Rules of Department of Insurance, Financial Institutions and Professional Registration Division 2110—Missouri Dental Board Chapter 4—Sedation

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Title 20—DEPARTMENT OF INSURANCE, FINANCIAL INSTITUTIONS AND PROFESSIONAL REGISTRATION Division 2110—Missouri Dental Board Chapter 4—Sedation

20 CSR 2110-4.010 Definitions

PURPOSE: This rule defines terms used throughout the rules of Chapter 4.

(1) The following words and terms, when used in this chapter, shall have the following meanings.

(A) American Society of Anesthesiologists (ASA) Classifications—A five- (5-) category classification system used to assess a patient prior to sedation/anesthesia. Patients are categorized into one (1) of the five (5) following classes:

1. Class I—There is no organic, physiologic, biochemical, or psychiatric disturbance. The pathological process for which the operation is to be performed is localized and is not a systemic disturbance. The patient has no limits on his/her activity level and in general is to be considered in good or excellent health;

2. Class II—Mild-to-moderate systemic disturbance caused either by the condition to be treated surgically or by other pathophysiological processes. The disease processes are stable or medically controlled and they are not functionally limiting. Examples: tightly-controlled insulin or non-insulin dependent diabetes; stable asthma; symptomatic hypertension; controlled thyroid disease; smoker; obesity; or severe anxiety;

3. Class III—Severe systemic disturbance or disease from whatever cause, even though it may not be possible to define the degree of disability with finality. Activity is significantly limited by the disease, but is not totally incapacitating. The patient may easily decompensate under stress. Examples: severe asthma; poorly controlled diabetes mellitus; angina, especially if unstable or frequent; or status post (S/P) myocardial infarction of cerebral vascular accident (CVA) less than six (6) months ago;

4. Class IV—Indicative of the patient with severe systemic disorder that is a constant threat to life and not always correctable by the operative procedure. Functionally incapacitating; a totally unstable patient who is in and out of lethal states. Examples: unstable angina; congestive heart failure/chronic obstructive pulmonary disease (CHF/COPD) requiring supplemental oxygen (O₂) or wheel-chair confinement, uncontrolled systemic disease (diabetes mellitus); or symptomatic dysrhythmias; or

5. Class V—The moribund patient who has little chance of survival but is submitted to operation in desperation. A hospitalized patient of the expectant category.

(B) Analgesia—The diminution or elimination of pain.

(C) Anesthesiologist—A physician licensed by the Missouri State Board of Registration for the Healing Arts in accordance with Chapter 334, RSMo, with privileges in general anesthesia at an institution accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) or the American Osteopathic Association (AOA).

(D) Certified registered nurse anesthetist— A licensed registered professional nurse recognized as an advanced practice nurse by the Missouri State Board of Nursing, who is certified to administer anesthesia by a nationally recognized certifying body approved by the Missouri State Board of Nursing in accordance with Chapter 335, RSMo.

(E) Deep sedation—A drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.

(F) Deep sedation/general anesthesia permit—A document issued by the Missouri Dental Board to a dentist that allows the dentist to administer deep sedation/general anesthesia.

(G) Deep sedation/general anesthesia site certificate—A document issued by the Missouri Dental Board to a specific dental office where deep sedation/general anesthesia is administered.

(H) Dental office—A facility where dentistry is practiced in accordance with the provisions of section 332.071, RSMo.

(I) Dentist—One who is currently licensed to practice as a dentist in Missouri and is ultimately responsible for the sedation procedure of a dental patient under his/her care.

(J) Dentist-in-charge—A dentist duly licensed by the board to practice at a facility in which sedation anesthesia services are to be offered and who assumes the responsibility to assure that the facility is properly equipped and the sedation team is properly trained.

(K) Enteral minimal sedation—A minimal level of sedation by a technique of administration in which the drug is absorbed through the gastrointestinal tract or oral mucosa.

Enteral minimal sedation is not enteral moderate sedation, parenteral moderate sedation, deep sedation, or general anesthesia.

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(L) Enteral moderate sedation-A minimal-to-moderate level of sedation by a technique of administration in which the drug is absorbed through the gastrointestinal tract or oral mucosa (i.e., oral, rectal, or sublingual). Enteral moderate sedation is not parenteral moderate sedation, deep sedation, or general anesthesia. Drugs used for enteral moderate sedation shall not exceed one and one-half (1.5) times the maximum recommended dose (MRD) for a period of twelve (12) hours before and after the patient appointment (i.e., MRD for Triazolam is one-half milligram (0.5 mg). One and one-half (1.5) times the MRD for Triazolam is three-fourths milligram (0.75 mg) total dose for one (1) appointment).

(M) Enteral moderate sedation permit—A document issued by the Missouri Dental Board to a dentist that allows the dentist to administer enteral moderate sedation.

(N) Facility inspection—An inspection confirming the adequacy of the dental office to provide enteral, parenteral, or pediatric moderate sedation and/or deep sedation/general anesthesia by consultants or other personnel appointed by the board to ensure public safety.

(O) General anesthesia—A drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.

(P) Incremental dosing—Administration of multiple doses of a drug until a desired effect is reached, but not to exceed the maximum recommended dose (MRD).

(Q) Inhalation—A technique of administration in which a gaseous or volatile agent is introduced into the lungs and whose primary effect is due to absorption through the gas/blood interface.

(R) Local anesthesia—The elimination of sensation, especially pain, in one (1) part of the body by the topical application or regional injection of a drug. Note: Although the use of local anesthetics is the foundation of pain control in dentistry and has a long record of safety, dentists must be aware of the maximum, safe dosage limits for each patient.

(S) Maximum recommended dose (MRD)—Maximum United States Food and Drug Administration (FDA) recommended



dose of a drug, as printed in FDA-approved labeling for unmonitored home use. Drugs used for enteral moderate sedation shall not exceed one and one-half (1.5) times the maximum recommended dose (MRD) for a period of twelve (12) hours before and after the patient appointment (i.e., MRD for Triazolam is one-half milligram (0.5 mg). One and one-half (1.5) times the MRD for Triazolam is three-fourths milligram (0.75 mg) total dose for one (1) appointment).

(T) Minimal sedation (Anxiolysis)—A minimally depressed level of consciousness produced by a pharmacological method, which retains the patient's ability to independently and continuously maintain an airway and respond normally to tactile stimulation and verbal command. Although cognitive function and coordination may be modestly impaired, ventilatory and cardiovascular functions are unaffected.

Note: In accord with this particular definition, the drug(s) and/or techniques used should carry a margin of safety wide enough never to render unintended loss of consciousness. Further, patients whose only response is reflex withdrawal from repeated painful stimuli would not be considered to be in a state of minimal sedation. When the intent is minimal sedation for adults, the appropriate initial dosing of a single enteral drug is no more than the maximum recommended dose (MRD) of a drug that can be prescribed for unmonitored home use. The use of preoperative sedatives for children (aged twelve (12) and under) except in extraordinary situations must be avoided due to the risk of unobserved respiratory obstruction during transport by untrained individuals. Children (aged twelve (12) and under) can become moderately sedated despite the intended level of minimal sedation; should this occur, the guidelines for moderate sedation apply. Nitrous oxide/oxygen may be used in combination with a single enteral drug in minimal sedation. Nitrous oxide/oxygen when used in combination with sedative agent(s) may produce minimal, moderate, or deep sedation or general anesthesia.

