~~comment: What is the procedure for this permit transfer process? Will all current pediatric sedation permit holders be notified in writing from the BOD describing the process? Will any permit holder not changing their permit be allowed only to perform sedations on adult (>18yo) patients when using itinerant anesthesia according to the following definition below?~~

**(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.*

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

~~Comment: There is no documentation required that shows conscious sedation permit applicants have training similar to that required for pediatric conscious sedation permit holders as stated below.~~

(3) Pediatric Conscious Sedation Permit.

Has received formal training in the use of pediatric conscious sedation

~~The training requirements below do not specify training in pediatric sedation. Was the intention to permit applicants demonstrating training in IV sedation where patients are adults?~~

(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.

~~Can a dentist be granted both types of conscious sedation permits?~~

~~Since dentists permitted to administer conscious sedation may administer pediatric conscious sedation, what is the rationale for changing permits at the next renewal cycle?~~

(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

~~Comment: Should the definition be changed to state: "A pediatric dentist, as recognized by the American Dental Association."~~

Ritter, Cynthia

From: DS Gesek [dsgesek@comcast.net]  
Sent: Sunday, May 05, 2013 5:38 PM  
To: david\_flynn@doh.state.fl.us; Foster, Sue; Dan Gesek; Ritter, Cynthia; Barry Setzer  
Cc: Robert Eliot Primosch; Gary Myers; Nick White  
Subject: Re: New Anesthesia Rules

Importance: High

Hello Barry

I will answer the questions posed with the caveat that the staff or board attorney can correct me if I misinterpret your questions.

1. Anyone with permit can bring a qualified anesthesia provider into the office to perform anesthesia and this includes children
2. I am unaware of any non pediatric dentists who hold pediatric conscious sedation permits. One of the criteria is that the dentist needs to be a pediatric dentist by training.
3. The answer is and not or
4. All pediatric dentists with conscious permits will be changed to Pediatric permits at the next renewal
5. All permit holders that are pediatric dentists will be required to change their permit to a pediatric conscious sedation permit. None will be allowed to hold a conscious sedation permit.
6. I read the rule that if there is a patient in your practice who requires anesthesia for a procedure, you could have someone do the anesthesia for you or you could perform anesthesia to the level of your permit.
7. A dentist with any permit will be able to have a medical anesthesiologist come in to the office and perform procedures on that patient as long as competent and properly trained via standard of care.
8. Conscious sedation permit holders can perform anesthesia to the level of their permit. I am unaware of any restrictions prior to or after the majority of changes were made
9. There is no mention of specific training either way
10. no dentist can have two types of permits.
11. Pediatric dentists have their own special permit class based on their training which was initiated after they received their initial permit. We are converting all to pediatric permits at this time for completeness.
12. I have no issue either way. The intent of the BOD is that to have a pediatric permit one must be a trained pediatric dentist. that is the only way to get this type of permit.

Hope this helps

See you all soon

Dan

----- Original Message -----

From: "Barry Setzer" <barry.setzer@me.com>  
To: "Dan Gesek" <dsgesek@comcast.net>; <Cynthia\_Ritter@doh.state.fl.us>  
Cc: "Nick White" <drnickwhite@netscape.net>; "Gary Myers" <gcrashm@gmail.com>; "Robert Eliot Primosch" <rprimosch@dental.ufl.edu>  
Sent: Thursday, May 02, 2013 2:27 PM  
Subject: New Anesthesia Rules

Dear Dan,

I have been asked by the leadership of the Florida Academy of Pediatric Dentistry (FAPD) to have you, Dr. Melzer and the BOD clarify several questions that we have about the new Anesthesia Rules. Would you please review our comments and questions and help us answer our member's questions.

Would you please forward to Dr. Melzer as I don't have his e-mail address.

Ritter, Cynthia

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**From:** Carol W. Stevens [gumdoc1@comcast.net]  
**Sent:** Thursday, February 07, 2013 1:07 PM  
**To:** Ritter, Cynthia  
**Cc:** Carol Stevens  
**Subject:** Anesthesia Rule  
**Attachments:** 64B5-14.008 Requirements for General Anesthesia or Deep Sedation.doc

Dear Cindy,

I have attached the Word Document which edits 64B5-14.008, 64B5-14.009, and 64B5-14.010.

