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Sequence Number: 03-17-15
 Rule ID(s): 5896
 File Date: 3/24/15
 Effective Date: 6/22/15

Rulemaking Hearing Rule(s) Filing Form

Rulemaking Hearing Rules are rules filed after and as a result of a rulemaking hearing (Tenn. Code Ann. § 4-5-205).

Pursuant to Tenn. Code Ann. § 4-5-229, any new fee or fee increase promulgated by state agency rule shall take effect on July 1, following the expiration of the ninety (90) day period as provided in § 4-5-207. This section shall not apply to rules that implement new fees or fee increases that are promulgated as emergency rules pursuant to § 4-5-208(a) and to subsequent rules that make permanent such emergency rules, as amended during the rulemaking process. In addition, this section shall not apply to state agencies that did not, during the preceding two (2) fiscal years, collect fees in an amount sufficient to pay the cost of operating the board, commission or entity in accordance with § 4-29-121(b).

Agency/Board/Commission:	Board of Dentistry
Division:	
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Revision Type (check all that apply):

- Amendment
 New
 Repeal

Rule(s) Revised (ALL chapters and rules contained in filing must be listed here. If needed, copy and paste additional tables to accommodate multiple chapters. Please enter only ONE Rule Number/Rule Title per row)

Chapter Number	Chapter Title
0460-02	Rules Governing the Practice of Dentistry
Rule Number	Rule Title
0460-02-.07	Anesthesia and Sedation

(Place substance of rules and other info here. Statutory authority must be given for each rule change. For information on formatting rules go to <http://state.tn.us/sos/rules/1360/1360.htm>)

Chapter
0460-02
Rules Governing the Practice of Dentistry

Amendments

Rule 0460-02-.07 Anesthesia and Sedation is amended by deleting subpart (6)(a)2(ii) in its entirety, and substituting instead the following language, and is further amended by deleting subpart (6)(a)2(iii) in its entirety, so that as amended, the new subpart (6)(a)2(ii) shall read:

- (ii) Completion of a continuing education course consisting of a minimum of sixty (60) hours of didactic instruction plus the management of at least twenty (20) patients which provides competency in parenteral conscious sedation. The course content must be consistent with that described for an approved continuing education program in these techniques in the ADA Guidelines for Teaching the Comprehensive Control of Anxiety and Pain in Dentistry, 2000 edition, or its successor publication.

Authority: T.C.A. §§ 63-5-105, 63-5-107, 63-5-108, 63-5-112, 63-5-115, 63-5-117, 63-5-122, and 63-5-124.

Rule 0460-02-.07 Anesthesia and Sedation is amended by deleting subpart (6)(b)1(ix) in its entirety and substituting instead the following language, so that as amended, the new subpart shall read:

- (ix) Inspections of the anesthesia and sedation equipment shall be made each day the equipment is used and a log kept recording the inspection and its results.

Authority: T.C.A. §§ 63-5-105, 63-5-107, 63-5-108, 63-5-112, 63-5-115, 63-5-117, 63-5-122, and 63-5-124.

Rule 0460-02-.07 Anesthesia and Sedation is amended by deleting part (6)(b)3 in its entirety and substituting instead the following language, so that as amended, the new part shall read:

- 3. Patient evaluation. Patients subjected to conscious sedation must be suitably evaluated prior to the start of any sedative procedure. In healthy or medically stable individuals (ASA I, II) this may be simply a review of their current medical history and medication use. However with individuals who may not be medically stable or who have a significant health disability (ASA III, IV) consultation with their primary care physician or consulting medical specialist is recommended.

Authority: T.C.A. §§ 63-5-105, 63-5-107, 63-5-108, 63-5-112, 63-5-115, 63-5-117, 63-5-122, and 63-5-124.

Rule 0460-02-.07 Anesthesia and Sedation is amended by deleting subpart (6)(b)6(iii) in its entirety and substituting instead the following language, so that as amended, the new subpart shall read:

- (iii) A cardiac defibrillator or automated external defibrillator must be available.

Authority: T.C.A. §§ 63-5-105, 63-5-107, 63-5-108, 63-5-112, 63-5-115, 63-5-117, 63-5-122, and 63-5-124.

Rule 0460-02-.07 Anesthesia and Sedation is amended by deleting items (7)(a)1(i)(I) and (7)(a)1(i)(III) in their entirety and substituting instead the following language and is further amended by deleting item (7)(a)1(i)(IV) in its entirety, so that as amended, the new items shall read:

- (I) Successful completion of a minimum of one (1) year advanced training in anesthesiology and related academic subjects beyond the undergraduate dental school level in a training program as described in the most recent version of the ADA Guidelines for Teaching the Comprehensive Control of Pain and Anxiety in Dentistry, or

- (III) Proof of successful completion of a residency program in general anesthesia of not less than one (1) calendar year that is approved by the Board of Directors of the American Dental Society of Anesthesiology for eligibility for the Fellowship in General Anesthesia or proof that the applicant is a Diplomate of the American Board of Dental Anesthesiology.

Authority: T.C.A. §§ 63-5-105, 63-5-107, 63-5-108, 63-5-112, 63-5-115, 63-5-117, 63-5-122, and 63-5-124.

Rule 0460-02-.07 Anesthesia and Sedation is amended by deleting subpart (7)(b)1(ix) in its entirety and substituting instead the following language, so that as amended, the new subpart shall read:

- (ix) Inspections of the deep sedation/general anesthesia equipment shall be made each day the equipment is used and a log kept recording the inspection and its results.