(U) Moderate sedation—A drug induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. Generally, no interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained. Note: In accord with this particular definition, the drugs and/or techniques used should carry a margin of safety wide enough to render unintended loss of consciousness unlikely. Repeated dosing of an agent before the effects of previous dosing can be fully appreciated may result in a greater alteration of the state of consciousness than is the intent of the dentist. Further, a patient whose only response is reflex withdrawal from a painful stimulus is not considered to be in a state of moderate sedation. The following definitions apply to the administration of moderate or greater sedation:

1. Titration—Administration of incremental doses of a drug until a desired effect is reached. Knowledge of each drug's time of onset, peak response, and duration of action is essential to avoid over sedation. Although the concept of titration of a drug to effect is critical for patient safety, when the intent is moderate sedation, the dentist must know whether the previous dose has taken full effect before administering an additional drug increment; and

2. Supplemental dosing—During moderate sedation, supplemental dosing is a single additional dose of the initial dose of the initial drug that may be necessary for prolonged procedures. The supplemental dose should not exceed one-half (0.5) of the initial dose and should not be administered until the dentist has determined the clinical half-life of the initial dosing has passed. The total aggregate dose must not exceed one and one-half (1.5) times the MRD on the day of treatment.

(V) Moderate sedation site certificate—a document issued by the Missouri Dental Board to a specific dental office where enteral or parenteral moderate sedation is administered.

(W) On-site evaluation—A performance evaluation of the competency of the sedation team by consultants appointed by the board to ensure public safety.

(X) Operating dentist—The Missouri licensed dentist who is performing the dental procedure on a sedated patient. The operating dentist is ultimately responsible for all patient care, including sedation, regardless of whether the care is rendered personally by the dentist, or by another qualified sedation provider.

(Y) Parenteral moderate sedation—A level of minimal to moderate sedation by a technique of administration in which the drug bypasses the gastrointestinal tract, i.e., routes of administration: intravenous (I.V.), intramuscular (I.M.), intranasal (I.N.), subcutaneous (S.C.), submucosal (S.M.), or intraosseous (I.O.). Parenteral moderate sedation is not deep sedation or general anesthesia.

(Z) Parenteral moderate sedation permit— A document issued by the Missouri Dental Board to a dentist that allows the dentist to administer parenteral moderate sedation.

(AA) Pediatric moderate sedation permit-

A document issued by the Missouri Dental Board to a dentist to administer moderate sedation to pediatric patients as defined in subsection (1)(BB) of this rule.

(BB) Pediatric patient—A patient aged twelve (12) or under. The use of preoperative sedatives for children (aged twelve (12) and under) except in extraordinary situations must be avoided due to the risk of unobserved respiratory obstruction during transport by untrained individuals. Children (aged twelve (12) and under) can become moderately sedated despite the intended level of minimal sedation; should this occur, the guidelines for moderate sedation apply.

(CC) Qualified sedation provider—Any of the following who have satisfied the provisions of this rule:

1. A currently licensed dentist in Missouri with a valid permit to administer enteral, parenteral, or pediatric moderate sedation;

2. A currently licensed anesthesiologist; or

3. A currently licensed certified registered nurse anesthetist.

(DD) Sedation team—Those individuals, including the qualified sedation provider and operating dentist, qualified pursuant to 20 CSR 2110-4.030(7)(B) involved with the treatment and/or monitoring of a sedation patient.

(EE) Time-oriented anesthesia record— Documentation at appropriate time intervals of drugs, doses, and physiologic data obtained during patient monitoring.

(FF) Transdermal—A technique of administration in which the drug is administered by patch or iontophoresis through skin.

(GG) Transmucosal—A technique of administration in which the drug is administered across mucosa such as intranasal, sub-lingual, or rectal.

(2) The following words and terms, when used in this chapter, shall have the following meanings.

(A) Continual—Repeated regularly and frequently in a steady succession.

(B) Continuous—Prolonged without any interruption at any time.

(C) Immediately available—On site in the facility and available for immediate use.

AUTHORITY: sections 332.031 and 332.361, RSMo 2000, and section 332.071, RSMo Supp. 2012.* This rule originally filed as 4 CSR 110-4.010. Original rule filed Sept. 15, 2004, effective April 30, 2005. Moved to 20 CSR 2110-4.010, effective Aug. 28, 2006. Rescinded and readopted: Filed July 26, 2012, effective Feb. 28, 2013.



*Original authority: 332.031, RSMo 1969, amended 1981, 1993, 1995; 332.071, RSMo 1969, amended 1976, 1995, 2003, 2004, 2006; and 332.361, RSMo 1969, amended 1981.

20 CSR 2110-4.020 Moderate Sedation

PURPOSE: This rule provides for the regulation of the administration of moderate sedation in a dental office.

(1) Because sedation and general anesthesia are a continuum, it is not always possible to predict how an individual patient will respond. Hence, practitioners intending to produce a given level of sedation should be able to diagnose and manage the physiologic consequences (rescue) for patients whose level of sedation becomes deeper than initially intended. For all levels of sedation, the practitioner must have the training, skills, drugs, and equipment to identify and manage such an occurrence until either assistance arrives (emergency medical service) or the patient returns to the intended level of sedation without airway or cardiovascular complication.

(2) No dentist shall administer enteral and/or parenteral moderate sedation unless the dentist possesses a moderate sedation permit issued by the Missouri Dental Board. (A dentist is not required to possess a permit for the prescription or administration of drugs prescribed for minimal sedation and/or pain control.) This permit shall be renewed by June 1 every five (5) years from the year of issuance.

(3) No dentist shall prescribe sedative agents for enteral moderate sedation unless the dentist possesses an enteral or parenteral moderate sedation permit issued by the Missouri Dental Board. No dentist shall prescribe parenteral moderate sedation agents unless the dentist possesses a parenteral moderate sedation permit issued by the Missouri Dental Board.

(4) No dentist shall administer moderate sedation to a pediatric patient, as defined in 20 CSR 2110-4.010, unless the dentist possesses a pediatric moderate sedation permit. A dentist possessing a pediatric moderate sedation permit may administer moderate sedation using either enteral or parenteral techniques; however, techniques utilizing intravenous administration are restricted to qualified deep sedation/general anesthesia providers as defined in 20 CSR 2110-4.040. Moderate sedation services provided to pediatric patients shall be done in accordance with the American Academy of Pediatric

Dentistry 2006 Guidelines for Monitoring and Management of Pediatric Patients During and After Sedation for Diagnostic and Therapeutic Procedures.

(5) No dental office shall be the site for the administration of enteral, parenteral, or pediatric moderate sedation without being issued a moderate sedation site certificate by the Missouri Dental Board. This site certificate shall be renewed by June 1 every five (5) years from the year of issuance. The dentistin-charge is responsible for submitting the application and maintaining the documentation as required in sections (12) and (14) of this rule.

(6) If the primary administrator of enteral, parenteral, or pediatric moderate sedation in a dental office is a certified registered nurse anesthetist, the operating dentist must possess the appropriate moderate sedation permit for the service being provided.

(7) If the primary administrator of enteral, parenteral, or pediatric moderate sedation in a dental office is an anesthesiologist or a certified registered nurse anesthetist, the operating dentist must order the anesthesia services and is responsible for the readiness of the dental office, preoperative patient evaluation and appropriate medical consultations, the coordination of and emergency preparedness of the sedation team, and the maintenance of appropriate records. The dentist must evaluate the patient prior to the procedure, remain in the dental office, and evaluate the patient prior to discharge.

(8) To qualify for a permit to administer enteral moderate sedation, a dentist shall-

(A) Document satisfactory completion of-

1. An enteral moderate sedation training course consistent with the *American Dental Association Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students* as adopted by the October 2007 American Dental Association (ADA) House of Delegates; or

2. An ADA-accredited post-doctoral training program that affords training necessary to administer enteral moderate sedation; or

3. An enteral moderate sedation course approved by the Missouri Dental Board; and (B) Document—

1. Current certification in Advanced Cardiac Life Support (ACLS); and

2. Completion during the past five (5) years of a minimum of fifteen (15) hours of other board-approved continuing education pertaining to airway management in sedated patients.

