BOARD OF DENTISTRY
ANESTHESIA COMMITTEE AGENDA
VIA TELEPHONE CONFERENCE CALL
OCTOBER 23, 2013
6:00 P.M. EDT
Call In Number (888) 670-3525, Participant Pass Code: 5805370981

I. CALL TO ORDER

II. REVIEW OF MINUTES
June 18, 2013 001

III. ITEMS FOR TOPIC DISCUSSION
A. Drafts for Rules 64B5-14.008, 14.009 and 14.010, FAC
1. 64B5-14.008, Deep Sedation and General Anesthesia 004
2. 64B5-14.010, Pediatric Sedation 007
3. 64B5-14.009, Conscious Sedation 010
B. Request from Dr. Hector Vila to Temporarily Suspend the Requirement for Pediatric Dentists to Maintain Certain Drugs 013
C. Draft for Rule 64B5-14.003, Training, Education, Certification and Requirements for Issuance of Permits 015
D. Request for Rule Development for minimal sedation requirements/guidelines from Dr. Betty Klement 016
E. Request for Rule Development, Rule 64B5-14.010, Pediatric Conscious Sedation from Dr. Barry Setzer 019
F. Comments Re Conscious Sedation Permits by Dr. Antonio Castro 029

IV. FOR YOUR INFORMATION

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.

DRAFT

BOARD OF DENTISTRY
ANESTHESIA COMMITTEE
VIA TELEPHONE CONFERENCE CALL
JUNE 18, 2013
6:00 P.M. EDT
Call In Number (888) 670-3525, Participant Pass Code: 5805370981

CALL TO ORDER

The meeting was called to order by Dr. Melzer, Chair. Those present for all or part of the meeting included the following:

Committee members present:
Dr. Carl Melzer, Chair
Dr. Carol Stevens
Dr. Wade Winker
Dr. William Kochenour
Dr. Betty Klement
Dr. Jeffrey Sevor, Perio Advisor
Dr. Barry Setzer, Pediatric Advisor
Dr. Clive Rayner, OMS Advisor

Staff present:
David Flynn, Esq. Board Counsel
Sue Foster, Board Director
Cindy Ritter, Program Administrator

Others present:
Dr. Larry Nissan
Dr. Nick White
Dr. Dan Gesek
Dr. Jim Haddix
Dr. Frank Sierra
Dr. Charles Llano
Ms. Adrienne Rodgers, Esq.
Mr. Trevor Mask, F.D.H.A.
Dr. Don Erbs, F.D.A.
Mr. Ron Watson, F.D.A.
Dr. Hector Vila
Dr. Alexander Van Ovost, IRSC
Ms. Catherine Cabanzon, R.D.H.

REVIEW OF MINUTES

August 16, 2012

The minutes of the August 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. Kochenour
Vote: unanimous

Dr. Winker recognized Dr. Barry Setzer, Pediatric Advisor to the Committee, for receiving the Humanitarian Award at the recent FNDC Conference.

ITEMS FOR TOPIC DISCUSSION

Letter from Florida Dental Association – Request to Clarify by Rule Florida Statutes Relating to the Administration of Local Anesthesia

The Committee reviewed a letter from Dr. Kim Jernigan, FDA President, regarding rule 64B5-14.002(9), Prohibitions. She is requesting, on behalf of the Florida Dental Association, that a dental

hygienist be permitted to administer local anesthesia to only non-sedated patients. The FDA feels that nitrous-oxide inhalation analgesia and anti-anxiety medications (anxiolysis) are forms of sedation and therefore patients under the effects of these two modalities cannot be administered local anesthesia by a dental hygienist. A proposed rule was included.

Following discussion, the following action was taken by the Committee:

This proposed rule from the Florida Dental Association should be sent to the Council on Dental Hygiene for review and then placed on the August, 2013 board meeting agenda. The board may need to review a previous motion from the May meeting and discuss possibly vacating this motion.

Rule Draft - 64B5-14.003, FAC, Training, Education, Certification, and Requirements for Issuance of Permits
Changes were recommended to the pediatric conscious sedation permit to include 4 hours of airway management. Also, the language regarding approval of a program by the Board was deleted as this formal training is affiliated with universities.