Authority: T.C.A. §§ 63-5-105, 63-5-107, 63-5-108, 63-5-112, 63-5-115, 63-5-117, 63-5-122, and 63-5-124.

Rule 0460-02-.07 Anesthesia and Sedation is amended by deleting part (7)(b)3 in its entirety and substituting instead the following language, so that as amended, the new part shall read:

- 3. Patient evaluation. Patients subjected to deep sedation/general anesthesia must be suitably evaluated prior to the start of any sedative procedure. In healthy or medically stable individuals (ASA I, II) this may be simply a review of their current medical history and medication use. However with individuals who may not be medically stable or who have a significant health disability (ASA III, IV) consultation with their primary care physician or consulting medical specialist is recommended.

Rule 0460-02-.07 Anesthesia and Sedation is amended by deleting subpart (7)(b)5(v) in its entirety and substituting instead the following language, so that as amended, the new subpart shall read:

- (v) Respirations must be monitored by end tidal CO₂ unless precluded or invalidated by the nature of the patient, procedure, or equipment;

Authority: T.C.A. §§ 63-5-105, 63-5-107, 63-5-108, 63-5-112, 63-5-115, 63-5-117, 63-5-122, and 63-5-124.

Rule 0460-02-.07 Anesthesia and Sedation is amended by deleting subpart (7)(b)6(iv) in its entirety and substituting instead the following language, so that as amended, the new subpart shall read:

- (iv) A cardiac defibrillator or automated external defibrillator must be available.

Authority: T.C.A. §§ 63-5-105, 63-5-107, 63-5-108, 63-5-112, 63-5-115, 63-5-117, 63-5-122, and 63-5-124.

* If a roll-call vote was necessary, the vote by the Agency on these rulemaking hearing rules was as follows:

Board Member	Aye	No	Abstain	Absent	Signature (if required)
Charles E. Holt, Jr.	X				
Nadim J. Jubran	X				
Mary R. Warner	X				
Ernest J. DeWald	X				
Katherine N. Hall	X				
Airica Brooke Puckett	X				
Mary Ellen Vaughn	X				
Stephen J. Maroda	X				
Randall P. Prince	X				
Dan T. Meadows	X				
Bettye Lynn Richert	X				

I certify that this is an accurate and complete copy of rulemaking hearing rules, lawfully promulgated and adopted by the Board of Dentistry (board/commission/ other authority) on 11/07/2014 (mm/dd/yyyy), and is in compliance with the provisions of T.C.A. § 4-5-222.

I further certify the following:

Notice of Rulemaking Hearing filed with the Department of State on: 11/07/14 (mm/dd/yy)

Rulemaking Hearing(s) Conducted on: (add more dates). 01/08/15 (mm/dd/yy)

Date: 11/12/15

Signature: Jennifer L. Putham

Name of Officer: Jennifer Putham

Assistant General Counsel

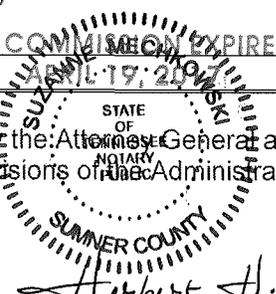
Title of Officer: Department of Health

Subscribed and sworn to before me on: 1-12-15

Notary Public Signature: Suzanne McElkousc

My commission expires on: MY COMMISSION EXPIRES JAN 19, 2017

All rulemaking hearing rules provided for herein have been examined by the Attorney General and Reporter of the State of Tennessee and are approved as to legality pursuant to the provisions of the Administrative Procedures Act, Tennessee Code Annotated, Title 4, Chapter 5.



Herbert H. Slatery III
Herbert H. Slatery III
Attorney General and Reporter

3/20/2015
Date

Department of State Use Only

Filed with the Department of State on: 3/24/15
Effective on: 6/22/15
Tre Hargett
Tre Hargett
Secretary of State

SECRETARY OF STATE
RECEIVED

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Public Hearing Comments

One copy of a document containing responses to comments made at the public hearing must accompany the filing pursuant to T.C.A. § 4-5-222. Agencies shall include only their responses to public hearing comments, which can be summarized. No letters of inquiry from parties questioning the rule will be accepted. When no comments are received at the public hearing, the agency need only draft a memorandum stating such and include it with the Rulemaking Hearing Rule filing. Minutes of the meeting will not be accepted. Transcripts are not acceptable.

Dr. John Werther, a member of the Dental Board's Anesthesia Committee, proposed the following verbiage be added following the word CO2 and before the semi-colon: "unless precluded or invalidated by the nature of the patient, procedure, or equipment."

He stated that this change would make the ruling verbatim consistent with the American Association of Oral and Maxillofacial Surgeons 2012 Parameters of Care.

The Board voted to accept this change.

Regulatory Flexibility Addendum

Pursuant to T.C.A. §§ 4-5-401 through 4-5-404, prior to initiating the rule making process as described in T.C.A. § 4-5-202(a)(3) and T.C.A. § 4-5-202(a), all agencies shall conduct a review of whether a proposed rule or rule affects small businesses.

(If applicable, insert Regulatory Flexibility Addendum here)

(1) The extent to which the rule or rule may overlap, duplicate, or conflict with other federal, state, and local governmental rules.

This rule amendment does not overlap, duplicate, or conflict with other federal, state, and local government rules.

(2) Clarity, conciseness, and lack of ambiguity in the rule or rules.