3. Additional hours, not to exceed five (5), acquired beyond the required number may be carried forward into the renewal cycle.

(9) To qualify for a permit to administer parenteral moderate sedation, a dentist shall—

(A) Document satisfactory completion of a postgraduate program that is a minimum of twelve (12) continuous months in length and is approved or accredited to teach postgraduate dental or medical education by the ADA, the Accreditation Council for Graduate Medical Education of the American Medical Association (AMA), or the Education Committee of the American Osteopathic Association (AOA). This program shall include:

1. Sixty (60) hours of didactic training in pain and anxiety control and related subjects in accordance with the guidelines of the ADA adopted by the October 2007 ADA House of Delegates;

2. Successful management of parenteral moderate sedation in twenty (20) dental patients. Management of parenteral moderate sedation shall be defined as performing and responsible for all aspects of the sedation procedure from patient selection to patient discharge post sedation for each of the twenty (20) dental patients;

3. General anesthesia training in which there is four (4) weeks documented operating room clinical experience in airway management;

4. Certification of competency by the course director in airway management; and

5. Certification of competency by the course director in parenteral moderate sedation;

(B) Document current certification in Advanced Cardiac Life Support (ACLS); and

(C) Successfully complete an on-site evaluation by consultants appointed by the board. On-site evaluations shall be conducted in accordance with 20 CSR 2110-4.030.

(10) To qualify for a permit to administer pediatric moderate sedation, a dentist shall-

(A) Document satisfactory completion of an ADA-accredited post-doctoral training program that is a minimum of twelve (12) continuous months in length and which affords comprehensive and appropriate training necessary to administer and manage moderate sedation in pediatric patients. This program shall include:

1. A minimum of sixty (60) hours of didactic training in pain and anxiety control in pediatric patients;

2. Successful management of moderate sedation in twenty (20) pediatric dental patients. Management shall be defined as

responsible for all aspects of the sedation procedure from patient selection to patient discharge post sedation;

3. General anesthesia training in which there is four (4) weeks documented clinical experience in airway management;

4. Certification of competency by the course director in airway management; and

5. Certification of competency by the course director in pediatric moderate sedation;

(B) Document current certification in Advanced Cardiac Life Support (ACLS) course or Pediatric Advanced Life Support (PALS); and

(C) Successfully complete an on-site evaluation by consultants appointed by the board. On-site evaluations shall be conducted in accordance with 20 CSR 2110-4.030.

(11) To qualify for a moderate sedation site certificate—

(A) The dentist-in-charge of the dental office shall document that—

1. The primary administrator of enteral, parenteral, or pediatric moderate sedation is a qualified sedation provider as set forth in 20 CSR 2110-4.010(1)(CC);

2. All moderate sedation team members (two (2) minimum) and the dentist, possess and maintain current certification in the American Heart Association's Basic Life Support for the Healthcare Provider (BLS), or an equivalent certification approved by the Missouri Dental Board. Board-approved courses shall meet the American Heart Association guidelines for cardiopulmonary resuscitation (CPR) and emergency cardiovascular care (ECC) and provide written and manikin testing on the course material by an instructor who is physically present with the students. Online only courses will not be accepted to satisfy the BLS requirement or ACLS;

3. All moderate sedation team members, including the dentist, have completed a board-approved course in monitoring sedated patients during the past five (5) years;

4. The dental office is properly maintained and equipped as set forth in 20 CSR 2110-4.030; and

5. The dental office has written protocols for sedation of dental patients as set forth in 20 CSR 2110-4.030 including but not limited to the following:

A. Preoperative patient evaluation and selection prior to enteral, parenteral, or pediatric moderate sedation;

B. Informed consent procedures;

C. Sedation monitoring procedures;

D. Maintaining appropriate records during sedation procedures;

E. Patient discharge assessment; and

F. Responding to emergencies incident to the administration of enteral, parenteral, or pediatric moderate sedation; and

(B) The dental office shall undergo a facility inspection as set forth in 20 CSR 2110-4.030 to confirm the adequacy of the dental office and the qualifications of the sedation team.

(12) The board shall issue an enteral, parenteral, or pediatric moderate sedation permit upon receipt of a completed application form, payment of the appropriate fee specified in 20 CSR 2110-2.170, proof of having met the requirements of sections (7), (8), or (9) of this rule, and determination that the applicant is a licensee in good standing. To be in good standing the licensee's dental license(s) must be current and not under restriction or discipline in any state. The requirements of this section must be completed within one (1) year of the date of submission of the application form.

(13) The board shall issue a moderate sedation site certificate upon receipt of a completed application form, payment of the appropriate fee specified in 20 CSR 2110-2.170, and proof of having met the requirements of section (10) of this rule. The requirements of this section must be completed within one (1) year of the date of submission of the application form.

(14) To renew a permit to administer enteral, parenteral, or pediatric moderate sedation a dentist shall, at least ninety (90) days prior to the expiration of the current permit—

(A) Submit a completed renewal application form provided by the board;

(B) Obtain a passing grade after completing the American Dental Society of Anesthesiology Conscious Sedation Fellowship Exam or other board-approved exam. The examination must be completed every five (5) years;

(C) Submit to the board a minimum of five (5) unedited, complete patient records of the permitted dentist administering enteral, parenteral, or pediatric moderate sedation in the dental office from the preceding five (5) years, documenting management of moderate sedation patients in accordance with the criteria set forth in 20 CSR 2110-4.030;

(D) Submit the renewal fee specified in 20 CSR 2110-2.170 payable to the Missouri Dental Board; and

(E) Document-

1. Current certification in Advanced Cardiac Life Support (ACLS); and

2. Completion during the past five (5) years of a minimum of fifteen (15) hours of other board-approved continuing education

pertaining to airway management in sedated patients.

3. Additional hours, not to exceed five (5), acquired beyond the required number may be carried forward into the renewal cycle.

(15) To renew a moderate sedation site certificate the dentist-in-charge shall, at least ninety (90) days prior to the expiration of the current site certificate—

(A) Submit a completed renewal application form provided by the board;

(B) Submit the renewal fee specified in 20 CSR 2110-2.170 payable to the Missouri Dental Board;

(C) Attest that the primary administrator of enteral, parenteral, or pediatric moderate sedation is a qualified sedation provider as set forth in 20 CSR 2110-4.010(1)(CC);

(D) Document that the sedation team, as well as the permitted dentist, possess and maintain current certification in the American Heart Association's Basic Life Support for the Healthcare Provider (BLS) or an equivalent certification approved by the Missouri Dental Board. Board-approved courses shall meet the American Heart Association guidelines for cardiopulmonary resuscitation (CPR) and emergency cardiovascular care (ECC) and provide written and manikin testing on the course material by an instructor who is physically present with the students. Online only courses will not be accepted to satisfy the BLS requirement, or the American Red Cross recognized equivalent certification, or ACLS;

(E) Document that all moderate sedation team members, including the operating dentist, have completed a board-approved course in monitoring sedated patients during the past five (5) years; and

(F) Undergo a facility inspection as set forth in 20 CSR 2110-4.030 to confirm the adequacy of the dental office and the qualifications of the sedation team.

(16) Each dentist possessing a permit to administer enteral, parenteral, or pediatric moderate sedation shall maintain current certification in Advanced Cardiac Life Support (ACLS) at all times the sedation permit is active.

(17) A dentist holding a current enteral conscious sedation permit on or before the effective date of this rule shall be authorized to perform all means of enteral moderate sedation set forth in 20 CSR 2110-4.010(1)(L) and, upon renewal, shall receive a permit to administer enteral moderate sedation upon



compliance with the renewal requirements set forth in section (13) of this rule.