My chief concern is Paragraph (4) which lists the "Emergency Equipment which must be present". This paragraph in the current writing of the rule is incomplete. The document attached has modified the rule for consistency and standardization.

Thank you for forwarding this to the appropriate Board members.

Sincerely, Carol Stevens

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Spam

Not spam

Forget previous vote

#### 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 equipment, positive pressure oxygen and sufficient light to provide emergency treatment. The recovery room shall also be of adequate size and design to allow emergency access and management. The recovery room shall be situated to allow the patient to be observed by the dentist or an office team member at all times.
- (3) The following equipment must be readily available to the operatory and recovery room and maintained in good working order:
  - (a) A positive pressure oxygen delivery system and backup system, including full face mask for adults and for pediatric patients, if pediatric patients are treated;
  - (b) Oral and nasal airways of various sizes;
  - (c) Blood pressure cuff and stethoscope; and
  - (d) Cardioscope – electrocardiograph (EKG) machine, pulse oximeter, and end tidal carbon dioxide, to provide continuous monitoring of heart rhythm and rate, oxygen saturation of the blood, and ventilation. This equipment shall be used for each procedure.
  - (e) Precordial stethoscope;
  - (f) Suction with backup suction, **also including suction catheters and tonsil suction;**
  - (g) Thermometer; and
  - (h) **A backup lighting system. (included in Conscious Sedation; not General Anesthesia)**
- (4) The following emergency equipment must be present, **readily available and maintained in good working order:**
  - (a) Appropriate I.V. set-up, including appropriate hardware and fluids;
  - (b) Laryngoscope with current batteries;
  - (c) McGill forceps and endotracheal tubes;
  - (d) Appropriate syringes;
  - (e) Tourniquet and tape;
  - (f) CPR board or chair suitable for CPR;
  - (g) Stylet;
  - (h) Spare bulbs and batteries;
  - (i) Defibrillator equipment appropriate for the patient population being treated; and
  - (j) Cricothyrotomy equipment.
- (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) A narcotic and benzodiazepine antagonist;
  - (e) An antihistamine;
  - (f) A corticosteroid;
  - (g) Nitroglycerine;
  - (h) A bronchodilator;
  - (i) An antihypoglycemic agent;
  - (j) Amiodarone;
  - (k) A vasopressor;
  - (l) An anticonvulsant;

- (m) Antihypertensive; (included in Conscious Sedation; not in General Anesthesia);
- (n) Anticholinergic; (included in Conscious Sedation; not in General Anesthesia);
- (o) Antiemetic;
- (p) A vasodilator; (not included in Conscious Sedation)
- (q) A muscle relaxant; (not included in Conscious Sedation)
- (r) An appropriate antiarrhythmic medication; (not included in Conscious Sedation)
- (s) Adenosine; (not included in Conscious Sedation) and
- (t) Dantrolene, when used with volatile gases.

\*\*\*\*\*January 2011 Rule 64B5 included Sodium Bicarbonate .... How did this get changed?

- (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;
  - (o) Hyperventilation/Hypoventilation;
  - (p) Cardiac arrest; and (Included in Conscious Sedation - but not General Anesthesia.)**
  - (q) Cardiac arrhythmias. (not included in General Anesthesia & Conscious Sedation)**

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) Physical and risk assessment (e.g., 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 taken at appropriate intervals during the procedure;
    2. Drugs administered during the procedure, including route of administration, dosage, time and sequence of administration;
    3. Duration of the procedure;
    4. Documentation of complications or morbidity;
    5. Status of patient upon discharge, and to whom the patient is discharged;
    6. Names of participating personnel. *(The names of the participating personnel should be "included in the anesthesia record".)*