This rule amendment reflects clarity, conciseness, and lack of ambiguity.

(3) The establishment of flexible compliance and/or reporting requirements for small businesses.

This rule amendment does not create any compliance or reporting requirements for small businesses.

(4) The establishment of friendly schedules or deadlines for compliance and/or reporting requirements for small businesses.

This rule amendment does not create any compliance or reporting requirements for small businesses.

(5) The consolidation or simplification of compliance or reporting requirements for small businesses.

This rule amendment does not create any compliance or reporting requirements for small businesses.

(6) The establishment of performance standards for small businesses as opposed to design or operational standards required in the proposed rule.

This rule amendment does not establish performance standards for small businesses as opposed to design or operational standards required for the proposed rule.

(7) The unnecessary creation of entry barriers or other effects that stifle entrepreneurial activity, curb innovation, or increase costs.

This rule amendment does not create unnecessary barriers or other effects that stifle entrepreneurial activity, curb innovation, or increase costs.

Impact on Local Governments

Pursuant to T.C.A. §§ 4-5-220 and 4-5-228 "any rule proposed to be promulgated shall state in a simple declarative sentence, without additional comments on the merits of the policy of the rules or regulation, whether the rule or regulation may have a projected impact on local governments." (See Public Chapter Number 1070 (<http://state.tn.us/sos/acts/106/pub/pc1070.pdf>) of the 2010 Session of the General Assembly)

(Insert statement here)

The proposed rule amendments should not have an impact on local governments as they only affect dentists who possess a conscious sedation permit or a deep sedation/general anesthesia permit.

Additional Information Required by Joint Government Operations Committee

All agencies, upon filing a rule, must also submit the following pursuant to T.C.A. § 4-5-226(i)(1).

- (A)** A brief summary of the rule and a description of all relevant changes in previous regulations effectuated by such rule;

Rule 0460-02-.07(6)(a)2 is amended by deleting subpart (iii).

Rule 0460-02-.07(6)(b)1(ix) is being amended to add the words "and sedation."

Rule 0460-02-.07 (6)(b)3 is being amended to change the word "indicated" to "recommended" when referring to a patient's need for consultation with their primary care physician before receiving sedation if they are deemed medically unstable or have a significant health disability.

Rule 0460-02-.07 (6)(b)6(iii) is being amended to include an automated external defibrillator be available at the site of anesthesia and sedation.

Rule 0460-02-.07(7)(a)1(i)(I) changes a reference from the 2000 ADA Guidelines for Teaching the Comprehensive Control of Pain and Anxiety in Dentistry to the "most recent version.

Rule 0460-02-.07(7)(a)1(i)(V) is being deleted due to an unnecessary reference to a general anesthesia permit (which is already covered in earlier paragraphs).

Rule 0460-02-.07 (7)(b)3 is being amended to change the word "indicated" to "recommended" when referring to a patient's need for consultation with their primary care physician before receiving sedation if they are deemed medically unstable or have a significant health disability.

Rule 0460-02-.07 (7)(b)5(v) is being amended to only requiring monitoring of end tidal CO2.

Rule 0460-02-.07 (7)(b)6(iv) is being amended to require that an automated external defibrillator to be available under emergency management.

- (B)** A citation to and brief description of any federal law or regulation or any state law or regulation mandating promulgation of such rule or establishing guidelines relevant thereto;

None.

- (C)** Identification of persons, organizations, corporations or governmental entities most directly affected by this rule, and whether those persons, organizations, corporations or governmental entities urge adoption or rejection of this rule;

These proposed rule amendments will only affect dentists who possess a conscious sedation permit or a deep sedation/general anesthesia permit. Only the licensees who possess a permit will bear the costs of the proposed rules.

- (D)** Identification of any opinions of the attorney general and reporter or any judicial ruling that directly relates to the rule;

None.

- (E)** An estimate of the probable increase or decrease in state and local government revenues and expenditures, if any, resulting from the promulgation of this rule, and assumptions and reasoning upon which the estimate is based. An agency shall not state that the fiscal impact is minimal if the fiscal impact is more than two percent (2%) of the agency's annual budget or five hundred thousand dollars (\$500,000), whichever is less;

These rule amendments should not result in any increase or decrease in state and local government revenues and expenditures.

- (F) Identification of the appropriate agency representative or representatives, possessing substantial knowledge and understanding of the rule;

Jennifer Putnam, Assistant General Counsel, Department of Health.

- (G) Identification of the appropriate agency representative or representatives who will explain the rule at a scheduled meeting of the committees;

Jennifer Putnam, Assistant General Counsel, Department of Health.

- (H) Office address, telephone number, and email address of the agency representative or representatives who will explain the rule at a scheduled meeting of the committees; and

Department of Health, 665 Mainstream Drive, Nashville, 37205, (615)741-1611, Jennifer.Putnam@tn.gov.

- (I) Any additional information relevant to the rule proposed for continuation that the committee requests.

0460-02-.07 ANESTHESIA AND SEDATION.

