Rules of
Department of Economic Development
Division 110—Missouri Dental Board
Chapter 4—Sedation

Title 4—DEPARTMENT OF ECONOMIC DEVELOPMENT
Division 110—Missouri Dental Board
Chapter 4—Sedation

4 CSR 110-4.010 Definitions

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

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

(A) 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).

(B) Anxiolysis—the diminution or elimination of anxiety. Anxiolysis is not conscious sedation.

(C) Conscious sedation—a minimally depressed level of consciousness that retains the patient's ability to independently and continuously maintain an airway and respond appropriately to physical stimulation and verbal command, and that is produced by a pharmacologic or non-pharmacologic method, or a combination thereof. Conscious sedation is not deep sedation or general anesthesia.

(D) Conscious sedation permit—a document issued by the Missouri Dental Board to a dentist that allows the dentist to administer enteral and/or parenteral conscious sedation.

(E) Conscious sedation site certificate—a document issued by the Missouri Dental Board to a specific dental office where conscious sedation is administered.

(F) Deep sedation—a controlled state of depressed consciousness accompanied by partial loss of protective reflexes, including the inability to continually maintain an airway independently and/or to respond purposefully to verbal command, and is produced by a pharmacologic or non-pharmacologic method or a combination thereof.

(G) 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.

(H) 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.

(I) 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.

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

(K) 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.

(L) Enteral conscious sedation—a technique of administration in which the drug is absorbed through the gastrointestinal tract or oral mucosa (i.e. oral, rectal, or sublingual). Enteral conscious sedation is not parenteral conscious sedation, deep sedation or general anesthesia.

(M) Facility inspection—an inspection confirming the adequacy of the dental office to provide enteral and/or parenteral conscious sedation by consultants appointed by the board to insure public safety.

(N) General anesthesia—a controlled state of unconsciousness accompanied by partial or complete loss of protective reflexes, including the inability to independently and continuously maintain an airway and respond purposefully to physical stimulation or verbal command, and is produced by a pharmacologic or non-pharmacologic method or a combination thereof.

(O) 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.

(P) On-site evaluation—a performance evaluation of the competency of the sedation team by consultants appointed by the board to insure public safety.

(Q) Parenteral conscious sedation—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.), intraoccular (I.O). Parenteral conscious sedation is not deep sedation or general anesthesia.

(R) Sedation team—those individuals qualified pursuant to 4 CSR 110-4.030(7)(B) and employed by the dental office involved with the treatment and/or monitoring of a sedation patient.

(S) 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 and/or parenteral conscious sedation;

2. A currently licensed [physician] anesthesiologist; or

3. A currently licensed nurse anesthetist.

AUTHORITY: sections 332.031 and 332.361, RSMo 2000 and 332.071, RSMo Supp. 2004. Original rule filed Sept. 15, 2004, effective April 30, 2005.*

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

4 CSR 110-4.020 Conscious Sedation

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

(1) No dentist shall administer enteral and/or parenteral conscious sedation unless the dentist possesses a conscious 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 anxiolysis and/or pain control.) This permit shall be renewed by June 1 every five (5) years from the year of issuance.

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

(3) No dentist shall administer enteral and/or parenteral conscious sedation at a dental office unless the office has been issued a site certificate by the Missouri Dental Board. No dental office shall be the site for the administration of enteral and/or parenteral conscious sedation without being issued a 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 dentist-in-charge is responsible for submitting the application and maintaining the documentation as required in sections (8) and (10) of this rule.

(4) If the primary administrator of enteral and/or parenteral conscious sedation in a dental office is an anesthesiologist or a nurse anesthetist, the 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 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.

(5) To qualify for an enteral conscious sedation permit, a dentist shall:

(A) Document satisfactory completion of:

1. Training consistent with Part I and Part III of the American Dental Association (ADA) *Guidelines for Teaching the Comprehensive Control of Pain and Anxiety in Dentistry*; or

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

3. An enteral conscious sedation course approved by the Missouri Dental Board; and

(B) Document completion during the past five (5) years of—

1. An Advanced Cardiac Life Support (ACLS) course; or

2. A minimum of fifteen (15) hours of other board-approved continuing education pertaining to medical emergencies, anesthesia complications, or patient management while under sedation.

