

234 CMR 6.00: ADMINISTRATION OF ANESTHESIA AND SEDATION

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6.01: Scope

In order to ensure the protection and safety of patients, every dental facility must be properly equipped, supplied and permitted for the administration of specific types of anesthesia and levels of sedation, and every dentist and/or dental hygienist must be properly educated, trained, and permitted for the specific type of anesthesia or sedation being administered. To guarantee a wide margin of safety for the patient, the qualifications and requirements for permits for anesthesia administration shall be based on a continuum of types of procedures, equipment, drugs, qualifications and training of personnel necessary and appropriate for each type of anesthesia or sedation to be administered at the site.

The following standards are based on the *ADA Guidelines for The Use of Sedation and General Anesthesia by Dentists 2007* and the *Guidelines for Office Anesthesia On-site Evaluation of the Massachusetts Society of Oral and Maxillofacial Surgeons, 2006*, and shall be applied in determining the adequacy of the facility and competence of the personnel administering anesthesia and/or sedation.

(1) A dentist licensed to practice dentistry in the Commonwealth pursuant to M.G.L. c. 112, §§ 45 and 45A, may administer local anesthesia in a facility that complies with the requirements of 234 CMR 6.15.

(2) Facility Permits. A dental facility where general anesthesia or deep sedation, moderate sedation, minimal sedation and/or nitrous oxide-oxygen are administered shall have a Facility Permit D issued by the Board for the type of anesthesia to be administered, unless the facility is exempt from permitting requirements pursuant to 234 CMR 6.03(1)(c).

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- (3) A Facility Permit D is not required for the administration of local anesthesia only.
- (4) Individual Anesthesia Permits for a Qualified Dentist. A qualified licensee pursuant to M.G.L. c. 112, § 45 is required to obtain an Individual Anesthesia Permit issued by the Board for the type of anesthesia to be administered before he or she may administer general anesthesia, deep sedation, moderate sedation, minimal sedation, or nitrous oxide-oxygen in a dental facility having a Facility D Permit for the type of anesthesia the dentist will be administering.
- (5) Individual Anesthesia Permit for Qualified Dental Hygienist. A qualified dental hygienist is required to obtain a Permit L issued by the Board for the administration of local anesthesia under the direct supervision of a licensed dentist.
- (6) A dentist issued an individual anesthesia permit may administer anesthesia or sedation of the type authorized by his/her individual anesthesia permit only at those sites which have a Facility Permit issued by the Board for the type of anesthesia being administered by said dentist, unless the facility is exempt from these standards under 234 CMR 6.03(1)(c).
- (7) Anesthesia Administration Evaluations. The Board may conduct anesthesia administration evaluations as deemed necessary by the Board to ensure compliance with the requirements in 234 CMR 6.00. Such an evaluation may include observing the administration of anesthesia appropriate to the permit sought by the licensee. Every applicant shall be given notice by the Board of all deficiencies reported as a result of the evaluation. The Board may provide the applicant with a reasonable period of time in which any deficiencies must be corrected. If the results of the evaluation are deemed unsatisfactory, the Board may conduct a second evaluation, within a reasonable time, or upon written request of the applicant.
- (8) Inspections. The Board may require an on-site inspection of any facility, medications, equipment and qualifications of personnel utilized in the administration of general anesthesia, deep sedation, moderate sedation or nitrous oxide-oxygen sedation.
- (9) Refusal to permit an anesthesia evaluation or inspection shall constitute a valid ground for denial, suspension or revocation of an anesthesia permit.

6.02: Definitions

ADA Sedation Guidelines means the *American Dental Association Policy Statement: The Use of Sedation and General Anesthesia by Dentists; The Guidelines for Teaching Pain Control Sedation to Dentists and Dental Students 2007; and The Guidelines for the Use of Sedation and General Anesthesia by Dentists.*

AHA/ACLS Guidelines means the *2005 American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care.*

Analgesia means the diminution or elimination of pain. An analgesic (colloquially known as a "painkiller") is any member of the diverse group of drugs used to control pain.

Anesthesia means an artificially induced insensibility to pain usually achieved by the administration of gases or the use of drugs.

ASA I, II, III, and IV are classifications of patient physical status as determined by the American Society of Anesthesiologists (ASA).

Conscious Sedation means sedation in which protective reflexes are normal or minimally altered. The patient remains conscious and maintains the ability to independently maintain an airway and respond appropriately to verbal command. Conscious sedation also includes the use of other sedative agents and/or pre-medication in combination with nitrous oxide-oxygen.

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Continual means repeated regularly and frequently in a steady succession.

Continuous means prolonged without any interruption at any time.

Deep Sedation means a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained. (American Society of Anesthesiologists, adopted October 2009)

Enteral means any technique of administration in which the agent is absorbed through the gastrointestinal (GI) tract or oral mucosa (*i.e.*, oral, rectal, sublingual).