(18) A dentist holding a current parenteral conscious sedation permit on or before the effective date of this rule shall be authorized to perform all means of parenteral moderate sedation set forth in 20 CSR 2110-4.010(1)(Y) and, upon renewal, shall receive a permit to administer parenteral moderate sedation upon compliance with the renewal requirements set forth in section (13) of this rule.

(19) A dental office holding a current conscious sedation site certificate on or before the effective date of this rule shall be authorized to be the site for the administration of enteral, parenteral, or pediatric moderate sedation and, upon renewal, shall receive a moderate sedation site certificate.

(20) A dentist holding a permit of authorization for the administration of parenteral moderate sedation may use enteral moderate sedation without a permit for enteral moderate sedation. A dentist holding a permit of authorization for the administration of deep sedation/general anesthesia under 20 CSR 2110-4.040 may use enteral, parenteral, and/or pediatric moderate sedation without a permit for enteral, parenteral, and/or pediatric moderate sedation.

(21) The dentist-in-charge of a dental office in receipt of a moderate sedation site certificate must ensure that the moderate sedation team meets the clinical requirements and the dental office meets the standards for utilization as set forth in 20 CSR 2110-4.030.

(22) At any time, the board may inspect a dental office where enteral, parenteral, or pediatric moderate sedation is administered in order to verify compliance with the minimum requirements of this rule.

(23) If at any time the board learns that a dentist who holds a permit to administer enteral, parenteral, or pediatric moderate sedation, or a moderate sedation site certificate has failed to meet the minimum qualifications set out in this rule, the board may pursue disciplinary action in accordance with section 332.321, RSMo.

(24) Due to narrow therapeutic dose ranges for moderate sedation, use of thiopental, methohexital, and propofol for moderate sedation of dental patients will be restricted to qualified deep sedation/general anesthesia providers as defined in 20 CSR 2110-4.040. (25) The provisions of this rule are declared severable. If any provision of this rule is held invalid by a court of competent jurisdiction, the remaining provisions of this rule shall remain in full force and effect unless otherwise determined by a court of competent jurisdiction.

AUTHORITY: sections 332.031 and 332.361, RSMo 2000, and section 332.071, RSMo Supp. 2012.* This rule originally filed as 4 CSR 110-4.020. Original rule filed Sept. 15, 2004, effective April 30, 2005. Moved to 20 CSR 2110-4.020, effective Aug. 28, 2006. Rescinded and readopted: Filed July 26, 2012, effective Feb. 28, 2013.

*Original authority: 332.031, RSMo 1969, amended 1981, 1993, 1995; 332.071, RSMo 1969, amended 1976, 1995, 2003, 2004, 2006; and 332.361, RSMo 1969, amended 1981.

20 CSR 2110-4.030 Guidelines for Administration of Moderate Sedation

PURPOSE: This rule provides for the requirements and guidelines dentists are required to follow in the administration of sedative drugs.

(1) Introduction.

(A) These guidelines are provided to certificate holders in the administration of enteral or parenteral moderate sedation.

(B) Implicit in the administration of sedative drugs is the dictum that they be used in a safe and effective manner.

(C) The goals of moderate sedation are—

1. Sufficient control of patient behavior to enable the practitioner to provide quality treatment;

2. Prompt recovery so that the patient leaves the office in a state of consciousness as close to normal for that patient as possible; and

3. Promotion of a positive psychological response to treatment.

(2) Patient Records.

(A) The patient's record shall provide a legible database that aids in treatment planning and selection of the sedation technique and shall furnish the following:

- 1. Database-
 - A. Full name;
- B. Address (home and work);
- C. Telephone number (home and
- work);
 - D. Date of birth and sex;
 - E. Height and weight;

F. Name of parent or guardian, if applicable;

G. Name and telephone number of person to notify in event of emergency; and

H. Patient's physician's name and telephone number;

2. Medical history-

A. Chief complaint followed by history of the present illness or a brief statement about the patient's problem; and

B. Past medical history and systems review including, but not limited to:

(I) Physician(s) of record;

(II) Hospitalizations within the last five (5) years;

(III) Allergies;

(IV) Present medications (prescription, nonprescription, homeopathic): dosages, intervals, and recent changes;

(V) Major medical illnesses, disorders, or abnormalities;

(VI) Prior anesthetic complications;

(VII) Breathing or respiratory difficulties;

(VIII) Previous hospitalizations; and

(IX) Review of the following with interrogative clarification of positive responses:

- (a) Myocardial infarction;
- (b) Hepatitis or liver disease;
- (c) Hypertension;
- (d) Renal disease;
- (e) Dysrhythmias;
- (f) Anemia;
- (g) Angina;
- (h) Bleeding dyscrasias;
- (i) Heart murmur;
- (j) Human immunodeficiency

virus (HIV);

ders; and

- (k) Congestive heart failure;
- (l) Mitral valve prolapse;
- (m) Rheumatic fever;
- (n) Artificial joint;
- (o) Diabetes;

(p) Neurological/seizure disor-

(q) Obstructive sleep apnea; and 3. Core physical examination—

A. Observation of patient's physical stature, posture, and relative ambulatory ability;

- B. Observation of patient's attentiveness, responsiveness, and verbal ability;
 - C. Oral examination;
 - D. Potential airway problems;

E. Baseline blood pressure, heart rate and rhythm, and respiration rate; and

F. Temperature—only if necessary for present problem.

(3) Pre-Operative Patient Evaluation and Selection.

(A) Patients who are administered moderate sedation must be suitably evaluated to include, but not be limited to the following:

1. An appropriate review of the patient's database by the dentist to determine that data pertaining to all of the following are present:

A. Patient age;

B. Patient weight;

C. Individual responsible for informed consent; and

D. Emergency contact person and telephone number;

2. An appropriate review of the medical history with opportunity for interrogative clarification by the dentist. The record must indicate that the dentist reviewed the medical history;

3. An appropriate review of the core physical examination. The record must indicate the dentist reviewed the findings;

4. An appropriate review of all medications used by the patient, both prescription and non-prescription. The record must indicate the dentist reviewed the medication inventory;

5. Documented American Society of Anesthesiologists classification; and

6. Documented consultation with physicians of record when indicated.

(4) American Society of Anesthesiologists (ASA) classifications must be documented and substantiated.

(A) American Society of Anesthesiologists (ASA) classifications:

1. Class I—There is no organic, physiologic, biochemical, or psychiatric disturbance. The pathological process for which the operation is to be performed is localized and is not a systemic disturbance. The patient has no limits on his/her activity level, and in general is to be considered in good or excellent health.

2. Class II—Mild-to-moderate systemic disturbance caused either by the condition to be treated surgically or by other pathophysiological processes. The disease processes are stable or medically controlled and they are not functionally limiting. Examples: tightlycontrolled insulin or non-insulin dependent diabetes; stable asthma; symptomatic hypertension; controlled thyroid disease; smoker; obesity; or severe anxiety.

3. Class III—Severe systemic disturbance or disease from whatever cause, even though it may not be possible to define the degree of disability with finality. Activity is significantly limited by the disease, but is not totally incapacitating. The patient may easily decompensate under stress. Examples: severe asthma; poorly controlled diabetes mellitus; angina, especially if unstable or frequent; status post (S/P) myocardial infarction of cerebral vascular accident (CVA) less than six (6) months ago.

4. Class IV—Indicative of the patient with severe systemic disorder that is a constant threat to life and not always correctable by the operative procedure. Functionally incapacitating; a totally unstable patient who is in and out of lethal states. Examples: unstable angina; congestive heart failure/ chronic obstructive pulmonary disease (CHF/COPD) requiring supplemental oxygen (O_2) or wheel-chair confinement, uncontrolled systemic disease (diabetes mellitus); or symptomatic dysrhythmias.