#### 64B5-14.009 Requirements for Conscious Sedation

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) 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 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;
  - (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 or capnometer;
  - (f) **Suction with backup suction, also including suction catheters and tonsil suction;**
  - (g) Thermometer; and
  - (h) A backup lighting system; **(included in Conscious Sedation; not General Anesthesia)**
- (4) The following emergency equipment must be present, **readily available and maintained in good working order:**
  - (a) Appropriate I.V. set-up, including appropriate hardware and fluids;
  - (b) **Laryngoscope with current batteries;**
  - (c) **McGill forceps and endotracheal tubes;**
  - (d) Appropriate syringes;
  - (e) Tourniquet and tape;
  - (f) **CPR board or chair suitable for CPR;**
  - (g) **Stylet;**
  - (h) **Spare bulbs and batteries;**
  - (i) Defibrillator equipment appropriate for the patient population being treated; and
  - (j) **Cricothyrotomy equipment.**
- (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) A narcotic and benzodiazepine antagonist;
- (e) An antihistamine;
- (f) A corticosteroid;
- (g) Nitroglycerine;
- (h) A bronchodilator;
- (i) An antihypoglycemic agent;
- (j) Amiodarone;
- (k) A vasopressor;
- (l) An anticonvulsant;
- (m) Antihypertensive; (not included in General Anesthesia)**
- (n) Anticholinergic; (not included in General Anesthesia)**
- (o) Antimetic;
- (p) A vasodilator; (not included in Conscious Sedation)**
- (q) A muscle relaxant; (not included in Conscious Sedation)**
- (r) An appropriate antiarrhythmic medication; (not included in Conscious Sedation)**
- (s) Adenosine. (not included in Conscious Sedation)**

(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;
- (o) Hyperventilation/Hypoventilation;
- (p) Cardiac arrest; and (not included in General Anesthesia)**
- (q) Cardiac arrhythmias. (not included in General Anesthesia & Conscious Sedation)**

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;
- (b) Physical and risk assessment (e.g., 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 taken at appropriate intervals during the procedure;

2. Drugs administered during the procedure, including route of administration, dosage, time and sequence of administration;
3. Duration of the procedure;
4. Documentation of complications or morbidity;
5. Status of patient upon discharge, and to whom the patient is discharged;
6. Names of participating personnel. *(The names of the participating personnel should be "included in the anesthesia record")*

**(e) The patient who is administered a drug(s) for conscious sedation must be continuously monitored intraoperatively by pulse oximetry. A precordial/pretracheal stethoscope must be available to assist in the monitoring of heart and respiratory rate. A sphygmomanometer shall be immediately available.**

#### **64B5-14.010 Requirements for Pediatric Conscious Sedation**

Pediatric Conscious Sedation Permit applicants and permit holders shall comply with the following requirements at each location where anesthesia procedures are preformed. 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 cardiopulmonary resuscitation (CPR) board or chair 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 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) 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) **Suction with backup suction, also including suction catheters and tonsil suction;**
  - (f) Thermometer;
  - (g) A backup lighting system; and **(included in Conscious Sedation; not General Anesthesia)**
  - (h) A scale for weighing pediatric patients.
- (4) The following emergency equipment must be present, **readily available and maintained in good working order:**
  - (d) Appropriate I.V. set-up, including appropriate hardware and fluids;
  - (e) **Laryngoscope with current batteries;**
  - (f) **McGill forceps and endotracheal tubes;**
  - (g) **Suction with backup suction, also including suction catheters and tonsil suction;**
  - (h) Appropriate syringes;

- (i) Tourniquet and tape;
- (j) CPR board or chair suitable for CPR;
- (k) Styler;
- (l) Spare bulbs and batteries;
- (m) Defibrillator equipment appropriate for the patient population being treated; and
- (n) Cricothyrotomy equipment.

(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) A narcotic (e.g., Naloxone) and benzodiazepine (e.g., Flumazenil) antagonists, if these agents are used;
- (e) An antihistamine (e.g., Diphenhydramine HCl);
- (f) A corticosteroid (e.g., Hydrocortisone);
- (g) Nitroglycerine;
- (h) A bronchodilator (e.g., Albuterol inhaler);
- (i) An antihypoglycemic agent (e.g., 50% glucose);
- (j) Amiodarone;
- (k) A vasopressor;
- (l) An anticonvulsant;
- (m) **Antihypertensive; (not included in General Anesthesia)**
- (n) **Anticholinergic; and (not included in General Anesthesia)**
- (o) Antimetic.

????????????