Facility Permits are issued by the Board before a qualified dentist licensed pursuant to M.G.L. c. 45 or a medical anesthesiologist licensed by the Massachusetts Board of Registration in Medicine may administer general anesthesia and/or deep sedation, moderate sedation, minimal sedation or nitrous oxide-oxygen in a dental office. A dentist owning or operating a dental facility or practice must obtain a Facility Permit in order to allow the administration of these categories of anesthesia services to be provided on the premises. The types of Facility Permits issued by the Board are:

- (a) Facility Permit D-A authorizes the administration of general anesthesia, deep, moderate, minimal sedation, and nitrous oxide-oxygen sedation at the site named on the Permit, as performed by a qualified dentist licensed to practice under M.G.L. c. 112, § 45 or by a medically licensed anesthesiologist.
- (b) Facility Permit D-B1 authorizes the administration of moderate, minimal and nitrous oxide-oxygen sedation at the site named on the Permit, as performed by a qualified dentist licensed to practice under M.G.L. c. 112, § 45 or by a medically licensed anesthesiologist.
- (c) Facility Permit D-B2 authorizes the administration of minimal sedation at the site named on the Permit, as performed by a qualified dentist licensed to practice under M.G.L. c. 112, § 45, or by a medically licensed anesthesiologist.
- (d) Facility Permit D-C authorizes the administration of nitrous oxide-oxygen sedation on the premises named on the permit by a qualified dentist licensed to practice dentistry in the Commonwealth under M.G.L. c. 112, § 45, or by a medically licensed anesthesiologist.
- (e) Facility Permit D-H authorizes the dental facility or practice site named on the Permit to contract for or host a mobile or portable anesthesia service offered by a qualified dentist licensed under M.G.L. c. 112, § 45 who holds a Facility Permit D-P, or offered by a medically licensed anesthesiologist.
- (f) Facility Permit D-P authorizes a qualified dentist to use his/her portable or mobile anesthesia equipment, drugs and personnel for the administration of general anesthesia, deep sedation, moderate sedation, minimal sedation, or nitrous oxide-oxygen sedation at a dental facility or dental practice that possesses a Facility Permit D-H.

General Anesthesia means a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug induced depression of neuromuscular function. Cardiovascular function may be impaired. (American Society of Anesthesiologists, adopted October 2009)

Immediately Available means physically located in the facility and ready for immediate response or utilization.

Incremental Dosing means administration of multiple doses of a drug until a desired effect is reached, but not to exceed the maximum recommended dose.

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Individual Anesthesia Permits are permits authorizing qualified dentists to administer deep sedation and general anesthesia, moderate sedation, minimal sedation, and/or nitrous oxide-oxygen sedation that may be issued by the Board to a dentist licensed to practice pursuant to M.G.L. c. 112, § 45 who meets the qualifications specified in 234 CMR 6.10, 6.11, 6.12, 6.13, and/or 6.14. The following individual anesthesia permits may be issued:

- (a) Individual Permit A authorizes a qualified dentist to administer general anesthesia, deep sedation, moderate sedation, minimal sedation, and nitrous oxide-oxygen in a dental facility that has the required Facility Permit for the type of anesthesia being administered by said dentist.
- (b) Individual Permit B-1 authorizes a qualified dentist to administer moderate sedation and nitrous oxide-oxygen in conjunction with any other anesthetic or enteral sedative agents dispensed or administered in the dental facility that has the required Facility Permit for the type of anesthesia being administered by said dentist.
- (c) Individual Permit B-2 authorizes a qualified dentist to administer minimal sedation and/or nitrous oxide-oxygen in conjunction with an enteral agent dispensed or administered in the dental facility that has the required Facility Permit for the type of anesthesia being administered by said dentist.
- (d) Individual Permit C authorizes a qualified dentist to administer nitrous oxide-oxygen alone, or in conjunction with a local anesthetic in a dental facility that has the required Facility Permit for the type of anesthesia being administered by said dentist.

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

Local Anesthesia means the elimination of sensation, especially pain, in one part of the body by the topical application or regional injection of a drug. Administration of local anesthesia requires awareness of the maximum, safe dosage limits for each patient.

Maximum Recommended Dose means the maximum FDA-recommended dose of a drug as printed in FDA approved labeling for unmonitored home use.

Minimal Sedation (Anxiolysis) is a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and physical coordination may be impaired, airway reflexes, and ventilatory and cardiovascular functions are unaffected. (American Society of Anesthesiologists, adopted October 2009).

Mobile Anesthesia Permit P means a permit issued by the Board to a qualified dentist anesthesiologist who travels to a dental office(s) bringing equipment, supplies, drugs and qualified staff for the purpose of providing mobile or portable anesthesia or sedation services at a dental office which has the required Facility Permit D-H to contract or host an anesthesia service that uses portable or mobile dental anesthesia equipment, drugs, and personnel.

Moderate Sedation is a drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained. *American Society of Anesthesiologists*, adopted October 2009. Administration of moderate sedation includes parenteral, enteral and/or combination inhalation-ental conscious sedation.

Nitrous Oxide-oxygen Sedation means conscious sedation accomplished solely by the use of nitrous oxide-oxygen.

Operating Dentist means a dentist licensed pursuant to M.G.L. c. 112, § 45 to practice dentistry in the Commonwealth who provides treatment to the patient.

Parenteral means a technique of administration in which drugs bypass the gastrointestinal (GI) tract, *e.g.* through intramuscular (IM), intravenous (IV), intranasal (IN), sub mucosal (SM), subcutaneous (SC), or intraosseous (IO) administration.

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Pediatric Advanced Life Support (PALS) Certification means that an individual has successfully completed a pediatric advanced life support course offered by the American Heart Association or other entity approved by the Board.

Permit L means a permit issued by the Board to a dental hygienist who is qualified to administer local anesthesia under the direct supervision of a dentist licensed to practice pursuant to M.G.L. c. 112, § 45.

Qualified Dentist means a dentist licensed pursuant to M.G.L. c. 112, § 45 to practice dentistry in the Commonwealth who has completed the appropriate education and training and holds a current permit to administer deep sedation and general anesthesia, moderate sedation, minimal sedation, and/or nitrous oxide-oxygen pursuant to 234 CMR 6.00.

Routes of Administration include parenteral, enteral, and inhalation-enteral methods.