Following discussion, the following action was taken by the Committee:

Motion: by Dr. Stevens to approve this draft
Second: by Dr. Winker
Vote: unanimous

Concerns from the Florida Academy of Pediatric Dentistry and responses prepared by Dr. Gesek
Dr. Barry Setzer, on behalf of the Pediatric Dental Association discussed Rule 64B5-14.0032(6) Equipment – regarding the equipment being available for inspection **and** the dentist supplying an inspection of the equipment report by a licensed health care risk manager. Following discussion, the Committee agreed that there should be a change from "and" to "or". Mr. Flynn will provide a rule draft for the August board meeting.

There was also discussion regarding the pediatric conscious sedation permit vs. the conscious sedation permit and questions regarding transfer of permits. There was also discussion regarding changing this to one permit, and what is the rationale for changing permits since dentists holding conscious sedation may administer pediatric conscious sedation. Dr. Melzer requested that any comments be sent to the Board office and there will be additional discussion on this at the August board meeting.

Drafts for Rules 64B5-14.008, 14.009 and 14.010, FAC
Dr. Stevens reviewed her proposed changes made to the above-cited anesthesia rules. She made these changes for consistency and standardization. Dr. Melzer stated that he and Dr. Rayner would review her edits and work with Mr. Flynn on proposals for the August meeting.

FOR YOUR INFORMATION
Chapter 64B5-14, FAC, Anesthesia

OLD BUSINESS
Dr. Haddix asked for clarification regarding the amount of classroom vs. online didactic training for dental hygienists taking the local anesthesia course. It was his understanding that 50% of the coursework had to be face to face and he had observed discrepancies with various courses around the state. Dr. Melzer asked that the staff research minutes to see what action was taken. Dr. Erbs stated the spirit of the statute was to have half of the didactic training in the classroom.

NEW BUSINESS
Dr. Melzer stated that he has been reviewing the applications for conscious sedation permits over the past 9 years and finds that the 60 hour course is insufficient training. He would like to see this go to a mini-residency of perhaps an 8 week course in anesthesia. Also, with the ACLS and PALS requirement, he does not see the need for basic CPR training.

ADJOURNMENT
The meeting was adjourned at 7:30 p.m.

64B5-14.008 Requirements for General Anesthesia or Deep Sedation: Operatory, Recovery Room, Equipment, Medicinal Drugs, Emergency Protocols, Records, and Continuous Monitoring.

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

(1) **Operatory**: The operatory where anesthesia is to be administered must:
- (a) Be of adequate size and design to permit physical access of emergency equipment and personnel and to permit effective emergency management;
- (b) Be equipped with a chair or table adequate for emergency treatment, including a chair or cardiopulmonary resuscitation (CPR) board suitable for CPR;
- (c) Be equipped with suction and backup suction equipment, also including suction catheters and tonsil suction.

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

(3) **Standard Equipment**: The following equipment must be readily available to the operatory and recovery room and maintained in good working order:
- (a) A positive pressure oxygen delivery system and backup system, including full face mask for adults and for pediatric patients, if pediatric patients are treated;
- (b) Oral and nasal airways of various sizes;
- (c) Blood pressure cuff and stethoscope;
- (d) Cardioscope – electrocardiograph (EKG) machine, pulse oximeter, and capnograph;
- (e) Precordial stethoscope;
- (f) Suction with backup suction, including suction catheters and tonsil suction;
- (g) Thermometer (Continuous temperature monitoring device, if volatile gases are used); and
- (h) A backup lighting system.

(4) **Emergency Equipment**: The following emergency equipment must be present, readily available and maintained in good working order:
- (a) Appropriate I.V. set-up, including appropriate hardware and fluids;
- (b) Laryngoscope with spare batteries and spare bulbs;
- (c) McGill forceps , endotracheal tubes, and stylet;
- (d) Appropriate syringes;
- (e) Tourniquet and tape;
- (f) CPR board or chair suitable for CPR;
- (g) Defibrillator equipment appropriate for the patient population being treated; and
- (h) Cricothyrotomy equipment.