(1) Definitions

- (a) Advanced Cardiac Life Support (ACLS). A certification that means a person has successfully completed an advanced cardiac life support course offered by a recognized accrediting organization.
- (b) American Society of Anesthesiologists (ASA) Patient Physical Status Classification
 1. ASA I - A normal healthy patient.
 2. ASA II - A patient with mild systemic disease.
 3. ASA III - A patient with severe systemic disease.
 4. ASA IV - A patient with severe systemic disease that is a constant threat to life.
 5. ASA V - A moribund patient who is not expected to survive without the operation.
 6. ASA VI - A declared brain-dead patient whose organs are being removed for donor purposes.
 7. E - Emergency operation of any variety (used to modify one of the above classifications, i.e., ASA III-E).
- (c) Antianxiety premedication (anxiolysis). The prescription of pharmacologic substances for the relief of anxiety and apprehension.
- (d) Certified Registered Nurse Anesthetist (CRNA). A registered nurse currently licensed by the Tennessee Board of Nursing who is currently certified as such by the American Association of Nurse Anesthetists.
- (e) 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 or verbal command and that is produced by a pharmacological or non-pharmacological method or a combination thereof.
- (f) Deep sedation. An induced 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 physical stimulation or verbal command, and is produced by a pharmacological or non-pharmacological method or a combination thereof.
- (g) Enteral. Any technique of administration in which the agent is absorbed through the gastrointestinal (GI) tract or oral mucosa [i.e., oral, rectal, sublingual].
- (h) General anesthesia. An induced state of unconsciousness accompanied by partial or complete loss of protective reflexes, including the inability to continually maintain an airway independently and respond purposefully to physical stimulation or verbal command, and is produced by a pharmacological or non-pharmacological method or a combination thereof.
- (i) Health Care Provider Life Support. The skills necessary to administer cardiopulmonary resuscitation (CPR) for victims of all ages.

(Rule 0460-02-.07, continued)

- (j) Hospital. A hospital licensed by the Department of Health's Division of Health Care Facilities.
 - (k) Inhalation. A technique of administration in which a gaseous or volatile agent is introduced into the pulmonary tree and whose primary effect is due to absorption through the pulmonary bed.
 - (l) Nitrous oxide inhalation analgesia. The administration by inhalation of a combination of nitrous oxide and oxygen producing an altered level of consciousness that retains the patient's ability to independently and continuously maintain an airway and respond appropriately to physical stimulation or verbal command.
 - (m) Pediatric Advanced Life Support (PALS). A certification that means a person has successfully completed an pediatric advanced life support course offered by a recognized accrediting organization.
 - (n) Parenteral. A technique of administration in which the drug bypasses the gastrointestinal (GI) tract [i.e., intramuscular (IM), intravenous (IV), intranasal (IN), submucosal (SM), subcutaneous (SC)].
 - (o) Physician. A person licensed to practice medicine and surgery pursuant to Tennessee Code Annotated Title 63, Chapters 6 or 9.
- (2) Permits required.
- (a) No permit is required for the administration of nitrous oxide inhalation analgesia; however, dentists must comply with the provisions of 0460-02-.07 (4).
 - (b) No permit is required for the use of antianxiety premedication (anxiolysis); however, dentists must comply with the provisions of 0460-02-.07 (5).
 - (c) Dentists must obtain a permit to administer conscious sedation. A conscious sedation permit may be limited or comprehensive.
 - 1. A limited conscious sedation permit authorizes dentists to administer conscious sedation by the enteral and/or combination inhalation-enteral method.
 - 2. A comprehensive conscious sedation permit authorizes a dentist to administer conscious sedation by the enteral, combination inhalation-enteral or parenteral method.
 - 3. Children thirteen (13) and under
 - (i) Dentists who administer conscious sedation by any method to children thirteen (13) and under must have a comprehensive conscious sedation permit.
 - (ii) Agents used to produce conscious sedation/deep sedation/general anesthesia in children thirteen (13) years of age and under must be given under the direct supervision of the dentist.
 - 4. Dentists issued limited or comprehensive conscious sedation permits must comply with rule 0460-02-.07 (6).

(Rule 0460-02-.07, continued)

- (d) Dentists must obtain a permit to administer deep sedation/general anesthesia and comply with rule 0460-02-.07 (7).
- (3) Determination of degree of sedation
- (a) The degree of sedation or consciousness level of a patient is the determinant for the application of these rules, not the route of administration. Determining the degree of sedation or level of consciousness of a patient is based upon:
 - 1. The type and dosage of medication that was administered or was proposed for administration to the patient;
 - 2. The age, physical size and medical condition of the patient receiving the medication; and
 - 3. The degree of sedation or level of consciousness that should reasonably be expected to result from that type and dosage of medication.
 - (b) In a proceeding of the board at which the board must determine the degree of sedation or level of consciousness of a patient, the board will base its findings on the provisions of subparagraph (a).
- (4) Nitrous oxide inhalation analgesia.
- (a) Nitrous oxide may be administered by a licensed dentist or a licensed and properly certified dental hygienist under the direct supervision of a licensed dentist. The administering or supervising dentist must be on the premises at all times that nitrous oxide is in use.
 - (b) An authorized person must constantly monitor each patient receiving nitrous oxide. In addition to dentists, any licensed dental hygienist or registered dental assistant who has complied with rules 0460-03-.06 or 0460-04-.05 is an authorized person and may monitor patients who are receiving nitrous oxide.
 - (c) Monitoring nitrous oxide. Monitoring patients receiving nitrous oxide inhalation analgesia as an adjunct to dental or to dental hygiene procedures consists of continuous direct clinical observation of the patient and begins after the dentist or dental hygienist has initiated the analgesia. The dentist must be notified of any change in the patient which might indicate an adverse effect on the patient. Those certified in nitrous oxide monitoring may terminate the administration of nitrous oxide inhalation analgesia.
 - (d) All equipment for the administration of nitrous oxide must be designed specifically to guarantee that an oxygen concentration of no less than thirty percent (30%) can be administered to the patient.
 - (e) All equipment for the administration of nitrous oxide must be equipped with a scavenger system.
- (5) Antianxiety premedication (anxiolysis).
- (a) The regulation and monitoring of this modality of treatment are the responsibility of the ordering dentist. The drugs used should carry a margin of safety wide enough to never render unintended loss of consciousness. If the administration is for antianxiety purposes, the appropriate initial dosing of a single enteral drug can be no more than the maximum recommended dose (MRD) of a drug that can be prescribed for non-

(Rule 0460-02-.07, continued)

monitored home use. The co-administration of nitrous oxide is allowed. If the MRD is exceeded then a limited conscious sedation permit is required.