- (p) A vasodilator; **(not included in Conscious Sedation or Pediatric Sedation)**
- (q) A muscle relaxant; **(not included in Conscious Sedation or Pediatric Sedation)**
- (r) An appropriate antiarrhythmic medication; **(not included in Conscious Sedation or Pediatric)**
- (s) Adenosine. **(not included in Conscious Sedation or Pediatric Sedation)**

(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;
- (o) Hyperventilation/Hypoventilation;
- (p) **Cardiac arrest; and (not included in General Anesthesia)**

**(q) Cardiac arrhythmias. (not included in General Anesthesia & Conscious Sedation)**

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;

5. Status of patient upon discharge, and to whom the patient is discharged;

6. **Names of participating personnel.** *(The names of the participating personnel should be "included in the anesthesia record".)*

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

Interoperatively ?????? Should that be "intra" ? What is "inter" operative??

## CHAPTER 64B5-14 ANESTHESIA

64B5-14.001	Definitions
64B5-14.002	Prohibitions
64B5-14.003	Training, Education, Certification, and Requirements for Issuance of Permits
64B5-14.0032	Itinerate/Mobile Anesthesia – Physician Anesthesiologist
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64B5-14.0036	Treatment of Sedated Patients by Dentists Without an Anesthesia Permit
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64B5-14.007	Inspection of Facilities and Demonstration of Sedation Technique
64B5-14.008	Requirements for General Anesthesia or Deep Sedation
64B5-14.009	Conscious 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.

(4) Conscious sedation – A depressed level of consciousness produced by the administration of pharmacologic substances, that retains the patient's ability to independently and continuously maintain an airway and respond appropriately to physical stimulation and verbal command. This modality includes administration of medications via all parenteral routes, that is, intravenous, intramuscular, subcutaneous, submucosal, or inhalation, as well as enteral routes, that is oral, rectal, or transmucosal. The drugs, and techniques used should carry a margin of safety wide enough to render unintended loss of consciousness unlikely.

(5) Pediatric Conscious Sedation – A depressed level of consciousness produced by the administration of pharmacologic substances, that retains a child patient's ability to independently and continuously maintain an airway and respond appropriately to physical stimulation or verbal command. This modality includes administration of medication via all parenteral routes; that is intravenous, intramuscular, subcutaneous, submucosal, or inhalation, and all enteral routes; that is oral, rectal, or transmucosal. The drugs, doses, and techniques used should carry a margin of safety wide enough to render unintended loss of consciousness unlikely. For the purposes of this chapter, a child is defined as an individual under 18 years of age, or any person who has special needs, which means having a physical or mental impairment that substantially limits one or more major life activities.

(6) Nitrous-oxide inhalation analgesia – The administration by inhalation of a combination of nitrous-oxide and oxygen producing an altered level of consciousness that retains the patient's ability to independently and continuously maintain an airway and respond appropriately to physical stimulation or verbal command.

(7) Local anesthesia – The loss of sensation of pain in a specific area of the body, generally produced by a topically applied agent or injected agent without causing the loss of consciousness.

(8) Analgesia – Absence of sensibility of pain, designating particularly the relief of pain without loss of consciousness.

(9) Office team approach – A methodology employed by a dentist in the administration of general anesthesia, deep sedation, conscious sedation, and pediatric sedation whereby the dentist uses one or more qualified assistants/dental hygienists who, working under the direct supervision of the dentist, assist the dentist, and assist in emergency care of the patient.

(10) Minimal Sedation (anxiolysis) – The perioperative use of medication to relieve anxiety before or during a dental procedure

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

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

(12) Physician anesthesiologist – Any physician licensed pursuant to 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 administer 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, or ketamine.

*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.

#### **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 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; or

(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. Clinical training shall include personal administration for at least twenty patients including supervised training, clinical experience and demonstrated competence in airway management of the compromised airway.