(5) **Medicinal Drugs**: The following drugs or type of drugs with a current shelf life must be maintained and easily accessible from the operatory and recovery room:
- (a) Epinephrine;
- (b) Atropine;
- (c) Lidocaine;
- (d) A narcotic (e.g., Naloxone) and benzodiazepine (Flumazenil) antagonist, if these agents are used;
- (e) An antihistamine (e.g. Diphenhydramine);
- (f) A corticosteroid;

(g) Nitroglycerine;
(h) A bronchodilator (e.g. Albuterol inhaler);
(i) An antihypoglycemic agent;
(j) Amiodarone;
(k) A vasopressor;
(l) An anticonvulsant;
(m) Antihypertensive;
(n) Anticholinergic;
(o) Antiemetic;
(p) A vasodilator;
(q) A muscle relaxant;
(r) An appropriate antiarrhythmic medication;
(s) Adenosine; and
(t) Dantrolene, if volatile gases are used.

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

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

(7) Records: The following records are required when general anesthesia or deep sedation is administered:
(a) The patient's current written medical history, including known allergies and previous surgery;
(b) Physical 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, which are taken and 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 (See Rule 64B5-14.006,for Adverse Incident Reporting Requirements);
5. Status of patient upon discharge, and to whom the patient is discharged; and

6. Names of participating personnel.

(8) **Continuous Monitoring**: The patient who is administered drug(s) for general anesthesia or deep sedation must be continuously monitored intra-operatively by electrocardiograph (EKG), pulse oximeter, and capnograph to provide heart rhythm and rate, oxygen saturation of the blood, and ventilations (end-tidal carbon dioxide). This equipment shall be used for each procedure.

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

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

(1) **Operatory**: The operatory where the sedated child patient is to be treated must:
   a. Be of adequate size and design to permit physical access of emergency equipment and personnel and to permit effective emergency management;
   b. Be equipped with a chair or table adequate for emergency treatment, including a cardiopulmonary resuscitation (CPR) board of chair suitable for CPR;
   c. Be equipped with suction and backup suction equipment, also including suction catheters and tonsil suction.

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

(3) **Standard Equipment:** The following equipment must be readily available to the operatory and recovery room and maintained in good working order:
   a. A positive pressure oxygen delivery system and backup system, including full face mask for pediatric patients;
   b. 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;
   g. Thermometer;
   h. A backup lighting system; and
   i. A scale for weighing pediatric patients.

(4) **Emergency Equipment**: The following emergency equipment must be present, readily available and maintained in good working order:
   a. Appropriate I.V. set-up, including appropriate hardware and fluids;
   b. Laryngoscope with spare batteries and spare bulbs;
   c. McGill forceps, endotracheal tubes, and stylet;
   d. Suction with backup suction, also including suction catheters and tonsil suction;
   e. Appropriate syringes;
   f. Tourniquet and tape;
   g. CPR board or chair suitable for CPR;

h. Defibrillator equipment appropriate for the patient population being treated; and
i. Cricothyrotomy equipment.

(5) **Medicinal Drugs**: The following drugs or type of drugs with a current shelf life must be maintained and easily accessible from the operatory and recovery room:
a. Epinephrine;
b. 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;
n. Anticholinergic;
o. Antimetic;
p. A vasodilator;
q. A muscle relaxant;
r. An appropriate antiarrhythmic medication;
s. Adenosine.

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

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

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

a. The patient's current written medical history, including known allergies, history of previous surgery and anesthesia, and the patient's age, weight, and calculation of maximum allowable local anesthesia;

b. Physical and risk assessment (e.g., ASA Classification);

c. Base line vital signs, including pulse, percent hemoglobin oxygen saturation, and when possible, blood pressure; and

d. An anesthesia or sedation record which shall include:

i. Periodic vital signs recorded at appropriate intervals during the procedure;

ii. Drugs, including local anesthetics, administered during the procedure, including route of administration, dosage, time and sequence of administration;

iii. Duration of the procedure;

iv. Documentation of complications or morbidity;

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

vi. Names of participating personnel.

(8) **Continuous Monitoring**: 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 in the monitoring of heart and respiratory rate. A sphygmomanometer shall be immediately available.

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

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

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

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

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

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

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

(4) **Emergency Equipment**: The following emergency equipment must be present, readily available and must be maintained in good working order:

(a) Appropriate I.V. set-up, including appropriate hardware and fluids;
(b) Laryngoscope with spare batteries and spare bulbs;
(c) McGill forceps, endotracheal tubes, and stylet;
(d) Appropriate syringes;
(e) Tourniquet and tape;
(f) CPR board or chair suitable for CPR;
(g) Defibrillator equipment appropriate for the patient population being treated; and
(h) Cricothyrotomy equipment.