- (b) A dentist using antianxiety premedication must employ auxiliary personnel who are certified in Health Care Provider Life Support.
 - (c) All antianxiety premedications and all sedation techniques (except nitrous oxide and oxygen) used for children age thirteen (13) and under require a comprehensive conscious sedation permit.
- (6) Conscious sedation.
- (a) Dentists must obtain a permit from the Board of Dentistry to administer conscious sedation in the dental office. Conscious sedation permits are either limited or comprehensive.
 - 1. To obtain a limited conscious sedation permit, a dentist must provide proof of current certification in ACLS (a pediatric dentist may substitute PALS), and must provide proof of one (1) of the following:
 - (i) Completion of an ADA accredited postdoctoral training program which affords comprehensive training necessary to administer and manage enteral and/or combination inhalation-enteral conscious sedation, or
 - (ii) Completion of a continuing education course which consists of a minimum of twenty four (24) hours of didactic instruction plus ten (10) clinically-oriented experiences which provide competency in enteral and/or combination inhalation-enteral conscious sedation.
 - 2. To obtain a comprehensive conscious sedation permit, a dentist must provide proof of current certification in ACLS (a pediatric dentist may substitute PALS), and must provide proof of one (1) of the following:
 - (i) Completion of an ADA accredited postdoctoral training program which affords comprehensive training to administer and manage parenteral conscious sedation, or
 - (ii) Completion of a continuing education course consisting of a minimum of sixty (60) hours of didactic instruction plus the management of at least twenty (20) patients which provides competency in parenteral conscious sedation. The course content must be consistent with that described for an approved continuing education program in these techniques in the ADA Guidelines for Teaching the Comprehensive Control of Anxiety and Pain in Dentistry, 2000 edition, or its successor publication, ~~et.~~
 - ~~(iii) Possess on the effective date of this regulation a current valid intravenous conscious sedation permit issued by the board. Such dentist will be issued a new comprehensive conscious sedation permit and must comply with the general rules set forth in this regulation.~~
 - 3. Dentists who provide conscious sedation for children must provide evidence of adequate training in pediatric sedation techniques and in pediatric resuscitation including the recognition and management of pediatric airway and respiratory problems.

(Rule 0460-02-.07, continued)

4. A dentist who utilizes a Certified Registered Nurse Anesthetist (CRNA) to administer conscious sedation must have a valid comprehensive conscious sedation permit.
5. A dentist may utilize a physician (MD or DO), who is a member of the anesthesiology staff of an accredited hospital, or a permitted dentist to administer conscious sedation in that dentist's office. Such person must remain on the premises of the dental facility until all patients given conscious sedation meet discharge criteria. The office must comply with the general rules for conscious sedation, i.e. rule 0460-02-.07 (6) (b). A dentist utilizing such person and complying with these provisions does not require a conscious sedation permit.

(b) General rules for conscious sedation.

1. Physical facilities.

- (i) The treatment room must be large enough to accommodate the patient adequately on a table or in a dental chair and to allow an operating team, consisting of at least two persons, to move freely about the patient.
- (ii) The operating table or dental chair must allow the patient to be placed in a position such that the operating team can maintain the airway, allow the operating team to alter the patient's position quickly in an emergency, and provide a firm platform for the management of cardiopulmonary resuscitation.
- (iii) The lighting system must be adequate to allow an evaluation of the patient's skin and mucosal color and provide adequate light for the procedure.
- (iv) Suction equipment must be available that allows aspiration of the oral and pharyngeal cavities.
- (v) A system for delivering oxygen must have adequate full-face masks and appropriate connectors, and be capable of delivering oxygen to the patient under positive pressure.
- (vi) A recovery area must be provided that has available oxygen, adequate lighting, suction and electrical outlets. The recovery area may be the treatment room. A member of the staff must be able to observe the patient at all times during the recovery.
- (vii) An alternate lighting system sufficiently intense to allow completion of any procedure and an alternate suction device that will function effectively must be available for emergency use at the time of a general power failure.
- (viii) In offices where pediatric patients are treated, appropriate sized equipment must be available.
- (ix) Inspections of the anesthesia and sedation equipment shall be made each day the equipment is used and a log kept recording the inspection and its results.