5. Class V—The moribund patient who has little chance of survival but is submitted to operation in desperation. A hospitalized patient of the expectant category.

(B) Healthy or medically stable individuals (ASA Class I or II) require a review of the patient's current medical history and medications.

(C) ASA III, IV, and V patients are not candidates for enteral moderate sedation.

(D) ASA III, IV, and V patients are not candidates for parenteral moderate sedation outside a hospital setting.

(5) Informed Consent.

(A) Appropriate informed consent must be obtained prior to administration of enteral or parenteral moderate sedation.

(B) All of the following requirements for informed consent must be satisfied and documented prior to administration of moderate sedation:

1. The patient and/or guardian must be advised of the specific procedure inducing enteral, parenteral, or pediatric moderate sedation;

2. The patient and/or guardian must be advised of the risks associated with the delivery of enteral, parenteral, or pediatric moderate sedation;

3. The patient and/or guardian must be advised of the options to the delivery of the enteral, parenteral, or pediatric moderate sedation;

4. The patient and/or guardian must be advised that moderate sedatives given by the enteral route must not exceed one and onehalf (1.5) times the maximum recommended dose (MRD);

5. The patient and/or the guardian must be advised that unforeseen circumstances can occur and the dentist and the sedation team need permission in advance to change the plan of treatment if it is deemed in their professional judgment to be in the best interest of the patient;

6. The patient and/or guardian must be afforded the opportunity to have concerns and questions addressed by the dentist; and

7. The patient and/or guardian's consent must be documented.

(C) Refer to section (16) for a sample conscious sedation informed consent.

(6) Sedation Documentation Requirements.

(A) A time oriented anesthesia record must be documented including the dosage and administration of drugs and physiologic data obtained during patient monitoring.

(B) At a minimum, the anesthetic record must contain the following:

1. Names of the qualified sedation provider and sedation team members (dentist, anesthetist, assistants);

2. Date;

3. Documentation of nothing by mouth;
4. Vital signs recorded (blood pressure,

pulse rate, and percent of O_2 saturation): A. Preoperatively;

B. After delivery of initial medications (to include the local anesthesia); and

C. At a minimum every fifteen (15) minutes throughout the procedure;

5. Start and finish times for the anesthesia procedure and the operative procedure;

6. Agents delivered (name, dosage, route of administration, and flow rates);

7. Local anesthetics;

8. Inhalation agents;

9. Sedatives;

10. When medications are prescribed or dispensed, a copy of the prescription or a notation describing the medication should be in the patient's chart with the instructions for use;

11. Complications or unusual reactions (all pertinent data, vital signs, and/or medications, etc.); and

12. Discharge status.

(C) Monitoring data must be documented by qualified personnel capable of physical assessment of a sedated patient.

(7) Monitoring Procedures.

(A) Moderate sedation patients shall be monitored under the direct and continuous supervision of a sedation team member.

(B) For the purpose of supervising and monitoring a moderately sedated patient, members of the sedation team shall be—

1. Capable of physical assessment of a sedated patient;

2. Certified in the American Heart Association's Basic Life Support for the Healthcare Provider (BLS) or an equivalent certification approved by the Missouri Dental Board. Board-approved courses shall meet the American Heart Association guidelines for cardiopulmonary resuscitation (CPR) and emergency cardiovascular care (ECC) and



provide written and manikin testing on the course material by an instructor who is physically present with the students. Online only courses will not be accepted to satisfy the BLS requirement or Advanced Cardiopulmonary Life Support (ACLS);

3. Certified in monitoring moderate sedation from a board-approved course provider (certification of non-dentists shall be approved by their respective licensing authorities); and

4. Knowledgeable about medical emergency response incident to the use of enteral, parenteral, and pediatric moderate sedation, including the use of resuscitation equipment and emergency medications.

(C) Strict reliance on measuring a single physiologic parameter may be not only misleading but also potentially hazardous. As a rule, no single symptom may be diagnostic of a particular condition, but rather the total patient must be evaluated.

(D) Monitoring criteria include:

1. Oxygenation. Color of mucosa, skin or blood shall be continually evaluated. Oxygen saturation must be evaluated continuously by pulse oximetry;

2. Ventilation. Observation of chest excursions and/or auscultation of breath sounds; and

3. Circulation. Record initial blood pressure and pulse and thereafter, as appropriate.

(E) Monitoring methods can be divided into mechanical and non-mechanical means.

1. Non-mechanical means shall include:

A. Patient and blood color;

B. Respiratory rate, depth and rhythm;

C. Patient's response to verbal conversation is an excellent gauge to depth of sedation. Is it quick, appropriate, and clear, or is it difficult to obtain, inappropriate and markedly slurred;

- D. Body posturing; and
- E. Skin status.
- 2. Mechanical means shall include:
 - A. Blood pressure and pulse rate;
 - B. Pulse oximetry; and

C. Pretracheal stethoscope, electrocardiogram (ECG) and temperature monitor, if appropriate.

(F) A moderately sedated patient must have direct and continuous supervision and monitoring until oxygenation, respiration, and circulation are stable and the patient is appropriately responsive for discharge from the facility.

(8) Discharge Assessment and Procedures.

(A) The final responsibility for determining whether a patient is appropriately responsive and stable for discharge rests solely with the dentist. This may be done in consultation with a certified registered nurse anesthetist or an anesthesiologist.

(B) Patients who have unusual reactions to enteral, parenteral, or pediatric moderate sedation shall be assisted and monitored until stable for discharge. Recovery must be documented.

(C) The patient must be continually monitored during the recovery period and discharged only when the following criteria are met:

1. Cardiovascular function is satisfactory and stable;

2. Airway patency is uncompromised and satisfactory;

3. Patient is easily arousable and protective reflexes intact;

4. Patient's state of hydration is adequate;

5. Patient can verbalize appropriately;

6. Patient can sit unaided;

7. Patient can ambulate with minimal precautionary assistance;

8. For a very young child or disabled patient, the pre-sedated level of responsive-ness should be achieved;

9. Patients receiving reversal agents may only be discharged after a two- (2-) hour observation period from the last dose of reversal agent and must meet the usual discharge criteria;

10. Appropriate post-discharge supervision is confirmed; and

11. Written post-operative instructions reviewed with and signed by the individual responsible for post-discharge supervision.

(9) Personnel.

(A) The minimum number of individuals available to support a sedated patient shall be three (3): the dentist and two (2) members of the sedation team, which may include a certified registered nurse anesthetist or an anesthesiologist.

(B) All individuals that may be called upon to be responsible for supervising and monitoring sedated patients shall be qualified as set forth in (7)(B).

(10) Facilities and Equipment.

(A) Access and egress to the dental facility and the operatories used for moderate sedation shall meet the requirements of the Americans with Disabilities Act (ADA) and allow access for emergency medical personnel and equipment.

(B) The operatory should be large enough to permit personnel to move freely about the patient. Monitors shall be positioned for easy visualization. (C) The operating table or dental chair should be positioned to permit personnel to maintain the airway, allow quick alteration of patient position, provide a firm platform for the management of cardiopulmonary resuscitation, and provide access to the patient's oral cavity.

(D) The recovery area, whether the operatory or a separate area, shall allow continuous patient visualization by personnel and have sufficient room to treat any emergency. Further, it shall be equipped with systems to allow appropriate monitoring, for providing oxygen under pressure and suction, and provide adequate lighting and electrical outlets.

(E) Equipment shall include:

1. A suction system allowing tonsillar (enteral sedation) and catheter suction (parenteral sedation);

2. A positive pressure oxygen delivery system accommodating both adult and pediatric patients (if pediatric patients are treated);

3. Inhalation anesthetic systems coded to prevent accidental administration of the wrong gas and equipped with a fail-safe mechanism;

4. A portable oxygen unit with appropriate accessories;

5. A pulse oximetry monitor;

6. A defibrillator (an automatic defibrillator is recommended).

(F) An electrocardiograph is recommended equipment if the primary administrator of enteral and/or parenteral moderate sedation is competent in its use and interpretation.