Supplemental Dosing means the administration of a single additional dose of the initial drug administered during sedation.

Time-oriented Anesthesia Record means documentation of drugs, doses, and physiologic data obtained during patient monitoring at appropriate time intervals.

Titration means the administration of incremental doses of a drug until the desired effect is reached, and applies to achieving moderate and deeper levels of sedation.

Transdermal means a technique of administration in which a drug is administered by patch or iontophoresis through the skin.

Transmucosal means a technique of administration in which the drug is administered across mucosa such as intranasal, sublingual, or rectal.

6.03: Facility Permit: Anesthesia Permits Required for Facilities

(1) General Requirements.

- (a) Prior to the administration of general anesthesia and/or deep sedation, moderate sedation, minimal sedation, or nitrous oxide-oxygen in a dental office by a qualified dentist as described in 234 CMR 6.02, or a medical anesthesiologist licensed by the Massachusetts Board of Medicine, a dental facility must obtain a Facility Permit issued by the Board to allow the administration of these anesthesia services on the premises.
- (b) The Board may issue a Facility Permit for a specific office site in the name of a dentist who is qualified and licensed pursuant to M.G.L. c. 112, § 45.
- (c) Exemption: A Facility Permit is not required for the administration of anesthesia at those hospital and/or dental school settings that have been approved by the Joint Commission on Accreditation of Hospitals or the Commission on Accreditation of the Council on Education of the American Dental Association, or for hospitals and clinics licensed pursuant to M.G.L. c. 111, §§ 51 through 56. A private dental office of a licensed dentist that is located within a hospital or dental school facility, however, is subject to 234 CMR 6.00.
- (d) A Facility Permit issued by the Board shall be posted in each office in a public area.
- (e) A Facility Permit issued by the Board is not transferable to another person, site, location, facility or entity.

(2) Initial Application and Renewal of a Facility Permit.

- (a) Initial Application for a Facility Permit shall be submitted on forms provided by the Board and shall be accompanied by:
 1. The permit fee, to be determined annually by the Executive Office of Administration and Finance; and
 2. Documentation demonstrating compliance with any and all requirements for the permit for the type(s) of anesthesia to be administered at the site(s) named in the application.

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(b) Renewal of a Facility Permit shall be biennial, at the same time the applicant's license to practice dentistry is renewed, and shall be made on forms provided by the Board and accompanied by the permit fee, to be determined annually by the Executive Office of Administration and Finance.

6.04: Facility Permit D-A: Facility Requirements for the Administration of General Anesthesia and Deep Sedation

(1) Application. An applicant shall submit an accurate and complete application on form(s) provided by the Board and accompanied by the permit fee to be determined annually by the Executive Office of Administration and Finance. The application shall, at a minimum, include the following:

- (a) Applicant name and Massachusetts dental license number;
- (b) Name(s) of dental establishment(s), owner(s) of said establishment(s), and address(es) of the site(s) where anesthesia will be administered;
- (c) Documentation of provision and maintenance of equipment, materials, and drugs required for the administration of general anesthesia and deep, moderate, minimal and nitrous oxide-oxygen sedation; and either
 1. A written request for an on-site inspection conducted by the Board; or
 2. A certificate of successful completion of an on-site inspection conducted by the Massachusetts Society of Oral and Maxillofacial Surgeons, if eligible by membership in that organization.

(2) Equipment Required for Facility Permit D-A. The following equipment shall be required to be provided and maintained on-site:

- (a) Alternative light source for use during power failure;
- (b) Ambu-bag or portable bag-mask ventilator;
- (c) Automated or manual external defibrillator;
- (d) Current certifications in Advanced Cardiac Life Support (ACLS);
- (e) Disposable CPR masks, pediatric and adult;
- (f) Disposable syringes (assorted sizes);
- (g) Endotracheal tubes with inflatable cuffs and other equipment designed to maintain patient airway including:
 1. Pediatric endotracheal tubes, assorted sizes;
 2. Adult endotracheal tubes, assorted sizes;
 3. Connectors from tubes to gas delivery machines;
 4. Syringe for cuff inflation; and
 5. Stylet.
- (h) Endotracheal tube forceps;
- (i) Equipment for emergency crico-thyroidotomy and/or tracheostomy with appropriate connectors to deliver 100% oxygen and establish an emergency airway;
- (j) Equipment for the insertion and maintenance of an intravenous infusion
- (k) Equipment suitable for proper positioning of the patient for administration of cardio-pulmonary resuscitation, including a back board;
- (l) Equipment for continuous monitoring during anesthesia;
- (m) Gas delivery system capable of positive pressure ventilation, which must include:
 1. Oxygen;
 2. Safety-keyed hose attachments;
 3. Capability to administer 100% oxygen in all rooms (operatory, recovery, examination, and reception);
 4. Gas storage in compliance with safety codes;
 5. Adequate waste gas scavenging system; and
 6. Nasal hood or cannula.
- (n) Laryngoscope (straight and/or curved blades, assorted sizes; extra batteries and bulbs);
- (o) Latex free tourniquet;
- (p) List of emergency telephone numbers clearly visible;
- (q) Magill forceps or other suitable instruments;
- (r) Means of monitoring blood pressure (pediatric and adult);

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- (s) Means of monitoring heart rate and rhythm, with battery pack back-up;
- (t) Means of monitoring respirations;
- (u) Means of monitoring temperature;
- (v) Means of transporting patients;
- (w) Method to accurately record elapsed time;
- (x) Nasopharyngeal airways (pediatric and adult);
- (y) Oropharyngeal airways (pediatric and adult);
- (z) Oxygen (portable Cylinder E tank) pediatric and adult masks capable of giving positive pressure ventilation including bag-valve-mask system;
- (aa) Scavenger system, if inhalation agents are used;
- (bb) Sphygmomanometer and stethoscope (pediatric and adult);
- (cc) Suction:
 1. Suction catheter for endotracheal tube;
 2. Tonsillar suction tip;
 3. Suction equipment for use during power failure; and
 4. Capability of suction in all operatories and recovery rooms.
- (dd) Schedule and log for checking and recording dates when anesthesia accessories and supply of emergency drugs have been checked;
- (ee) If nitrous oxide and oxygen delivery equipment capable of delivering less than 25% oxygen is used, an in-line oxygen analyzer must be used; and
- (ff) Any other equipment as may be required by the Board.