2. Personnel.

(Rule 0460-02-.07, continued)

- (i) During conscious sedation at least one (1) person, in addition to the operating dentist, must be present.
 - (ii) Members of the operating team must be trained for their duties according to protocol established by the dentist and must be currently certified in Health Care Provider Life Support.
 - (iii) All operatory room and/or recovery personnel who provide clinical care shall hold a current, appropriate Tennessee license/registration pursuant to Tennessee Code Annotated, Title 63.
 - (iv) Unlicensed/unregistered personnel may not be assigned duties or responsibilities that require professional licensure.
 - (v) Notwithstanding the provisions of part (iv), duties assigned to unlicensed/unregistered personnel shall be in accordance with their training, education, and experience and under the direct supervision of a licensed dentist.
3. Patient evaluation. Patients subjected to conscious sedation must be suitably evaluated prior to the start of any sedative procedure. In healthy or medically stable individuals (ASA I, II) this may be simply a review of their current medical history and medication use. However with individuals who may not be medically stable or who have a significant health disability (ASA III, IV) consultation with their primary care physician or consulting medical specialist is ~~indicated~~ recommended.
4. Dental records. The dental record must include:
 - (i) A medical history including current medications and drug allergies;
 - (ii) Informed consent for the type of anesthesia used;
 - (iii) Baseline vital signs including blood pressure and pulse. If determination of baseline vital signs is prevented by the patient's age, physical resistance or emotional condition, the reason(s) should be documented;
 - (iv) A time-oriented anesthesia record which includes the drugs and dosage administered;
 - (v) Documentation of complications or morbidity; and
 - (vi) Status of the patient on discharge.
5. Monitoring
 - (i) Direct clinical observation of the patient must be continuous;
 - (ii) Interval recording of blood pressure and pulse must occur;
 - (iii) Oxygen saturation must be evaluated continuously by a pulse oximeter;
 - (iv) The patient must be monitored during recovery by trained personnel until stable for discharge;

(Rule 0460-02-.07, continued)

- (v) If monitoring procedures are prevented by the patient's age, physical resistance or emotional condition, the reason(s) should be documented; and
 - (vi) If a patient enters a deeper level of sedation than the dentist is qualified to provide, the dentist must stop the dental procedure until the patient returns to the intended level of sedation.
6. Emergency management.
- (i) Written protocols must be established by the dentist to manage emergencies related to conscious sedation including but not limited to laryngospasm, bronchospasm, emesis and aspiration, airway occlusion by foreign body, angina pectoris, myocardial infarction, hypertension, hypotension, allergic and toxic reactions, convulsions, hyperventilation and hypoventilation.
 - (ii) Training to familiarize the operating team with these protocols must be periodic and current. Regular staff education programs and training sessions shall be provided and documented which include sessions on emergencies, life safety, medical equipment, utility systems, infection control, and hazardous waste practices.
 - (iii) A cardiac defibrillator or automated external defibrillator must be available.
 - (iv) Equipment and drugs on a list available from the Board and currently indicated for the treatment of the above listed emergency conditions must be present and readily available for use. Emergency protocols must include training in the use of this equipment and these drugs.
7. Recovery and discharge.
- (i) Patients must be monitored for adequacy of ventilation and circulation. The dental record must reflect that ventilation and circulation are stable and the patient is appropriately responsive prior to discharge.
 - (ii) The dental office must develop specific criteria for discharge parameters for conscious sedation for both adult and pediatric patients.
 - (iii) The dental record must reflect that appropriate discharge instructions were given, and that the patient was discharged into the care of a responsible person.
- (7) Deep sedation/general anesthesia.
- (a) Dentists must obtain a permit from the Board of Dentistry to administer deep sedation/general anesthesia in the dental office.
 - 1. Obtaining the permit
 - (i) To obtain a deep sedation/general anesthesia permit, a dentist must provide proof of current certification in ACLS (a pediatric dentist may substitute PALS), and must provide certification of one (1) of the following:
 - (l) Successful completion of a minimum of one (1) year advanced training in anesthesiology and related academic subjects beyond the

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undergraduate dental school level in a training program as described in the most recent version of the ADA Guidelines for Teaching the Comprehensive Control of Pain and Anxiety in Dentistry, 2000 edition, or its successor publication, or

- (II) Proof of successful completion of a graduate program in oral and maxillofacial surgery which has been approved by the Commission on Accreditation of the American Dental Association; or
 - (III) Proof of successful completion of a residency program in general anesthesia of not less than one (1) calendar year that is approved by the Board of Directors of the American Dental Society of Anesthesiology for eligibility for the Fellowship in General Anesthesia or proof that the applicant is a Diplomate of the American Board of Dental Anesthesiology; or
 - (IV) ~~Possess on the effective date of this regulation a current, valid general anesthesia permit issued by the board. Such dentists will be issued a new deep sedation/general anesthesia permit and must comply with the general rules set forth in this regulation.~~
- (ii) Dentists who provide deep sedation/general anesthesia for children must provide evidence of adequate training in pediatric sedation techniques, in general anesthesia, and in pediatric resuscitation including the recognition and management of pediatric airway and respiratory problems.
2. A dentist may utilize a physician (MD or DO), who is a member of an anesthesiology staff of an accredited hospital, or another dentist who holds a deep sedation/general anesthesia permit to administer deep sedation or general anesthesia in that dentist's office. Such person must remain on the premises of the dental facility until all patients given deep sedation or general anesthesia meet discharge criteria. The office must comply with the general rules for deep sedation/general anesthesia, i.e. rule 0460-02-.07 (7) (b). A dentist utilizing such person and complying with these provisions does not require a deep sedation/general anesthesia permit.
 3. A dentist who utilizes a Certified Registered Nurse Anesthetist (CRNA) to administer deep sedation/general anesthesia must have a valid deep sedation/general anesthesia permit.
 4. A dentist who holds a deep sedation/general anesthesia permit may administer conscious sedation.
- (b) General rules for deep sedation/general anesthesia.
1. Physical facilities.
 - (i) The treatment room must be large enough to accommodate the patient adequately on a table or in a dental chair and to allow an operating team, consisting of at least three (3) persons, to move freely about the patient.
 - (ii) The operating table or dental chair must allow the patient to be placed in a position such that the operating team can maintain the airway, allow the operating team to alter the patient's position quickly in an emergency, and provide a firm platform for the management of cardiopulmonary resuscitation.