(G) Backup systems shall include:

1. A protocol for obtaining emergency assistance;

2. Battery-powered lighting of sufficient intensity to complete any procedure; and

3. Backup suction sufficient to complete any procedure.

(11) Resuscitation Equipment.

(A) An emergency kit should be readily accessible and portable. It should contain drugs and equipment of appropriate sizes to resuscitate a non-breathing, unconscious patient who may also be suffering varying degrees of cardiovascular collapse to sustain life until responsibility for the patient's care is assumed by appropriate medical personnel (e.g., emergency medical technicians (EMTs), physician, emergency room personnel).

(B) Resuscitation equipment shall be immediately accessible and appropriate for the route of administration of the permit holder.

(C) All moderate sedation permit holders should have immediate access to—

1. Airway and ventilation equipment-

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A. Oxygen;

B. Full face masks of appropriate sizes to accommodate all sedated patients;

C. Mechanism to deliver O_2 with positive pressure;

D. Equipment for performing an emergency cricothyroidotomy; and

E. Nasopharyngeal and oral airways;

2. Tonsillar suction;

3. Syringes and needles for intravenous (I.V.) drug administration; and

4. Unexpired medications as set forth in section (15).

(D) In addition, parenteral moderate sedation permit holders should have immediate access to-

1. I.V. solutions and equipment for establishment of an I.V. route, and appropriate fluids;

2. Sterile diluent for injection and/or mixing or dilution of drugs;

3. Catheter suction; and

4. Syringes and needles for I.V. drug administration.

(12) Site Certificate.

(A) No facility shall be the site for the administration of enteral and/or parenteral moderate sedation without being issued a site certificate pursuant to 20 CSR 2110-4.020.

(B) The board may require a facility requesting a site certificate for moderate sedation undergo a facility inspection. Facility inspections will be conducted by boardappointed consultants. A facility inspection will be deemed satisfactory when all criteria in subsections (12)(C) and (D) of this rule have been satisfactorily met.

1. All parenteral and pediatric moderate sedation permit applicants shall receive an on-site evaluation.

2. Enteral moderate sedation permit applicants may receive an on-site evaluation.

3. The board may, at any time, inspect a facility where moderate sedation is administered in order to verify compliance with the minimum requirements of the moderate sedation rule.

(C) The facility shall be properly maintained and equipped. The dentist-in-charge shall verify via notarized affidavit the following exists and is in good working order:

1. Adequate access and egress for emergency medical personnel to dental facility and operatories used for sedation;

2. Operatory and recovery room design enables appropriate monitoring and emergency response;

3. Emergency kit is accessible, portable, and contains drugs and equipment of appropriate sizes to resuscitate a non-breathing, unconscious patient; 4. Positive pressure oxygen and appro-

priate face masks;

- 5. Portable oxygen;
- 6. Tonsillar vacuum;
- 7. Pulse oximetry;
- 8. Pretracheal stethoscope;
- 9. Nasopharyngeal and oral airways;

10. Battery-powered lighting of sufficient intensity to complete any procedure;

11. Backup suction to complete any procedure; and

12. Defibrillator.

(D) Sedation team members shall be capable of safely executing procedures associated with enteral and/or parenteral and pediatric moderate sedation. The dentist-in-charge shall verify the following via notarized affidavit:

1. The primary administrator of enteral, parenteral, or pediatric moderate sedation is a qualified sedation provider as defined in subsection (1)(CC) of 20 CSR 2110-4.010 who maintains current certification and licensure in their field of practice;

2. Appropriate patient records are maintained as set forth in section (2) of this rule;

3. Appropriate patient selection criteria are employed as set forth in sections (3) and (4) of this rule. The dentist-in-charge and permitted dentists should be prepared to demonstrate knowledge of physical evaluation of patients, American Society of Anesthesiologists (ASA) classifications, and their application to appropriate patient selection;

4. Appropriate informed consent is utilized as set forth in section (5) of this rule;

5. Time oriented anesthesia records are appropriately maintained as set forth in section (6) of this rule;

6. Direct and continuous monitoring of sedated patients is accomplished by sedation team members through recovery until discharge as set forth in section (7) of this rule;

7. Appropriate documentation occurs for the management and treatment of sedated patients; and

8. Appropriate criteria are in place to determine when a patient can be safely discharged and appropriate post-operative instructions are given to responsible individuals who will supervise the sedated patient after discharge as set forth in section (8) of this rule.

(E) The sedation team shall be capable of responding to emergencies incident to the administration of enteral, parenteral, or pediatric moderate sedation. The sedation team should be prepared for the following emergencies and be competent in simulated responses:

1. General emergency response protocol; 2. Laryngospasm;

- 3. Acute airway obstruction;
- 4. Cardiopulmonary arrest;
- 5. Allergic reaction to drugs;
- 6. Hypotension;
- 7. Angina pectoris;
- 8. Possible myocardial infarction;
- 9. Emesis and aspiration of vomitus; and
- 10. Convulsions.

(13) Board-Approved Courses.

(A) A course satisfying the educational requirements for an enteral moderate sedation permit shall include, but not be limited to:

- 1. Appropriate definitions;
- 2. Appropriate patient records;

3. Review of history and physical evaluation;

4. ASA classification;

- 5. Indications for medical consultations;
- 6. Appropriate patient selection;

7. Properly maintained and equipped facilities;

8. Informed consent;

9. Pharmacological review of common sedatives and reversal agents;

10. Incremental dosing techniques not to exceed one and one-half (1.5) times the recommended dose of a sedative by the manufacturer.

11. Time oriented anesthesia record;

12. Monitoring and assessment of the sedated patient during treatment and recovery;

13. Appropriate documentation of the management and treatment of sedated patients;

14. Appropriate discharge criteria;

15. Post-sedation instructions;

16. Response to most common emergencies incident to administration of moderate sedation;

17. A minimum of ten (10) sedation experiences with direct clinical experience on a minimum of three (3) patients in a group of dentists/students no greater than five (5);

18. Simulated experience with an overly sedated patient and how to rescue that patient until they recover;

19. Drug Enforcement Administration (DEA) record keeping; and

20. Pass an independent examination such as the American Dental Society of Anesthesiology (ADSA) moderate sedation fellowship exam or other board-approved test measuring knowledge required of a dentist essential for safe and efficient moderate sedation of dental patients.

(B) The sedation monitoring course content shall include, but not be limited to:

- 1. Appropriate definitions;
- 2. Appropriate patient records;



3. Basic pharmacology, including but not limited to drug interactions with seda-tives;

4. Basic anatomy and physiology as it pertains to the sedated patient;

5. Reviewing patient records for essential data and screening medical histories;

6. ASA classification and appropriate patient selection;

7. Properly maintained and equipped facilities;

8. Informed consent;

9. Time oriented anesthesia record;

10. Monitoring and assessment of the sedated patient during treatment and recovery:

11. Appropriate documentation of the management and treatment of sedated patients;

12. Appropriate discharge criteria;

13. DEA record keeping;

14. Auxiliary roles in response to most common emergencies incident to administration of moderate sedation; and

15. An examination measuring knowledge necessary for safe, effective monitoring of a sedated dental patient.

(14) References.

- (A) Office Anesthesia Evaluation Manual American Association of Oral and Maxillofacial Surgeons
 9700 West Bryn Mawr Ave Rosemont, IL 60018
- (B) American Dental Association Guidelines for the Use of Sedation and General Anesthesia by Dentists as adopted by the October 2007 ADA House of Delegates, American Dental Association, 211 East Chicago Avenue, Chicago, IL 60611-2678.