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

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

(e) A dentist utilizing conscious sedation and his assistant/dental hygienist personnel shall be certified in an American Heart Association or American Red Cross or equivalent agency sponsored cardiopulmonary resuscitation course at the basic life support level to include one man CPR, two man CPR, infant resuscitation, and obstructed airway with a periodic update not to exceed two

years. Starting with the licensure biennium commencing on March of 2000, a dentist and all assistant/dental hygienist personnel shall also be trained in the use of either an Automated External Defibrillator or a defibrillator and electrocardiograph as part of their cardiopulmonary resuscitation course at the basic life support level. In addition to CPR certification, a dentist utilizing conscious sedation must be currently trained in ACLS (Advanced Cardiac Life Support) or ATLS (Advanced Trauma Life Support).

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

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

(3) Pediatric Conscious Sedation Permit.

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

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

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

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

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

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

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

(4) Nitrous-Oxide Inhalation Analgesia.

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

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

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

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

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

certification, a dentist utilizing pediatric conscious sedation must be currently trained in ACLS (Advanced Cardiac Life Support), ATLS (Advanced Trauma Life Support), or PALS (Pediatric Advanced Life Support).

(c) A dentist who regularly and routinely utilized nitrous-oxide inhalation analgesia on an outpatient basis in a competent and efficient manner for the three-year period preceding January 1, 1986, but has not had the benefit of formal training outlined in 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), (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).*

#### **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, and 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 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.*

**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. After the initial airway management course, the treating dentist shall continue to repeat a minimum of four hours in airway management every four years. The continuing education courses taken shall be credited toward the mandatory thirty hours of continuing education required for licensure renewal.

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

**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) 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), 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.*

#### **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.**

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

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

(a) Be of adequate size and design to permit physical access of emergency equipment and personnel and to permit effective emergency management;

(b) Be equipped with a chair or table adequate for emergency treatment, including a chair or cardiopulmonary resuscitation (CPR) board suitable for CPR;

(c) Be equipped with suction and backup suction equipment, also including suction catheters and tonsil suction.

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

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

(a) A positive pressure oxygen delivery system and backup system, including full face mask for adults and for pediatric patients, if pediatric patients are treated;

(b) Oral and nasal airways of various sizes;  
(c) Blood pressure cuff and stethoscope; and  
(d) Cardioscope – electrocardiograph (EKG) machine, pulse oximeter, and end tidal carbon dioxide, to provide continuous monitoring of heart rhythm and rate, oxygen saturation of the blood, and ventilation. This equipment shall be used for each procedure;

(e) Defibrillator equipment appropriate for the patient population being treated; and  
(f) Thermometer.

(4) The following emergency equipment must be present:

(a) Appropriate I.V. set-up, including appropriate hardware and fluids;

(b) Laryngoscope with current batteries;

(c) McGill forceps and endotracheal tubes;

(d) Suction with backup suction;

(e) Appropriate syringes;

(f) Tourniquet and tape;

(g) CPR board or chair suitable for CPR;

(h) Stylet;

(i) Spare bulbs and batteries;

(j) Cricothyrotomy equipment;

(k) Precordial stethoscope or capnometer; and

(l) Blood pressure cuff and stethoscope.

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

(a) Epinephrine;

(b) Atropine;

(c) Lidocaine;

(d) Amiodarone;

(e) An antihistamine;

(f) A vasodilator;

(g) A bronchodilator;

(h) An antihypoglycemic agent;

(i) A vasopressor;

(j) A corticosteroid;

(k) An anticonvulsant;

(l) A muscle relaxant;

(m) A narcotic and benzodiazepine antagonist;

(n) An appropriate antiarrhythmic medication;

(o) Nitroglycerine;

(p) Antiemetic;

(q) Adenosine; and

(r) Dantrolene, when used with volatile gases.

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

(a) Laryngospasm;

(b) Bronchospasm;

(c) Emesis and aspiration;

(d) Airway blockage by foreign body;

(e) Angina pectoris;

(f) Myocardial infarction;

(g) Hypertension/Hypotension;

- (h) Hypertensive crisis;
- (i) Allergic and toxicity reactions;
- (j) Convulsions;
- (k) Seizures;
- (l) Syncope;
- (m) Phlebitis;
- (n) Intra-arterial injection; and
- (o) Hyperventilation/Hypoventilation.