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

(a) Epinephrine;
(b) 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);
(f) A corticosteroid (e.g., Dexamethasone);
(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 (e.g., Valium);
(m) Antihypertensive;
(n) Anticholinergic;
(o) Antiemetic;
(p) A vasodilator;
(q) A muscle relaxant (e.g., Diazepam);
(r) An appropriate antiarrhythmic medication;
(s) Adenosine.

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

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

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

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

(a) The patient's current written medical history, including known allergies and previous surgery;
(b) Physical and risk assessment (e.g., ASA Classification);
(c) Base line vital signs, including blood pressure, and pulse; and
(d) A sedation or anesthesia record which shall include:
1. Continuous monitoring of vital signs, which are taken and recorded at 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 (See Rule 64B5-14.006, for Adverse Incident Reporting requirements);
5. Status of patient upon discharge, and to whom the patient is discharged; and
6. Names of participating personnel.

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

Hector Vila Jr. M.D.
Diplomat American Board of Anesthesiology
4304 AZEELE STREET, TAMPA, FLORIDA 33609

Members of the Board of Dentistry

First let me thank you for your service to the patients of the state of Florida. I am well aware of the countless hours of sacrifice that is required to serve as a board member.

I am an Anesthesiologist that for the last 5 years has devoted most of my time to providing office based dental anesthesia for children and special needs patients.

My Background includes years of dedication to patient safety including serving as a department of Health inspector for medical offices and as an expert witness for the Board of Medicine. I am past Chair of the American Society of Anesthesiologist's Ambulatory Surgery Committee and oversaw most of the outpatient surgery anesthesia guidelines in use today. I am currently the chair of the Standards Committee for the AAAASF (American Association for Accreditation of Ambulatory Surgical Facilities) and review outcomes from thousands of ambulatory facilities and revise standards to improve patient safety.

1. I am sure you are aware of the nationwide shortage of a number of medications including many of the code drug medications. In my years of reviewing thousands of adverse incidents from outpatient cases, I have never reviewed a case where there was a need for the acute administration of amiodarone, vasopressin, or Adenosine in the office. We are now faced with acute shortages of these medications in hospitals yet I see many dozens of these vials wasted each year from offices where they would never be used. The available studies certainly provide support that the likelihood of a primary cardiac event in a pedo office is almost zero. The more likely events involves airway and respiratory drive and the Board of Dentistry has appropriately placed more emphasis in this area.

So that critical emergency drugs can be more available on ambulances and in hospitals **I propose that the board temporarily suspend the requirement for amiodarone, vasopressin, and adenosine in offices where pediatric sedation is administered orally**. Offices where any form of intravenous sedation is used, should continue to have these medications present.

2. I support your proposed rewording of the language in anesthesia rule 64B5-14.0032 Itinerate/Mobile Anesthesia, regarding the use of a risk manager inspection of the of the EKG/End tidal carbon dioxide monitor to be more consistent with the intent to avoid excessive cost/burden of the rule by using Florida licensed risk managers.

Hector Vila Jr. M.D.
Diplomat American Board of Anesthesiology
4304 AZEELE STREET, TAMPA, FLORIDA 33609

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 **or** the dentist supplies documentation of an inspection of the equipment, which a licensed health care risk manager performed. A licensed health care risk manager inspection is valid for a period of twelve months; and*

(b) The dentist shall make the inspected equipment available during all required inspections if specifically requested in advance of the inspection and the equipment must be immediately available for an adverse incident inspection.

I anticipate being present at the workshop and will be happy to discuss if requested

Please do not hesitate to contact me if I may be of further assistance.

Very truly yours,

Hector Vila Jr. M.D.