(3) Drugs Required for Facility Permit D-A. The following drugs and/or categories of drugs shall be provided and maintained in accordance with the AHA/ACLS Guidelines (234 CMR 6.02) or as determined by the Board for emergency use. All drugs shall be current and not expired.

- (a) Acetylsalicylic acid (rapidly absorbable form);
- (b) Ammonia inhalants;
- (c) Anticonvulsant;
- (d) Antihistamine;
- (e) Antihypoglycemic agent;
- (f) Antihypertensive medications;
- (g) Antiemetic;
- (h) Atropine;
- (i) Bronchodilator;
- (j) Corticosteroid;
- (k) Dantrolene Sodium (required if a halogenated anesthesia agent *e.g.* halothane, enflurane, isoflurane is used or depolarizing skeletal muscle relaxants *e.g.* succinylcholine are administered);
- (l) Epinephrine pre-loaded syringes and ampules (pediatric and adult);
- (m) Lidocaine;
- (n) Intravenous antihypoglycemic agent (dextrose 50% or glucagon);
- (o) Medication to treat supraventricular tachycardia (*e.g.* adenosine, verapamil, *etc.*);
- (p) Muscle relaxants;
- (q) Narcotic antagonist and reversing agents;
- (r) Oxygen;
- (s) Sodium bicarbonate;
- (t) Succinylcholine;
- (u) Vasodilator;
- (v) Vasopressor; and
- (w) And any other drugs or categories of drugs as may be required by the Board.

6.05: Facility Permit D-B1: Facility Requirements for Administration of Moderate Sedation including Nitrous Oxide-oxygen in Conjunction with any Anesthetic or Enteral Sedative Agents Dispensed or Administered in the Dental Facility

(1) Application. An applicant shall submit an accurate and complete application on form(s) provided by the Board and accompanied by the permit fee to be determined annually by the Executive Office of Administration and Finance. The application shall, at a minimum, include the following:

- (a) Applicant name and Massachusetts dental license number;
- (b) Name(s) of dental establishment(s), owner(s) of said establishment, and address(es) of the site(s) where anesthesia will be administered;
- (c) Documentation of provision and maintenance of equipment, materials, and drugs required for the administration of moderate, minimal and nitrous oxide-oxygen sedation;
- (d) A written request for an on-site inspection conducted by the Board; and
- (e) Other information as may be requested by the Board.

(2) Equipment Required for a Facility Permit D-B1. The following equipment shall be required to be provided and maintained on-site:

- (a) Alternative light source for use during power failure;
- (b) Automated or manual external defibrillator;
- (c) Disposable syringes, assorted sizes;
- (d) Disposable CPR masks (pediatric and adult);
- (e) Equipment suitable for proper positioning of the patient for administration of cardio-pulmonary resuscitation, including a back board;
- (f) Equipment and maintenance of an intravenous infusion (if IV medications are to be administered by a qualified dentist who is educated and trained commensurate with the *ADA Guidelines of Teaching Pain Control Sedation to Dentists and Dental Students 2007*);
- (g) Gas delivery system capable of positive pressure ventilation, which must include:
 - 1. Oxygen;
 - 2. Safety-keyed hose attachments;
 - 3. Capability to administer 100% oxygen in all rooms (operatory, recovery, examination, and reception);
 - 4. Gas storage in compliance with safety codes;
 - 5. Adequate waste gas scavenging system; and
 - 6. Nasal hood or cannula.
- (h) Latex free tourniquet;
- (i) Means of monitoring vital signs (pediatric and adult);
- (j) Oxygen (portable Cylinder E tank) pediatric and adult masks capable of giving positive pressure ventilation (including bag-valve-mask system);
- (k) Pulse oximeter with battery pack;
- (l) Sphygmomanometer and stethoscope (pediatric and adult);
- (m) Suction;
- (n) Supervised area for recovery; and
- (o) Any other equipment as may be required by the Board.

(3) Drugs Required for a Facility Permit D-B1 Permit. The following drugs and/or categories of drugs shall be provided and maintained in accordance with the AHA/ACLS Guidelines (234 CMR 6.02) or as determined by the Board for emergency use. All drugs shall be current and not expired.

- (a) Acetylsalicylic acid (readily absorbable form);
- (b) Ammonia inhalants;
- (c) Anticonvulsant;
- (d) Antihistamine;
- (e) Antihypoglycemic agent;
- (f) Bronchodilator;
- (g) Corticosteroid;
- (h) Epinephrine preloaded syringes (pediatric and adult);
- (i) Two epinephrine ampules;
- (j) Oxygen;
- (k) Vasodilator;

6.05: continued

- (l) Vasopressor;
- (m) Reversal agents; and
- (n) Any other drug or category of drugs as may be required by the Board.