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- (iii) The lighting system must be adequate to allow an evaluation of the patient's skin and mucosal color and provide adequate light for the procedure.
 - (iv) Suction equipment must be available that allows aspiration of the oral and pharyngeal cavities.
 - (v) A system for delivering oxygen must have adequate full-face masks and appropriate connectors, and be capable of delivering oxygen to the patient under positive pressure.
 - (vi) A recovery area must be provided that has available oxygen, adequate lighting, suction and electrical outlets. The recovery area may be the treatment room. A member of the staff must be able to observe the patient at all times during the recovery.
 - (vii) An alternate lighting system sufficiently intense to allow completion of any procedure and an alternate suction device that will function effectively must be available for emergency use at the time of a general power failure.
 - (viii) In offices where pediatric patients are treated, appropriate sized equipment must be available.
 - (ix) Inspections of the deep sedation/general anesthesia equipment shall be made each day the equipment is used and a log kept recording the inspection and its results.
2. Personnel.
- (i) During deep sedation/general anesthesia at least two (2) persons, in addition to the operating dentist, must be present.
 - (ii) Members of the operating team must be trained for their duties according to protocol established by the dentist and must be currently certified in Health Care Provider Life Support.
 - (iii) When the same individual administering the deep sedation/general anesthesia is performing the dental procedure, there must be a second (2nd) individual trained in patient monitoring.
 - (iv) All operatory room and/or recovery personnel who provide clinical care shall hold a current, appropriate Tennessee license/registration pursuant to Tennessee Code Annotated, Title 63.
 - (v) Unlicensed/unregistered personnel may not be assigned duties or responsibilities that require professional licensure.
 - (vi) Notwithstanding the provisions of subpart (v), duties assigned to unlicensed/unregistered personnel shall be in accordance with their training, education, and experience and under the direct supervision of a licensed dentist.
3. Patient evaluation. Patients subjected to deep sedation/general anesthesia must be suitably evaluated prior to the start of any sedative procedure. In healthy or medically stable individuals (ASA I, II) this may be simply a review of their current

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medical history and medication use. However with individuals who may not be medically stable or who have a significant health disability (ASA III, IV) consultation with their primary care physician or consulting medical specialist is ~~indicated~~ recommended.

4. Dental records. The dental record must include:
 - (i) A medical history including current medications and drug allergies;
 - (ii) Informed consent for the type of anesthesia used;
 - (iii) Baseline vital signs including blood pressure, pulse and temperature. If determination of baseline vital signs is prevented by the patient's age, physical resistance or emotional condition the reason(s) should be documented;
 - (iv) A time-oriented anesthesia record which includes the drugs and dosage administered and an interval recording of blood pressure and pulse;
 - (v) Documentation of complications or morbidity; and
 - (vi) Status of the patient on discharge.
5. Monitoring.
 - (i) Direct clinical observation of the patient must be continuous;
 - (ii) Interval recording of blood pressure and pulse must occur;
 - (iii) Oxygen saturation must be monitored continuously by pulse oximeter;
 - (iv) Continuous EKG monitoring with electrocardioscope must occur;
 - (v) Respirations must be monitored for intubated patients by auscultation of breath sounds or end tidal CO₂ unless precluded or invalidated by the nature of the patient, procedure, or equipment;
 - (vi) If anesthetic agents implicated in the etiology of malignant hyperthermia are used, body temperature must continuously be monitored; and
 - (vii) The patient must be monitored during recovery by trained personnel until stable for discharge.
6. Emergency management.
 - (i) Written protocols must be established by the dentist to manage emergencies related to deep sedation/general anesthesia including but not limited to laryngospasm, bronchospasm, emesis and aspiration, airway occlusion by foreign body, angina pectoris, myocardial infarction, hypertension, hypotension, allergic and toxic reactions, convulsions, hyperventilation and hypoventilation.
 - (ii) If anesthetic agents implicated in the etiology of malignant hyperthermia are used, protocols to treat the malignant hyperthermia must be established.

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- (iii) Training to familiarize the operating team with these protocols must be periodic and current. Regular staff education programs and training sessions shall be provided and documented which include sessions on emergencies, life safety, medical equipment, utility systems, infection control, and hazardous waste practices.
 - (iv) A cardiac defibrillator or automated external defibrillator must be available.
 - (v) Equipment and drugs on a list available from the Board and currently indicated for the treatment of the above listed emergency conditions must be present and readily available for use. Emergency protocols must include training in the use of this equipment and these drugs.
- 7. Recovery and discharge.
 - (i) Patients must be monitored for adequacy of ventilation and circulation. The dental record must reflect that ventilation and circulation are stable and the patient is appropriately responsive prior to discharge.
 - (ii) The dental office must develop specific criteria for discharge parameters for deep sedation/general anesthesia for both adult and pediatric patients.
 - (iii) The dental record must reflect that appropriate discharge instructions were given, and that the patient was discharged into the care of a responsible adult.
- (8) Continuing education. In order to maintain a limited or comprehensive conscious sedation or deep sedation/general anesthesia permit, a dentist must:
 - (a) Maintain current certification in ACLS (a pediatric dentist may substitute PALS); or
 - (b) Certify attendance every two (2) years at a board approved course comparable to ACLS or PALS and devoted specifically to the prevention and management of emergencies associated with conscious sedation or deep sedation/general anesthesia; and
 - (c) Obtain a minimum of four (4) hours of continuing education in the subject of anesthesia and/or sedation as part of the required forty (40) hours of continuing education for dental licensure. ACLS or PALS certification shall not be included as any part of the required four (4) hours.
- (9) Reporting injury or mortality.
 - (a) A written report shall be submitted to the board by the dentist within thirty (30) days of any anesthesia-related incident resulting in patient injury or mortality, which occurred when the patient was under the care of the dentist and required hospitalization. In the event of patient mortality, concurrent with a sedation or anesthesia-related incident, this incident must be reported to the board within two (2) working days, to be followed by the written report within thirty (30) days.
 - (b) A written report shall include:
 - 1. Description of dental procedure;
 - 2. Description of preoperative physical condition of the patient;
 - 3. List of the drugs and dosages administered;