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

(6) To qualify for a permit to administer enteral and parenteral conscious sedation, a dentist shall:

(A) Document satisfactory completion of a postgraduate program which 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;

2. Successful management of parenteral conscious sedation in twenty (20) patients;

3. General anesthesia training in which there is documented clinical experience in managing compromised airways;

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

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

(B) Document completion during the past five (5) years of—

1. An Advanced Cardiac Life Support (ACLS) course; or,

2. A minimum of fifteen (15) hours of other board-approved continuing education pertaining to medical emergencies, anesthesia complications, or patient management while under sedation.

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

(C) Successfully complete an on-site evaluation by consultants appointed by the board. On-site evaluations shall be conducted in accordance with 4 CSR 110-4.030.

(7) To qualify for a conscious sedation site certificate:

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

1. The primary administrator of enteral and/or parenteral conscious sedation is a qualified sedation provider as set forth in 4 CSR 110-4.010(1)(S);

2. All conscious sedation team members (two (2) minimum) and the dentist, possess and maintain current certification in cardiopulmonary resuscitation (CPR), basic life support (BLS), or ACLS;

3. All conscious sedation team members, including the dentist, possess certification from a board-approved course provider in monitoring conscious sedation. Such certification for non-dentists shall be that approved by their respective licensing authority;

4. The dental office is properly maintained and equipped as set forth in 4 CSR 110-4.030; and

5. The dental office has written protocols for sedation of dental patients as set forth in 4 CSR 110-4.030 including but not limited to the following:

A. Preoperative patient evaluation and selection prior to conscious 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 and/or parenteral conscious sedation.

(B) The dental office shall undergo a facility inspection as set forth in 4 CSR 110-4.030 to confirm the adequacy of the dental office and the competency of the sedation team.

(8) The board shall issue an enteral and/or parenteral conscious sedation permit upon receipt of a completed application form, payment of the appropriate fee specified in 4 CSR 110-2.170, proof of having met the requirements of sections (5) and/or (6) 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.

(9) The board shall issue a conscious sedation site certificate upon receipt of a completed application form, payment of the appropriate fee specified in 4 CSR 110-2.170, and proof of having met the requirements of section (7) of this rule. The requirements of this section must be completed within one (1) year of the date of submission of the application form.

(10) To renew a permit to administer enteral and/or parenteral conscious 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) Submit the renewal fee specified in 4 CSR 110-2.170 payable to the Missouri Dental Board; and

(C) Document completion during the past five (5) years of—

1. An Advanced Cardiac Life Support (ACLS) course; or

2. A minimum of fifteen (15) hours of other board-approved continuing education pertaining to medical emergencies, anesthesia complications, or patient management while under sedation.

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

(11) To renew a site certificate for enteral and/or parenteral conscious sedation 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 4 CSR 110-2.170 payable to the Missouri Dental Board;

(C) Attest that the primary administrator of enteral and/or parenteral conscious sedation is a qualified sedation provider as set forth in 4 CSR 110-4.010(1)(S);

(D) Document that the sedation team, as well as the permitted dentist, possess and

maintain current certification in CPR, BLS, or ACLS;

(E) Submit to the board a minimum of five (5) unedited, complete patient records of the permitted dentist, anesthesiologist, or nurse anesthetist administering conscious sedation in the dental office that may be chosen by the board from the preceding five (5) years, documenting management of conscious sedation patients in accordance with the criteria set forth in 4 CSR 110-4.030; and

(F) Undergo a facility inspection as set forth in 4 CSR 110-4.030 to confirm the adequacy of the dental office and the competency of the sedation team.

(12) A dentist holding a current intravenous conscious sedation (IVCS) permit or a parenteral conscious sedation permit on or before the effective date of this rule, shall be authorized to perform all means of parenteral conscious sedation set forth in 4 CSR 110-4.010(1)(Q).

(13) A dentist holding a current IVCS permit or a parenteral conscious sedation permit on or before the effective date of this rule shall, upon renewal, receive a permit to administer enteral and parenteral conscious sedation upon compliance with the renewal requirements set forth in section (10) of this rule.

(14) A dentist holding a permit of authorization for the administration of deep sedation/general anesthesia under 4 CSR 110-4.040 may use conscious sedation without a permit for conscious sedation.