6.06: Facility Permit D-B2: Facility Requirements for Administration of Minimal Sedation and/or Nitrous Oxide-oxygen in Conjunction with an Enteral Agent Dispensed or Administered in a Dental Facility

(1) Application. An applicant shall submit an accurate and complete application on form(s) provided by the Board and accompanied by the permit fee to be determined annually by the Executive Office of Administration and Finance. The application shall, at a minimum, include the following:

- (a) Applicant name and Massachusetts dental license number;
- (b) Name(s) of dental establishment(s), owner(s) of said establishment, and address(es) of the site(s) where anesthesia will be administered;
- (c) Documentation of provision and maintenance of equipment, materials, and drugs required for the administration of minimal and nitrous oxide-oxygen sedation;
- (d) A written request for an on-site inspection conducted by the Board; and
- (e) Any other information as may be requested by the Board.

(2) Equipment Required for a Facility Permit D-B2. The following equipment shall be required to be provided and maintained on-site:

- (a) Alternative light source for use during power failure;
- (b) Automated or manual external defibrillator;
- (c) Disposable CPR masks (pediatric and adult);
- (d) Disposable syringes, assorted sizes
- (e) Equipment suitable for proper positioning of the patient for administration of cardio-pulmonary resuscitation, including a back board;
- (f) Gas delivery system capable of positive pressure ventilation, which must include:
 - 1. Oxygen;
 - 2. Safety-keyed hose attachments;
 - 3. Capability to administer 100% oxygen in all rooms (operatory, recovery, examination, and reception);
 - 4. Gas storage in compliance with safety codes;
 - 5. Adequate waste gas scavenging; and
 - 6. Nasal hood or cannula.
- (g) Latex free tourniquet;
- (h) Means of monitoring vital signs (pediatric and adult);
- (i) Oxygen (portable Cylinder E tank) pediatric and adult masks capable of giving positive pressure ventilation (including bag-valve-mask system);
- (j) Pulse oximeter with battery pack;
- (k) Sphygmomanometer and stethoscope (pediatric and adult);
- (l) Suction;
- (m) Supervised area for recovery; and
- (n) Any other equipment as may be required by the Board.

(3) Drugs Required for a Facility Permit D B-2. The following drugs and/or categories of drugs shall be provided and maintained in accordance with the AHA/ACLS Guidelines (234 CMR 6.02) or as determined by the Board for emergency use. All drugs shall be current and not expired.

- (a) Acetylsalicylic acid (readily absorbable form);
- (b) Ammonia inhalants;
- (c) Anticonvulsant;
- (d) Antihistamine;
- (e) Antihypoglycemic agent;
- (f) Bronchodilator;
- (g) Corticosteroid;
- (h) Epinephrine-preloaded syringes (pediatric and adult);
- (i) Oxygen;

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- (j) Reversal agents;
- (k) Two epinephrine ampules;
- (l) Vasodilator;
- (m) Vasopressor; and
- (n) Any other drugs or categories of drugs as may be required by the Board.

6.07: Facility Permit D-C: Administration of Nitrous Oxide-oxygen Sedation Only

(1) Application. An applicant shall submit an accurate and complete application on form(s) provided by the Board and accompanied by the permit fee to be determined annually by the Executive Office of Administration and Finance. The application shall, at a minimum, include the following:

- (a) Applicant name and Massachusetts dental license number;
- (b) Name(s) of dental establishment(s), owner(s) of said establishment(s), and address(es) of the site(s) where anesthesia will be administered; and
- (c) Documentation of the provision and maintenance of equipment, materials, and drugs required for emergency response and the administration of nitrous oxide-oxygen sedation.

(2) Equipment Required for a Facility Permit D-C.

- (a) Alternative light source for use during power failure;
- (b) Automated or manual external defibrillator, except that the manual defibrillator shall only be operated by an individual certified in ACLS or PALS;
- (c) Disposable CPR masks (pediatric and adult);
- (d) Disposable syringes (assorted sizes);
- (e) Gas delivery system capable of positive pressure, which must include:
 1. An oxygen fail-safe system;
 2. Safety-keyed hose attachments;
 3. Capability to administer 100% oxygen in all rooms (operator, recovery, examination, and reception);
 4. Gas storage in compliance with safety codes;
 5. Adequate waste gas scavenging; and
 6. Nasal hood or cannula.
- (f) Pulse oximeter;
- (g) Sphygmomanometer and stethoscope (pediatric and adult);
- (h) Suction; and
- (i) Any other equipment as may be required by the Board.

(3) Drugs Required for a Facility Permit D-C. The following drugs and/or categories of drugs shall be provided and maintained in accordance with the AHA/ACLS Guidelines (234 CMR 6.02) or as determined by the Board for emergency use. All drugs shall be current and not expired.

- (a) Acetylsalicylic acid (readily absorbable form);
- (b) Ammonia inhalants;
- (c) Antihistamine;
- (d) Antihypoglycemic agent;
- (e) Bronchodilator;
- (f) Epinephrine preloaded syringes (pediatric and adult);
- (g) Two epinephrine ampules;
- (h) Oxygen;
- (i) Vasodilator; and
- (j) Any other drugs or categories of drugs as may be required by the Board.

6.08: Mobile Facility Permit D-H: Facility Requirements for Dental Offices Using Mobile and/or Portable Anesthesia Services

Each dental facility or practice site utilizing mobile or portable anesthesia services is required to have a Facility Permit D-H. The operating dentist shall be responsible for ensuring that the qualified dental anesthesiologist has the proper individual anesthesia permit issued by the Board, and that the portable anesthesia service is appropriately permitted and equipped in accordance with 234 CMR 6.00 for the level of pain control and/or sedation to be provided.