(15) Emergency Drugs.

(A) Minimum required emergency drugs for enteral sedation.

- 1. Ammonia carpules;
- 2. Antihistamines;
- 3. Benzodiazepine antagonist;
- 4. Bronchodilator inhaler;

5. Concentrated glucose fifty percent (50%), (cake icing, candy, orange juice);

6. Epinephrine (1:1,000 at a minimum);and7. Nitroglycerin.

(B) Minimum required emergency drugs for parenteral sedation.

- 1. Ammonia carpules;
- 2. Antihistamines;
- 3. Atropine (or related drugs);
- 4. Benzodiazepine antagonist;
- 5. Bronchodilator inhaler;
- 6. Concentrated glucose fifty percent
- (50%), (cake icing, candy, orange juice);

7. Corticosteroid:

8. Epinephrine (1:1,000 at a minimum):

9. Narcotic antagonist; and

10. Nitroglycerin.

(C) Suggested but not required emergency drugs.

1. Aminophylline;

2. Hyperstat or Labetalol (or related drugs);

3. Lidocaine (one hundred (100) mg injectables);

4. Sodium bicarbonate; and

5. Succinylcholine chloride.

(16) Sample Informed Consent for Moderate Sedation.

The purpose of this document is to provide an opportunity for patients to understand and give permission for moderate sedation when provided along with dental treatment. Each item should be checked off after the patient has the opportunity for discussion and questions.

<u>1</u>. I understand that the purpose of moderate sedation is to more comfortably receive necessary care. Moderate sedation is not required to provide the necessary dental care. (See #4 options.)

2. I understand that moderate sedation is a drug-induced state of reduced awareness and decreased ability to respond. Moderate sedation is not sleep from which I can be easily awakened. My ability to respond normally returns when the effects of the sedative wear off.

<u>3.</u> I understand that my moderate sedation will be achieved by the following route:

____Oral Administration: I will take a pill approximately _____ minutes before my appointment. The sedation will last approximately _____ to ____ hours. Patients like oral sedation because they do not need an "I.V." line. However the level of sedation is less predictable than with "I.V." sedation.

_____Intravenous (I.V.) Administration: The anesthesia provider will inject the sedative. The length of sedation may be shorter and the level more predictable than with oral sedation. The I.V. sedation will last approximately ____ to ____ hours.

4. I understand that the options to moderate sedation are:

a. No sedation: The necessary procedure is performed under local anesthetic with the patient fully aware. b. Nitrous oxide sedation: Commonly called laughing gas, nitrous oxide provides relaxation but the patient is still generally aware of surrounding activities. Its effects can be reversed in five (5) minutes with oxygen.

c. General anesthetic: Commonly called deep sedation, a patient under general anesthetic has no awareness and must have their breathing temporarily supported. General anesthesia is more appropriate for longer procedures lasting three (3) or more hours.

5. I understand that there are risks or limitations to all procedures. For sedation these include:

(Oral Sedation) Inadequate sedation with initial dosage may require the patient to undergo the procedure without full sedation or delay the procedure for another time. Due to unpredictable patient response, it is not recommended that oral sedatives be given in successive or additive doses.

_____An atypical reaction to sedative drugs that may require emergency medical attention and/or hospitalization.

_____Inability to discuss treatment options with the doctor should the circumstance require a change in treatment plan.

6. If, during the procedure, a change in treatment is required, I authorize the dentist and the sedation team to make whatever change they deem in their professional judgment is necessary.

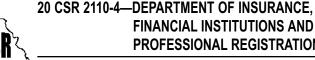
7. I have had the opportunity to discuss moderate sedation and have my questions answered by sedation team members including the dentist, if I so desire.

<u>8.</u> I hereby consent to moderate sedation in conjunction with my dental care.

Patient/Guardian Date Witness

AUTHORITY: sections 332.031 and 332.361, RSMo 2000, and section 332.071, RSMo Supp. 2012.* This rule originally filed as 4 CSR 110-4.030. Original rule filed Sept. 15, 2004, effective April 30, 2005. Moved to 20 CSR 2110-4.030, effective Aug. 28, 2006. Amended: Filed July 26, 2012, effective Feb. 28, 2013.

*Original authority: 332.031, RSMo 1969, amended 1981, 1993, 1995; 332.071, RSMo 1969, amended 1976, 1995, 2003, 2004, 2006; and 332.361, RSMo 1969, amended 1981.



PROFESSIONAL REGISTRATION

20 CSR 2110-4.040 Deep Sedation/General Anesthesia

PUBLISHER'S NOTE: The secretary of state has determined that the publication of the entire text of the material which is incorporated by reference as a portion of this rule would be unduly cumbersome or expensive. This material as incorporated by reference in this rule shall be maintained by the agency at its headquarters and shall be made available to the public for inspection and copying at no more than the actual cost of reproduction. This note applies only to the reference material. The entire text of the rule is printed here

PURPOSE: This rule provides for the regulation of the administration of deep sedation/general anesthesia.

(1) Because sedation and general anesthesia are a continuum, it is not always possible to predict how an individual patient will respond. Hence, practitioners intending to produce a given level of sedation should be able to diagnose and manage the physiologic consequences (rescue) for patients whose level of sedation becomes deeper than initially intended. For all levels of sedation, the practitioner must have the training, skills, drugs, and equipment to identify and manage such an occurrence until either assistance arrives (emergency medical service) or the patient returns to the intended level of sedation without airway or cardiovascular complication.

(2) No dentist shall administer deep sedation/general anesthesia unless the dentist possesses a permit issued by the Missouri Dental Board. This permit shall be renewed by June 1 every five (5) years from the year of issuance.

(3) No dental office shall be the site for the administration of deep sedation/general anesthesia without being issued a site certificate issued by the Missouri Dental Board. The site certificate shall be renewed by June 1 every five (5) years from the year of issuance. The dentist-in-charge is responsible for submitting the application and maintaining the documentation as required in sections (7) and (9) of this rule.

(4) No dentist shall prescribe deep sedation/general anesthesia agents unless the dentist possesses a deep sedation/general anesthesia permit.

(5) If the primary administrator of deep seda-

tion/general anesthesia in a dental office is a certified registered nurse anesthetist, the operating dentist must possess a deep sedation/general anesthesia permit.

(6) If the primary administrator of deep sedation/general anesthesia in a dental office is an anesthesiologist or a certified registered nurse anesthetist, the operating dentist must order the anesthesia services, is responsible for the readiness of the dental office, preoperative patient evaluation and appropriate medical consultations, the coordination of and emergency preparedness of the anesthesia team, and the maintenance of appropriate records. The operating dentist must evaluate the patient prior to the procedure, remain in the dental office, and evaluate the patient prior to discharge.

(7) To qualify for a permit to administer deep sedation/general anesthesia, a dentist shall-

(A) Document satisfactory completion of-

1. An advanced educational program accredited by the American Dental Association (ADA) Commission on Dental Accreditation that affords comprehensive and appropriate training necessary to administer and manage deep sedation or general anesthesia, commensurate with Part IV.C of these guidelines. For all levels of sedation and anesthesia, dentists, who are currently providing sedation and anesthesia in compliance with their state rules and/or regulations prior to adoption of this document, are not subject to these additional requirements; or

2. An ADA-accredited post-doctoral training program in oral and maxillofacial surgery; or

3. An anesthesia training program that is approved and accredited to teach postgraduate medical education by the Accreditation Council for Graduate Medical Education of the American Medical Association (AMA), or the Education Committee of the American Osteopathic Association (AOA); or

4. A Diplomate of the American Dental Board of Anesthesiology;

(B) Document completion of an Advanced Cardiac Life Support (ACLS) course or board-approved equivalent during the past five (5) years or a minimum of fifteen (15) hours of other board-approved continuing education pertaining to medical emergencies, anesthetic complications, or patient management while under deep sedation/general anesthesia. Additional hours, not to exceed five (5), acquired beyond the required number may be carried forward into the renewal cycle;

(C) Undergo and successfully complete an on-site evaluation by consultants appointed by

the board or other qualified personnel approved by the board to confirm the adequacy of the facility and the competency of the personnel. On-site evaluations shall be conducted in accordance with the guidelines in the current American Association of Oral and Maxillofacial Surgeons (AAOMS) Office Anesthesia Evaluation Manual; and

(D) Document that the facility to be used for deep sedation/general anesthesia has been issued a deep sedation/general anesthesia site certificate.