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4. Detailed description of techniques utilized in administering the drugs;
 5. Description of adverse occurrence to include:
 - (i) Detailed description of symptoms of any complications including, but not limited to, onset and type of symptoms in the patient;
 - (ii) Treatment instituted on patient; and
 - (iii) Response of the patient to treatment; and
 6. Description of the patient's condition on termination of any procedure undertaken.
- (10) Permit process (limited conscious sedation, comprehensive conscious sedation, deep sedation/general anesthesia).
- (a) To obtain a limited or comprehensive conscious sedation permit or deep sedation/general anesthesia permit, a dentist must apply on an application form provided by the board and submit the appropriate fee as established by the board.
 - (b) The applicant must submit acceptable proof to the Board:
 1. For a limited conscious sedation permit:
 - (i) That the educational requirements of 0460-02-.07 (6) (a) 1. are met; and
 - (ii) Compliance with general rules 0460-02-.07 (6) (b).
 2. For a comprehensive conscious sedation permit:
 - (i) That the educational requirements of 0460-02-.07 (6) (a) 2. are met; and
 - (ii) Compliance with general rules 0460-02-.07 (6) (b).
 3. For a deep sedation/general anesthesia permit:
 - (i) That the educational requirements of 0460-02-.07 (7) (a) have been met; and
 - (ii) Compliance with general rules 0460-02-.07 (7) (b).
 - (c) A permit must be renewed every two (2) years by payment of the appropriate renewal fee as established by the board and by certification of the continuing education requirement [0460-02-.07 (8)] and by certification of compliance with the general rules for conscious sedation [0460-02-.07 (6) (b)] or deep sedation/general anesthesia [0460-02-.07 (7) (b)].

(11) Anesthesia Consultants

- (a) In addition to the Board Consultant and his/her duties, as provided in Rule 0460-01-.03, Anesthesia Consultants shall be appointed by the board to assist the board in the administration of this rule. All Anesthesia Consultants shall be licensed to practice dentistry in Tennessee and shall all hold current, valid comprehensive conscious sedation or deep sedation/general anesthesia permits.

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- (b) The Anesthesia Consultants shall be:
 1. A periodontist;
 2. A pediatric dentist;
 3. A general dentist; and
 4. Two (2) oral and maxillofacial surgeons.
- (c) The Anesthesia Consultants shall advise the Board of Dentistry regarding the continuing education courses, to be approved by the Board, to satisfy the requirements in subpart (6) (a) 1. (ii), item (6) (a) 2. (i) (II) and subparagraph (8) (b).

Authority: T.C.A. §§4-5-202, 4-5-204, 63-5-105, 63-5-107, 63-5-108, 63-5-112, 63-5-115, 63-5-117, 63-5-122, and 63-5-124. **Administrative History:** Original rule filed December 11, 1991; effective January 25, 1992. Amendment filed May 15, 1996; effective September 27, 1996. Amendment filed February 18, 2003; effective May 4, 2003. Amendment filed December 28, 2004; effective March 13, 2005. Amendment filed July 10, 2006; effective September 23, 2006. Amendment filed September 25, 2008; effective December 9, 2008. Amendments filed October 22, 2010; effective January 20, 2011.

0460-02-.08 LICENSURE RENEWAL. All licensed dentists must renew their licenses to be able to legally continue in practice. Licensure renewal is governed by the following:

- (1) Renewal application
 - (a) The due date for licensure renewal is the last day of the month in which a licensee's birthday falls pursuant to the Division of Health Related Boards "birthdate renewal system" contained on the renewal certificate as the expiration date.
 - (b) Methods of Renewal
 1. Internet Renewals - Individuals may apply for renewal and pay the necessary fees via the Internet. The application to renew can be accessed at:

www.tennesseeanytime.org
 2. Paper Renewals - For individuals who have not renewed their license online via the Internet, a renewal application form will be mailed to each individual licensed by the Board to the last address provided to the Board. Failure to receive such notification does not relieve the licensee from the responsibility of meeting all requirements for renewal.
 - (c) A license issued pursuant to these rules is renewable by the expiration date. To be eligible for renewal an individual must submit to the Division of Health Related Boards on or before the expiration date the following:
 1. A completed renewal application form.
 2. The renewal and state regulatory fees as provided in Rule 0460-01-.02.
 3. If licensed pursuant to rule 0460-02-.03, a letter of request accompanied by a letter of recommendation from the dean or director of the educational institution.