(1) Application. An applicant shall submit an accurate and complete application on form(s) provided by the Board and accompanied by the permit fee to be determined annually by the Executive Office of Administration and Finance. The application shall, at a minimum, include the following:

- (a) Applicant name and Massachusetts dental license number;
- (b) Name(s) of dental establishment(s), owner(s) of said establishment(s), and address(es) of the site(s) where anesthesia will be administered; and
- (c) Documentation of the provision and maintenance of equipment, materials, and drugs and emergency response protocols required by the Board pursuant to 234 CMR 6.08(2).

(2) Equipment and Drugs Required for Facility Permit D-H. Equipment and Drugs Required for Facility Permit D-H. A facility that hosts a mobile or portable dental anesthesia service will be required, at a minimum, to have the following equipment supplies and drugs:

(a) Equipment and Supplies:

1. Alternative light source for use during power failure;
2. Automated or manual external defibrillator, except that the manual defibrillator shall only be operated by an individual certified in ACLS or PALS;
3. Disposable CPR masks (pediatric and adult);
4. Disposable syringes, assorted sizes;
5. Latex-free tourniquet;
6. Oxygen (portable Cylinder E tank) pediatric and adult masks capable of giving positive pressure ventilation (including bag-valve-mask system);
7. Sphygmomanometer and stethoscope (pediatric and adult);
8. Suction; and
9. Any other equipment as may be required by the Board.

(b) Drugs. The following drugs and/or categories of drugs shall be provided and maintained in accordance with the AHA/ACLS Guidelines (234 CMR 6.02) or as determined by the Board for emergency use. All drugs shall be current and not expired

1. Acetylsalicylic acid (readily absorbable form);
2. Ammonia inhalants;
3. Antihistamine;
4. Antihypoglycemic agent;
5. Bronchodilator;
6. Epinephrine preloaded syringes (pediatric and adult);
7. Two epinephrine ampules;
8. Oxygen;
9. Vasodilator; and
10. Any other drugs or categories of drugs as may be required by the Board.

(3) The operating dentist shall be responsible for ensuring that the qualified dental anesthesiologist has the proper anesthesia permit and that the portable anesthesia service is appropriately permitted for the level of pain control and/or sedation to be provided.

6.09: Facility Permit D-P: Requirements for the Use and Provision of Portable and/or Mobile Anesthesia Services

(1) A qualified dentist anesthesiologist who travels to dental facilities or practice sites for the purpose of delivering anesthesia services or sedation services at the site must hold a Mobile Facility D-P Permit for the use of portable and/or mobile anesthesia equipment, supplies and personnel.

6.09: continued

(2) Application. Each applicant shall submit an accurate and complete application on form(s) provided by the Board and accompanied by the permit fee to be determined annually by the Executive Office of Administration and Finance. The application shall, at a minimum, include the following:

- (a) Applicant name and Massachusetts dental license number, and copy of current Individual Anesthesia Permit number or copy of a permit application pending approval by the Board;
- (b) Name(s) of dental establishment(s), owner(s) of said establishment(s), and address(es) of the site(s) where mobile or portable anesthesia will be administered;
- (c) Documentation of provision and maintenance of equipment, materials, and drugs required for the administration of the type of anesthesia to be administered;
- (d) Request for an on-site inspection by the Board of the applicant's equipment, supplies, anesthesia administration protocols, and site(s) where anesthesia will be administered;
- (e) Names and qualifications of staff who will assist the applicant in the administration of anesthesia;
- (f) Copies of the following:
 - 1. Proof of current ACLS (BLS for auxiliaries) certification for the applicant and other dental professionals, as applicable for the type of anesthesia or sedation to be administered by the applicant;
 - 2. Medical history form to be utilized by the applicant;
 - 3. Anesthesia chart;
 - 4. Schedule of drug and equipment checks;
 - 5. Written protocol for management of emergencies;
 - 6. Schedule of emergency drills; and
 - 7. List of drugs and equipment that the applicant will provide at each site.
- (g) Other information as may be requested by the Board.

(3) The holder of a Facility Permit D-P shall comply with requirements of 234 CMR 6.00 pertaining to the category of anesthesia/sedation to be administered including:

- (a) Equipment and drugs;
- (b) Auxiliary personnel;
- (c) Patient evaluation;
- (d) Pre-operative preparation;
- (e) Patient monitoring and documentation;
- (f) Management of recovery and discharge of patients;
- (g) Management of pediatric and special needs patients; and
- (h) Emergency management.

(4) The holder of a Facility Permit D-P shall:

- (a) Comply with requirements of the Board pursuant to 234 CMR 5.05 and the reporting of adverse occurrences, pursuant to 234 CMR 6.17;
- (b) Employ and provide immediate supervision of at least one dental or clinical auxiliary who is trained and qualified to assist in anesthesia administration and who is fully familiar with the procedures and protocols of the permit holder at each site where anesthesia is being administered by said permit holder;
- (c) Schedule and perform maintenance checks of all equipment conducted by a certified equipment vendor at least once per year, and retain maintenance records for a minimum of three years;
- (d) Conduct annual emergency drills for all staff involved in the administration of anesthesia, and retain records that describe the dates of the training activities, content of the training, and the attendance roster for a minimum of three years; and
- (e) Place a copy of the anesthesia chart in the patient's dental record at the site where the anesthesia was administered.

(5) The Facility Permit D-P, or a copy thereof, shall be prominently displayed in the facility by the qualified dental anesthesiologist whenever and wherever he/she is providing anesthesia services.