(8) To qualify for a deep sedation/general anesthesia site certificate the dental office must-

(A) Be properly equipped in accordance with the AAOMS Office Anesthesia Evaluation Manual. 8th Edition. 2012. American Association of Oral and Maxillofacial Surgeons, 9700 West Bryn Mawr Avenue, Rosemont, IL 60018-5701, which is incorporated by reference, including but not limited to the capability of delivering positive pressure oxygen, blood pressure and electrocardiographic (ECG) monitoring, and pulse oximetry. This rule does not incorporate any subsequent amendments or additions;

(B) Have and maintain personnel capable of handling procedures and emergencies incident to the administration of deep sedation/general anesthesia including but not limited to:

1. All deep sedation/general anesthesia sedation team members (two (2) minimum) and the operating dentist possess and maintain current certification in the American Heart Association's Basic Life Support for the Healthcare Provider (BLS), or an equivalent certification approved by the Missouri Dental Board. Board-approved courses shall meet the American Heart Association guidelines for cardiopulmonary resuscitation (CPR) and emergency cardiovascular care (ECC) and provide written and manikin testing on the course material by an instructor who is physically present with the students. Online only courses will not be accepted to satisfy the BLS requirement or ACLS; and

2. All deep sedation/general anesthesia sedation team members, including the operating dentist, have completed a board-approved course in monitoring sedated patients during the past five (5) years. Certification of nondentists shall be approved by their respective licensing authorities;

(C) Undergo and successfully complete a facility inspection by consultants appointed by the board or other qualified personnel approved by the board to confirm the adequacy of the facility and the qualifications of the



deep sedation/general anesthesia sedation team; and

(D) The dentist in charge of the dental office shall document that—

1. The administrator of deep sedation/general anesthesia is a qualified sedation provider as defined in 20 CSR 2110-4.010; and

2. All anesthesia team members, including the operating dentist, possess and maintain current certification in the American Heart Association's Basic Life Support for the Healthcare Provider (BLS) or an equivalent certification approved by the Missouri Dental Board. Board-approved courses shall meet the American Heart Association guidelines for cardiopulmonary resuscitation (CPR) and emergency cardiovascular care (ECC) and provide written and manikin testing on the course material by an instructor who is physically present with the students. Online only courses will not be accepted to satisfy the BLS requirement or ACLS.

(9) The board shall issue a deep sedation/general anesthesia permit upon receipt of a completed application form provided by the board, payment of the appropriate fee, proof of having met the requirements of section (7) of this rule and determination that the applicant is a licensee in good standing. To be in good standing the licensee's dental license(s) must be current and not under restriction or discipline in any state. The requirements of this section and the on-site evaluation must be completed within one (1) year of the date of submission of the application form.

(10) The board shall issue a deep sedation/general anesthesia site certificate upon receipt of a completed application form provided by the board, payment of the appropriate fee, and proof of having met the requirements of section (8) of this rule. The requirements of this section and the on-site evaluation for each site to be authorized must be completed within one (1) year of the date of submission of the application form.

(11) The board may authorize a dentist initially applying for a deep sedation/general anesthesia permit to administer deep sedation/general anesthesia in order to complete an on-site evaluation according to subsection (8)(C) of this rule providing all other requirements outlined in sections (7) and (9) have been met. Such authorization shall be in writing and in effect for a period not to exceed ninety (90) days.

(12) To renew a deep sedation/general anesthesia permit a dentist shall, at least ninety (90) days prior to the expiration of the current permit—

(A) Submit a completed renewal application form provided by the board;

(B) Submit the renewal fee specified in 20 CSR 2110-2.170 payable to the Missouri Dental Board;

(C) Document-

1. Current certification in Advanced Cardiac Life Support (ACLS); and

2. Completion during the past five (5) years of a minimum of fifteen (15) hours of other board-approved continuing education pertaining to airway management in sedated patients.

3. Additional hours, not to exceed five (5), acquired beyond the required number may be carried forward into the renewal cycle;

(D) Successfully complete an on-site evaluation as defined in subsection (6)(C) of this rule.

(13) To renew a site certificate for deep sedation/general anesthesia the dentist-in-charge shall, at least ninety (90) days prior to the expiration of the current site certificate—

(A) Submit a completed renewal application form provided by the board;

(B) Submit the renewal fee specified in 20 CSR 2110-2.170 payable to the Missouri Dental Board;

(C) Attest that the primary administrator of deep sedation/general anesthesia is a qualified sedation provider as set forth in 20 CSR 2110-4.010(1)(CC);

(D) Document that anesthesia team members, including the operating dentist, possess and maintain current certification in the American Heart Association's Basic Life Support for the Healthcare Provider (BLS) or an equivalent certification approved by the Missouri Dental Board. Board-approved courses shall meet the American Heart Association guidelines for cardiopulmonary resuscitation (CPR) and emergency cardiovascular care (ECC) and provide written and manikin testing on the course material by an instructor who is physically present with the students. Online only courses will not be accepted to satisfy the BLS requirement or ACLS;

(E) Document that all deep sedation/general anesthesia sedation team members, including the operating dentist, have completed a board-approved course in monitoring sedated patients during the past five (5) years; and

(F) Undergo and successfully complete a facility inspection by consultants appointed by the board or other qualified personnel approved by the board to confirm the adequacy of the facility and the qualifications of the

deep sedation/general anesthesia sedation team.

(14) Each dentist possessing a permit to administer deep sedation/general anesthesia shall maintain current certification in Advanced Cardiac Life Support (ACLS) at all times the sedation permit is active.

(15) A dentist holding a permit for authorization for the administration of deep sedation/general anesthesia under the provisions of this rule may administer enteral, parenteral, or pediatric moderate sedation without a permit for enteral and/or parenteral moderate sedation as required under 20 CSR 2110-4.020.

(16) At any time, the board may inspect sites where deep sedation/general anesthesia is administered in order to verify compliance with the minimum requirements of this rule.

(17) If at any time the board learns that a dentist who holds a deep sedation/general anesthesia permit, or a deep sedation/general anesthesia site certificate, has failed to meet the minimum qualifications set out in this rule, the board may pursue disciplinary action in accordance with section 332.321, RSMo.

(18) The provisions of this rule are declared severable. If any provision of this rule is held invalid by a court of competent jurisdiction, the remaining provisions of this rule shall remain in full force and effect unless otherwise determined by a court of competent jurisdiction.

AUTHORITY: sections 332.031 and 332.361, RSMo 2000, and section 332.071, RSMo Supp. 2012.* This rule originally filed as 4 CSR 110-4.040. Original rule filed Sept. 15, 2004, effective April 30, 2005. Moved to 20 CSR 2110-4.040, effective Aug. 28, 2006. Amended: Filed July 26, 2012, effective Feb. 28, 2013.

*Original authority: 332.031, RSMo 1969, amended 1981, 1993, 1995; 332.071, RSMo 1969, amended 1976, 1995, 2003, 2004, 2006; and 332.361, RSMo 1969, amended 1981.