Proposed Amendment
Fla. Admin. Code Rule 64B5-14.003
Training, Education, Certification, and Requirements for Issuance of Permits

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

(1) General Anesthesia Permit. No Change

(2) Conscious Sedation Permit.

a. No Change

b. No Change

c. Personal Administration of Conscious Sedation: The board shall award credit towards the required 20 dental patients, if and only if, the applicant is responsible for and remains with the patient from pre-anesthetic evaluation through discharge. The evaluation and responsibilities include the following: pre-anesthetic evaluation, induction, maintenance, emergency, recovery, and discharge. The board will not award credit for dental anesthetic procedures performed that are greater than or less than the administration of conscious sedation.

d. Through h. No Change

(3) Pediatric Conscious Sedation Permit

a. No Change

b. No Change

c. Personal Administration of Pediatric Conscious Sedation: Personal Administration of Pediatric Conscious Sedation: The board shall award credit towards the required 20 dental patients, if and only if, the applicant is responsible for and remains with the patient from pre-anesthetic evaluation through discharge. The evaluation and responsibilities include the following: pre-anesthetic evaluation, induction, maintenance, emergency, recovery, and discharge. The board will not award credit for dental anesthetic procedures performed that are greater than or less than the administration of pediatric conscious sedation.

d. Through e. No Change.

(4) Nitrous-Oxide Inhalation Analgesia. No Change

(5) Local Anesthesia Certificate or Permit. No Change

Ritter, Cynthia

From: bdklement@aol.com
Sent: Friday, August 09, 2013 10:35 AM
To: Ritter, Cynthia
Subject: Anesthesia Committee discussion re Minimal Sedation requirements/guidelines

Cindy,

I would like to have the Anesthesia Committee consider creating guidelines for the use of minimal sedation. I am not suggesting a permit. The ADA has a list of such guidelines which are incorporated in a separate email to you to follow.

Presently licensees are using a variety of enteral agents, often prescribed for a patient to take before coming to the office, administered to a patient preoperatively with the patient then left in the reception room unsupervised, or administered to the patient in an operatory and then left there unsupervised until time for the actual procedure to begin. Although the present rule is clear that the dosage of the single enteral agent given cannot exceed the maximum recommended dose (MDR) of a drug that can be prescribed for unmonitored home use, the patient may be routinely taking other drugs that can potentiate the sedative effect of the enteral agent employed.

Additionally, when nitrous oxide /oxygen is used in combination with the single enteral agent, the sedative effect is potentiated further.

An even greater sedative effect is probable if the licensee adds a narcotic analgesic during the procedure as currently allowed within the rule.

My concern is that we maintain the highest level of patient safety possible. Many other other state boards have adopted or are adopting a minimal sedation guideline.

There are a significant number of Florida dentists who already follow the ADA guidelines, having completed an appropriate course either within a pre-doctoral dental education curriculum or in a post-doctoral continuing competency course.

I am planning to be at both the Thursday meeting and part of Friday morning, and look forward to seeing you there. If you have any questions about what I have sent, please email or call (904-887-2211) me.

Thanks,

Betty Klement

Referred to Committee by Board, 8/22/13 @

• Post-operative verbal and written instructions must be given to the patient, parent, escort, guardian or care giver.

Emergency Management
If a patient enters a deeper level of sedation than the dentist is qualified to provide, the dentist must stop the dental procedure until the patient returns to the intended level of sedation. The qualified dentist is responsible for the sedative management, adequacy of the facility and staff, diagnosis and treatment of emergencies related to the administration of minimal sedation and providing the equipment and protocols for patient rescue.

Management of Children
For children 12 years of age and under, the American Dental Association supports the use of the American Academy of Pediatrics/American Academy of Pediatric Dentists *Guidelines for Monitoring and Management of Pediatric Patients During and After Sedation for Diagnostic and Therapeutic Procedures.*

Enteral and/or Combination Inhalation-Enteral Minimal Sedation Course Duration: Participants must be able to document current certification in Basic Life Support for Healthcare Providers and have completed a nitrous oxide competency course to be eligible for enrollment in this course. While length of a course is only one of the many factors to be considered in determining the quality of an educational program, the course should include a minimum of *16 hours*, plus clinically-oriented experiences during which competency in enteral and/or combined inhalation-enteral minimal sedation techniques is demonstrated. Clinically-oriented experiences may include group observations on patients undergoing enteral and/or combination inhalation-enteral minimal sedation. Clinical experience in managing a compromised airway is critical to the prevention of life-threatening emergencies. The faculty should schedule participants to return for additional clinical experience if competency has not been achieved in the time allotted. The educational course may be completed in a pre-doctoral dental education curriculum or a postdoctoral continuing education competency course. These Guidelines are not intended for the management of enteral and/or combination inhalation-enteral minimal sedation in children, which requires additional course content and clinical learning experience.