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

(7) The following records are required when general anesthesia is administered:

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

*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.*

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

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

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

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

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

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

- (a) A positive pressure oxygen delivery system and backup system, including full face mask for adults and for pediatric patients, if pediatric patients are treated;
- (b) Oral and nasal airways of various sizes;
- (c) Blood pressure cuff and stethoscope;
- (d) Suction and backup suction equipment, also including suction catheters and tonsil suction;
- (e) A pulse oximeter which provides continuous monitoring of pulse and rate of oxygen saturation of the blood shall be used during each procedure;
- (f) A backup lighting system;
- (g) A Precordial stethoscope or capnometer;
- (h) Defibrillator equipment appropriate for the patient population being treated; and
- (i) Thermometer.

(4) The following emergency equipment must be present:

- (a) Appropriate intravenous set-up, including appropriate hardware and fluids;
- (b) Appropriate syringes;
- (c) Tourniquet and tape.

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

- (a) Epinephrine;
- (b) Atropine;
- (c) Lidocaine;
- (d) Narcotic (e.g., Naloxone HCl) and benzodiazepine (e.g., Flumazenil) antagonists, if these agents are used;
- (e) An antihistamine (e.g., Diphenhydramine HCl);
- (f) A corticosteroid (e.g., Hydrocortisone);
- (g) Nitroglycerine;
- (h) A bronchodilator (e.g., Albuterol inhaler);
- (i) An antihypoglycemic (e.g., 50% glucose);
- (j) Amiodarone;
- (k) Vasopressor;
- (l) Anticonvulsant;
- (m) Antihypertensive;
- (n) Anticholinergic; and
- (o) Antiemetic.

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

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

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

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

(a) The patient's current written medical history, including known allergies and history of previous surgery and anesthesia history;

- (b) Physical and risk assessment (e.g., ASA classification);
- (c) Base line vital signs, including blood pressure, and pulse; and
- (d) A sedation record which shall include:

1. Periodic vital signs recorded at appropriate intervals during the procedure;
2. Drugs administered during the procedure, including route of administration, dosage, time and sequence of administration;
3. Duration of the procedure;

4. Documentation of complications or morbidity;
5. Status of patient upon discharge and to whom discharged; and
6. The patient who is administered a drug(s) for conscious sedation, must be continuously monitored intraoperatively by pulse oximetry. A precordial/pretracheal stethoscope must be available to assist in the monitoring of heart and respiratory rates. A sphygmomanometer shall be immediately available.

(e) Names of participating personnel.

*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.*

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

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

(1) The operatory where the sedated child patient is to be treated must:

(a) Be of adequate size and design to permit physical access of emergency equipment and personnel and to permit effective emergency management;

(b) Be equipped with a chair or table adequate for emergency treatment, including a CPR board or chair suitable for CPR;

(c) Be equipped with suction and backup suction equipment, also including tonsil suction and suction catheters.

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

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

(a) A positive pressure oxygen delivery system and backup system, including full face mask for pediatric patients;

(b) Airways of appropriate size for the pediatric patient;

(c) Blood pressure cuff and stethoscope;

(d) Suction and backup suction equipment, also including tonsil suction and suction catheters;

(e) A pulse oximeter which provides continuous monitoring of pulse and rate of oxygen saturation of the blood shall be used during each procedure;

(f) A scale for weighing pediatric patients; and

(g) Thermometer.

(4) The following emergency equipment must be present:

(a) Appropriate intravenous set-up, including appropriate hardware and fluids;

(b) Appropriate syringes;

(c) Tourniquet and tape; and

(d) Defibrillator equipment appropriate for the patient population being treated.

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

(a) Epinephrine;

(b) Atropine;

(c) Lidocaine;

(d) Narcotic (e.g., Naloxone HCl) and benzodiazepine (e.g., Flumazenil) antagonists, if these agents are used;

(e) An antihistamine (e.g., Diphenhydramine HCl);

(f) A corticosteroid (e.g., Hydrocortisone);

(g) Nitroglycerine;

(h) A bronchodilator (e.g., Albuterol inhaler);

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

(j) A vasopressor;

- (k) An anticonvulsant;
- (l) An antihypertensive;
- (m) Nitroglycerin;
- (n) An anticholinergic;
- (o) An antiemetic; and
- (p) Amiodarone.

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

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

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

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

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

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

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