(6) The operating dentist shall be responsible for verifying that the qualified dental anesthesiologist has the proper anesthesia permit and that the portable anesthesia service is appropriately permitted for the level of pain control and/or sedation to be provided.

6.09: continued

(7) The qualified dental anesthesiologist shall be responsible for verifying that the operating dentist and his/her clinical staff maintain current certification in ACLS or BLS for Healthcare Providers, as applicable given the type of anesthesia being administered.

(8) There shall be a written and signed agreement between the Facility Permit D-P applicant and the operating dentist for each site where anesthesia is to be administered by the Facility Permit D-P holder which, at a minimum describes how emergency response training and protocols will be developed and practiced, procedures for verifying qualifications of personnel who assist in the care and monitoring of the patient, responsibilities for pre- and post-operative patient assessment and monitoring, responsibilities for obtaining informed consent, and how compliance with applicable board statutes and regulations will be achieved and maintained at the site.

6.10: Requirements for Individual Anesthesia Permits for the Administration of General Anesthesia, Deep Sedation, Moderate Sedation, Minimal Sedation Nitrous Oxide-oxygen, and Local Anesthesia

(1) The Board may issue an anesthesia permit to administer deep sedation and general anesthesia, moderate sedation, minimal sedation, and nitrous oxide-oxygen sedation to a dentist licensed under the provisions of M.G.L. c. 112, § 45 who meets the qualifications described in 234 CMR 6.00.

(2) The Board may issue a dental hygienist licensed to practice pursuant to M. G. L. c. 112, § 51 a Permit L to administer local anesthesia under the direct supervision of a licensed dentist.

(3) Renewal of Individual Anesthesia Permits. An Individual Anesthesia Permit shall be renewed biennially by March 31st of even-numbered years. (234 CMR 4.10). The application for renewal of an Individual Anesthesia Permit shall be accompanied by the permit fee to be determined annually by the Executive Office of Administration and Finance.

Exemption: A dentist holding an Individual Anesthesia Permit issued on or before August 20, 2010 shall be exempt from the educational requirements contained in 234 CMR 6.00.

6.11: Individual Permit A: Administration of General Anesthesia and/or Deep Sedation

(1) Initial Application Requirements. An applicant shall submit an accurate and complete application on forms provided by the Board and accompanied by a fee established annually by the Executive Office of Administration and Finance, and includes documentation that demonstrates proof that the applicant:

- (a) Is a dentist licensed under M.G.L. c. 112, § 45 to practice in the Commonwealth;
- (b) Has current certification in ACLS or PALS;
- (c) Has successfully completed an education program accredited by the ADA Commission on Dental Accreditation that provides comprehensive and appropriate training necessary to administer and manage deep sedation or general anesthesia, commensurate with Part III C of the *ADA Guidelines for the Use of Sedation and General Anesthesia, 2007* at the time training was commenced; or
- (d) Is certified by the American Board of Oral and Maxillofacial Surgery (ABOMS); or
- (e) Is certified as a Fellow and/or has Board certification in Anesthesia issued by the American Dental Board of Anesthesiology.

(2) Auxiliary Personnel Required. A qualified dentist administering deep sedation and general anesthesia must have a minimum of three individuals present during the procedure:

- (a) A dentist qualified in accordance with 234 CMR 6.11; and
- (b) Two additional individuals who have been appropriately trained to assist in anesthesia administration and have current certification in BLS for the Healthcare Provider.
- (c) When the same individual administering the deep sedation or general anesthesia is performing the dental procedure, one of the additional appropriately trained auxiliaries must be designated specifically for patient monitoring.

6.11: continued

(3) **Patient Evaluation Required.** Patients considered for deep sedation or general anesthesia must be suitably evaluated prior to the start of any sedative procedure. For healthy or medically stable patients (ASA I, II), this must consist of a review of their current medical history and medication use and NPO status. For patients with a significant medical history (ASA III, IV), consultation with their primary care physician or consulting medical specialist may be required.

(4) **Pre-operative Preparation Required.** Pre-operative preparation for the administration of deep sedation or general anesthesia shall include:

- (a) The patient shall be advised regarding the procedure associated with the delivery of any sedative or anesthetic agents and a signed informed consent (234 CMR 5.15(3)(f)) for the proposed sedation/anesthesia shall be obtained prior to the administration of general anesthesia or deep sedation;
- (b) Determination of adequate oxygen supply and equipment necessary to deliver oxygen under positive pressure must be completed;
- (c) Baseline vital signs, including blood pressure, respiration, and heart rate, must be obtained and documented in the patient record. If the patient's behavior or condition prohibits such determination, this must be documented in the patient record. The temperature of pediatric patients administered general anesthesia/deep sedation must be monitored;
- (d) A medical history must be completed and problem-focused physical evaluation must be performed where deemed appropriate;
- (e) Specific dietary instructions must be provided to the patient based upon the type of sedative/anesthetic technique prescribed and patient's physical status;
- (f) Pre-operative verbal and written instructions must be given to the patient; and
- (g) An intravenous line, which is secured throughout the procedure, must be established except as provided for pediatric and/or special needs patients (*see* 234 CMR 6.11(7)).

(5) **Patient Monitoring and Documentation Required.**

(a) A qualified dentist administering deep sedation or general anesthesia must remain in the room with the patient to monitor the patient continuously until the patient meets the criteria for recovery and must not leave the facility until the patient meets the criteria for discharge and is discharged from the facility.