MINIMAL SEDATION GUIDELINES FOR FLORIDA DENTISTS

Patient Evaluation
Patients considered for minimal sedation must be suitably evaluated prior to the start of any sedative procedure. In healthy or medically stable individuals (ASA I, II) this may consist of a review of their current medical history and medication use. However, patients with significant medical considerations (ASA III, IV) may require consultation with their primary care physician or consulting medical specialist.

Pre-Operative Preparation
• The patient, parent, guardian or care giver must be advised regarding the procedure associated with the delivery of any sedative agents and informed consent for the proposed sedation must be obtained.
• Determination of adequate oxygen supply and equipment necessary to deliver oxygen under positive pressure must be completed.
• Baseline vital signs must be obtained unless the patient's behavior prohibits such determination.
• A focused physical evaluation must be performed as deemed appropriate.
• Preoperative dietary restrictions must be considered based on the sedative technique prescribed.
• Pre-operative verbal and written instructions must be given to the patient, parent, escort, guardian or care giver.

Personnel and Equipment Requirements
Personnel:
• At least one additional person trained in Basic Life Support for Healthcare Providers must be present in addition to the dentist.
Equipment:
• A positive-pressure oxygen delivery system suitable for the patient being treated must be immediately available.
• When inhalation equipment is used, it must have a fail-safe system that is appropriately checked and calibrated. The equipment must also have either (1) a functioning device that prohibits the delivery of less than 30% oxygen or (2) an appropriately calibrated and functioning in-line oxygen analyzer with audible alarm.
• An appropriate scavenging system must be available if gases other than oxygen or air are used.

Monitoring and Documentation
Monitoring: A dentist, or at the dentist's direction, an appropriately trained individual, must remain in the operatory during active dental treatment to monitor the patient continuously until the patient meets the criteria for discharge to the recovery area. The appropriately trained individual must be familiar with monitoring techniques and equipment. Monitoring must include:
• Oxygenation:
– Color of mucosa, skin or blood must be evaluated continually.
– Oxygen saturation by pulse oximetry may be clinically useful and should be considered.
• Ventilation:
– The dentist and/or appropriately trained individual must observe chest excursions continually.
– The dentist and/or appropriately trained individual must verify respirations continually.
• Circulation:
– Blood pressure and heart rate should be evaluated pre-operatively, post-operatively and intra-operatively as necessary (unless the patient is unable to tolerate such monitoring).
Documentation: An appropriate sedative record must be maintained, including the names of all drugs administered, including local anesthetics, dosages, and monitored physiological parameters.

Recovery and Discharge
• Oxygen and suction equipment must be immediately available if a separate recovery area is utilized.
• The qualified dentist or appropriately trained clinical staff must monitor the patient during recovery until the patient is ready for discharge by the dentist.
• The qualified dentist must determine and document that level of consciousness, oxygenation, ventilation and circulation are satisfactory prior to discharge.

Ritter, Cynthia

From: mensch47 [mensch47@aol.com]
Sent: Sunday, June 23, 2013 6:30 PM
To: Ritter, Cynthia
Cc: Foster, Sue
Subject: [Spam:******* SpamScore] Pediatric Conscious Sedation 64B5-14.010

Attachments: Pediatric Conscious Sedation - track changes.docx; Pediatric Conscious Sedation. - clean edited changes.docx; ATT8094596.txt


Pediatric Conscious Sedation -...


Pediatric Conscious Sedation. ...


ATT8094596.txt

Dear Cindy and Sue,

Per our conversation at the BOD June 18,2013 Anesthesia Committee meeting, I am enclosing a document with track changes and a clean copy with the changes that would make our rules more complete and contemporary and congruent with the AAPD and AAP national sedation guidelines.

Referred to Committee by Board, 8/22/13 @

64B5-14.010 Pediatric Conscious Sedation.

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

(1) Facility

The operatory where the sedated child patient is to be treated as well as the pre-op holding / recovery room (if one is utilized) 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) Have sufficient light to provide emergency treatment

The pre-op holding / recovery room must be situated so that the patient can be observed by the dentist or an office team member at all times.