(15) The dentist-in-charge of a dental office in receipt of a conscious sedation site certificate must insure that the conscious sedation team meet the clinical requirements and the dental office meets the standards for utilization as set forth in 4 CSR 110-4.030.

(16) At any time, the board may inspect a dental office where conscious sedation 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 permit to administer enteral and/or parenteral conscious sedation, or a site certificate where enteral and/or parenteral conscious sedation is administered, 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) Due to narrow therapeutic dose ranges for conscious sedation, use of thiopental, methohexital, and propofol for conscious sedation of dental patients will be restricted to qualified deep sedation/general anesthesia providers as defined in 4 CSR 110-4.040.

(19) 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: section 332.031 and 332.361 RSMo 2000 and 332.071 RSMo Supp. 2004. Original rule filed Sept. 15, 2004, effective April 30, 2005.*

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

4 CSR 110-4.030 Guidelines for Administration of Conscious 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 conscious 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 conscious 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;

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

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;

F. Temperature—only if necessary for present problem.

(3) Pre-Operative Patient Evaluation and Selection.

(A) Patients who are administered enteral or parenteral conscious 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: 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; 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) Patients who may not be medically stable or who have a significant health disability (ASA III) require a medical consultation from a physician. ASA III patients who are treated in the office setting must have evidence of the dentist's consultation with the treating physician (written or oral) in the record. Such consultation should elicit the physician's concurrence with decision to utilize the proposed office sedative technique.

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

(E) ASA IV and V patients are not candidates for parenteral sedation outside a hospital setting.

(5) Informed Consent.

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

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

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

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

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

4. The patient or the guardian must be advised that unforeseen circumstances do 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 judgement to be in the best interest of the patient;

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

6. 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) Conscious 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 consciously sedated patient, members of the sedation team shall be:

1. Capable of physical assessment of a sedated patient;

2. Certified in Basic Life Support (BLS), Cardiopulmonary Resuscitation (CPR), or Advanced Cardiopulmonary Life Support (ACLS);

3. Certified in monitoring conscious 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 and parenteral conscious 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 consciously 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 nurse anesthetist or an anesthesiologist.

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

(C) The patient must be continually observed 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 responsiveness should be achieved;

9. Appropriate post-discharge supervision confirmed; and

10. Post-operative instructions reviewed with 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 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 conscious 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 conscious 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 conscious sedation permit holders should have immediate access to:

1. Airway and ventilation equipment;

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 conscious 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 water 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 conscious sedation without being issued a site certificate pursuant to 4 CSR 110-4.020.

(B) The board may require a facility requesting a site certificate for conscious sedation undergo a facility inspection. Facility inspections will be conducted by board appointed consultants from the Conscious Sedation Evaluation Committee of the Missouri Dental Board. 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 sedation permit applicants shall receive an on-site evaluation;

2. Enteral conscious sedation permit applicants may receive an on-site evaluation; and

3. The board may, at any time, inspect a facility where conscious sedation is administered in order to verify compliance with the minimum requirements of the conscious 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 appropriate 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 conscious sedation. The dentist-in-charge shall verify the following via notarized affidavit:

1. The primary administrator of enteral and/or parenteral conscious sedation is a qualified sedation provider as defined in subsection (1)(S) of 4 CSR 110-4.010 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, 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 and/or parenteral conscious 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 conscious 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. Time oriented anesthesia record;

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

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

13. Appropriate discharge criteria;

14. Post-sedation instructions;

15. Response to most common emergencies incident to administration of conscious sedation; and

16. An examination measuring knowledge required of a dentist essential for safe and efficient conscious 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. Reviewing patient records for essential data and screening medical histories;

4. ASA classification and appropriate patient selection;

5. Properly maintained and equipped facilities;

6. Informed consent;

7. Time oriented anesthesia record;

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

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

10. Appropriate discharge criteria;

11. Auxiliary roles in response to most common emergencies incident to administration of conscious sedation; and

12. 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) *Guidelines for the Use of Conscious Sedation, Deep Sedation and General Anesthesia for Dentists*
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); and
7. 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 Conscious Sedation.

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

_____1. I understand that the purpose of conscious sedation is to more comfortably receive necessary care. Conscious sedation is not required to provide the necessary dental care. (See #4 options.)