(2) Equipment

The following equipment must be readily available to the operatory and pre-op holidng / recovery room and maintained in good working order:

(a) A positive pressure oxygen delivery system and a backup system, including bag-mask- value resuscitation equipment for the infant, child and adult;

(b)Oropharygneal and/ or nasopharyngeal airways ofall available sizes and surgical lubricant

(c) Manual sphygmomanometer, blood pressure cuffs (pediatric and adult sizes), and stethoscope and/or automated blood pressure unit

(d) Primary suction equipment and a portable backup, including Yankauer suctiontips;

(e) A pulse oximeter;

(f) A scale for weighing ;

(g) Thermometer;

(h) Appropriate intravenous set-up, including appropriate hardware, tourniquet, tape and fluids; or IO needle or delivery device

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(j) Assorted syringes (1, 3, and 5 mL;

(j) AED with pediatric and adult pads

(k) Hemostat and/or McGill forceps

(l) LMAs of assorted sizes

(m) Laryngoscope and blades

(n) Paper bag, lunch size

(o) Nasal cannula (pediatric and adult sizes) and tubing

(p) Non-rebreathing mask (pediatric and adult sizes) and tubing

(q) Precordial/ pretracheal stethoscope or capnometer

(3) Drugs

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

(a) Epinephrine;

(b) 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 / nebulizer);

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

(j) A vasopressor;

(k) An anticonvulsant;

(l) An antihypertensive;

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(n) An antiemetic; and

(o) Amiodarone.

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(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; (note: item is missing under Conscious Sedation Permit requirements)

(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; (note: define intention, what is the outcome that is be managed?)

(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.

(4) Record Documentation

The following information must be recorded and reviewed as part of the post-operative evaluation:

(a) The patient's past medical history, including known diseases and abnormalities, history of previous surgery, sedation and anesthesia, history of snoring/ sleep apnea and respiratory difficulties

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(b) The patient's current health status, including history of present illnesses;

(c) Current medications, including dose and frequency of administration

(d) Name and contact information of child's primary care provider, including date of last examination and any consultation notes obtained

(e) the patient's age, weight, and height (if BMI determination is to be made for obesity)

(f) Calculation of MRD for local anesthetic agent to be given.

(g) Focused physical evaluation including airway patency , tonsil size, breath sound, jaw hyperplasia,and respiratory function

(h) Risk assessment (e.g., ASA classification);

(j) Baseline vital signs, including pulse and respiratory rates, percent hemoglobin oxygen saturation, blood pressure, when possible based upon child's cooperation. If baseline vital signs are unobtainable, failed attempt must be recorded.

(j) Compliance to dietary restrictions and hours NPO

(k) Informed consent signed by parent/guardian

The following information must be recorded intraoperatively during the procedureal sedation:

(a) Periodic recorde, at appropriate intervals, for patient's vital signs from the monitors being employed, level of responsiveness, breath sounds, and exhibited behavior. 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.
(b) Drugs, including all sedative agents, local anesthetics, nitrous oxide/oxygen administered, including route, dosage, and time of administration. Drugs for moderate sedation must be administered in a dental office and the patient must be observed by a qualified office staff member.

The following information must be recorded post-operatively

(a) Duration of the procedure;

(b) Any complications or morbidity, including intervention applied

(c) Status of patient upon discharge (AAPD/AAP Discharge Criteria met), time discharged and to whom discharged.

(d) Names of participating personnel.

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.

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(4) The following emergency equipment must be present:

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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.

Concerns Regarding Conscious Sedation Permits for General Dentists

1) As a dental office inspector, I would like to suggest that the Board consider updating and clarifying certain areas of the guidelines. My concerns extend to the following:

   a) That during their training, general dentists shall have been required to do both the IV and the surgery simultaneously, as they will be doing, normally, in-office.

   b) After obtaining their conscious sedation permit, I recommend that the general dentist be required to attend continuing education courses in areas specifically related to anesthesia, such as:

      1. Anesthesia update
      2. Anesthesia emergencies
      3. Drugs used during anesthesia
      4. How to evaluate a patient for anesthesia

2) I highly recommend that every new location/office be inspected prior to allowing the dentist to perform conscious sedation there, even if the dentist has been permitted at another location.

   a) In the course of my inspections, I'm finding that some dentists travel/practice in several locations. This is becoming increasingly prevalent.

   b) My concern is that the dentist is not immediately accessible should the patient experience an emergency. There is no protocol in place to ensure how every emergency situation is to be covered.

Submitted by Dr. Antonio Castro
8/22/2013