_____2. I understand that conscious sedation is a drug-induced state of reduced awareness and decreased ability to respond. Conscious 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.

_____3. I understand that my conscious 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 conscious 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 conscious sedation and have my questions answered by sedation team members including the dentist, if I so desire.

_____8. I hereby consent to conscious sedation in conjunction with my dental care.

_____ _____ _____
Patient/Guardian Date Witness

AUTHORITY: sections 332.031 and 332.361 RSMo 2000 and 332.071 RSMo Supp. 2004. Original rule filed Sept. 15, 2004, effective April 30, 2005.*

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

4 CSR 110-4.040 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) 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 date of issuance.

(2) 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 date of issuance. The dentist-in-charge is responsible for submitting the application and maintaining the documentation as required in sections (6) and (8) of this rule.

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

(4) If the primary administrator of deep sedation/general anesthesia in a dental office is an anesthesiologist or a nurse anesthetist, the 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 dentist must evaluate the patient prior to the procedure, remain in the dental office, and evaluate the patient prior to discharge.

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

(A) Document satisfactory completion of:

1. A post-doctoral training program in anesthesia and related subjects that satisfies the requirements described in Part II of the American Dental Association (ADA) *Guidelines for Teaching the Comprehensive Control of Pain and Anxiety in Dentistry* at the time the training was commenced; 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); and

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

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

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

(A) Be properly equipped in accordance with the American Association of Oral and Maxillofacial Surgeons (AAOMS) *Office Anesthesia Evaluation Manual*, 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;

(C) Undergo and successfully complete an on-site evaluation by consultants appointed by the board to confirm the adequacy of the facility and competency of the personnel. On-site evaluations shall be conducted in accordance with guidelines in the current AAOMS *Office Anesthesia Evaluation Manual*; 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 4 CSR 110-4.030; and

2. All anesthesia team members, including the operating dentist, possess and maintain current certification in cardiopulmonary resuscitation (CPR), basic life support (BLS), or ACLS.

(7) 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 (5) 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.

(8) 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 (6) 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.

(9) The board may authorize a dentist initially applying for a deep sedation/general anesthesia permit to administer deep sedation/general anesthesia pending an on-site evaluation according to subsection (6)(C) of this rule providing all other requirements outlined in sections (5) and (7) have been met. Such authorization shall be in writing and in effect for a period not to exceed ninety (90) days.

(10) When the primary administrator of anesthesia at a dental office is not a dentist with a valid deep sedation/general anesthesia permit, the board may authorize the dentist initially applying for a deep sedation/general anesthesia site certificate to allow the primary administrator to administer deep sedation/general anesthesia pending an on-site evaluation according to subsection (6)(C) of this rule providing all other requirements outlined in sections (6) and (8) have been met. Such authorization shall be in writing and in effect for a period not to exceed ninety (90) days.

(11) Subsequent to an on-site evaluation as outlined in subsection (6)(C) of this rule, the board, at its discretion, may issue a temporary authorization to administer deep sedation/general anesthesia to any dental office, providing all other provisions of this rule have been met. Such authorization shall be in writing and in effect for a period not to exceed ninety (90) days. A reevaluation may be undertaken prior to the issuance of a site certificate. The fee for the reevaluation shall be the same as the initial evaluation.

(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 4 CSR 110-2.170 payable to the Missouri Dental Board;

(C) Document completion during the past five (5) years of—

1. An Advanced Cardiac Life Support (ACLS) course; or

2. A minimum of fifteen (15) hours of other board-approved continuing education pertaining to medical emergencies, anesthesia complications, or patient management while under sedation.

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 4 CSR 110-2.170 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 4 CSR 110-4.010(1)(S);

(D) Document that anesthesia team members, including the operating dentist, possess and maintain current certification in CPR, BLS, or ACLS; and

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

(14) A dentist holding a permit for authorization for the administration of deep sedation/general anesthesia under the provisions of this rule may administer enteral and/or parenteral conscious sedation without a permit for enteral and/or parenteral conscious sedation as required under 4 CSR 110-4.020.

(15) 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.

(16) 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.

(17) 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 332.071 RSMo Supp. 2004. Original rule filed Sept. 15, 2004, effective April 30, 2005.*

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