(b) Monitoring and documentation of patient administered deep sedation or general anesthesia shall include, but not be limited to, continuous monitoring and evaluation of :

1. Color of mucosa, skin or blood (monitoring only);
2. Oxygenation saturation by pulse oximetry;
3. For intubated patient, end-tidal CO₂;
4. For non-intubated patient, breath sounds via auscultation and/or end-tidal CO₂;
5. Respiration rate;
6. Heart rate and rhythm via ECG and pulse oximetry;
7. Blood pressure (unless the patient is unable to tolerate such monitoring which must be specifically noted in the patient record);
8. A device capable of measuring body temperature must be readily available; and
9. Body temperature whenever triggering agents associated with malignant hyperthermia are administered.

(c) **Anesthesia Chart.** The Anesthesia Chart shall contain documentation of all events related to the administration of the sedative or anesthetic agents, including but not limited to the following:

1. Time-oriented anesthesia record including the names of all drugs administered, including local anesthetics, and date, dosage and method of administration;
2. Pulse oximetry and end-tidal CO₂ measurements (if taken), heart rate, respiratory rate and blood pressure recorded at specific intervals during the procedure;
3. The duration of the procedure; and
4. The individuals present during the procedure.

(6) **Requirements for Management of Recovery and Discharge of Patients.** The recovery and discharge procedures for a patient administered deep sedation or general anesthesia, shall include, but not be limited to:

6.11: continued

- (a) Immediate availability of oxygen and suction equipment;
- (b) Continuous monitoring and documentation of the patient's blood pressure, heart rate, oxygenation and level of consciousness;
- (c) Determination and documentation that the level of consciousness, oxygenation, ventilation, and circulation are satisfactory for discharge; and
- (d) Documentation that post-operative verbal and written instructions have been provided to patient and responsible person.

(7) Requirements for Management of Pediatric and Special Needs Patients. The Board adopts the *American Academy of Pediatrics/American Academy of Pediatric Dentistry's Guidelines for Monitoring and Management of Pediatric Patients During and After Sedation of Diagnostic and Therapeutic Procedures*, and the American Dental Association's guidance on pediatric and special needs patients as contained in its *Policy Statement on The Use of Sedation and General Anesthesia by Dentists* (2007).

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

6.12: Individual Permit B-1: Administration of Moderate Sedation and Nitrous Oxide-oxygen in Conjunction with any Other Anesthetic or Enteral Sedative Agents Dispensed or Administered in a Dental Facility

(1) Initial Application Requirements. An applicant shall submit an accurate and complete application on forms provided by the Board and accompanied by a fee established annually by the Executive Office of Administration and Finance, and includes documentation that demonstrates proof the applicant:

- (a) Is a dentist licensed under M.G.L. c. 112, § 45 to practice in the Commonwealth;
- (b) Has current certification in ACLS or PALS;
- (c) Has successfully completed an education program accredited by the ADA Commission on Dental Accreditation that provides comprehensive and appropriate training necessary to administer and manage moderate sedation commensurate with the *ADA Guidelines for Teaching Pain Control Sedation to Dentists and Dental Students*, 2007, at the time training was commenced; or
- (d) Is certified by the American Board of Oral and Maxillofacial Surgery (ABOMS); or
- (e) Is certified as a Fellow and/or has Board certification in Anesthesia issued by the American Dental Board of Anesthesiology.

(2) Auxiliary Personnel Required. A qualified dentist inducing moderate sedation must have at least two additional individuals trained in BLS present during the administration of the anesthesia.

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

(4) Pre-operative Preparation Required. Pre-operative preparation for the administration of moderate sedation shall include:

- (a) The patient or legal representative shall be advised regarding the procedure associated with the delivery of any sedative or anesthetic agents and a signed informed consent shall be obtained pursuant to 234 CMR 5.15(3)(f) for the proposed sedation/anesthesia obtained prior to the administration of the anesthesia or sedative agent(s);

6.12: continued

- (b) Determination of adequate oxygen supply and equipment necessary to deliver oxygen under positive pressure must be completed;
 - (c) Baseline vital signs, including blood pressure, respiration, and heart rate, must be obtained and documented in the patient record. If the patient's behavior prohibits such determination, this must be documented in the patient record;
 - (d) A medical history must be completed and problem focused physical evaluation must be performed where deemed appropriate;
 - (e) Specific dietary instructions must be provided to the patient based upon the type of sedative/anesthetic technique prescribed and patient's physical status; and
 - (f) Pre-operative verbal and written instructions must be given to the patient and responsible person.
- (5) Patient Monitoring and Documentation Required.
- (a) A qualified dentist administering moderate sedation anesthesia must remain in the room with the patient to monitor the patient continuously until the patient meets the criteria for recovery and must not leave the facility until the patient meets the criteria for discharge and is discharged from the facility.
 - (b) Monitoring and documentation of patient administered moderate sedation anesthesia shall include, but not be limited to continuous monitoring and evaluation of:
 1. Color of mucosa, skin or blood (monitoring only);
 2. Oxygenation saturation by pulse oximetry;
 3. Level of consciousness (*e.g.* responsiveness to verbal command);
 4. Chest excursions;
 5. Ventilation either by auscultation of breath sounds, monitoring end-tidal CO₂ or by verbal communication with the patient; and
 6. ECG for patients with significant cardiovascular disease (may be considered).
 - (c) Anesthesia Chart. The Anesthesia Chart shall contain documentation of all events related to the administration of the sedative or anesthetic agents, including but not limited to the following:
 1. Time-oriented anesthetic record including the names of all drugs administered, including local anesthetics, dosages, and monitored physiologic parameters;
 2. Pulse oximetry, heart rate, respiratory rate, and blood pressure;
 3. The duration of the procedure; and
 4. The individuals present during the procedure.
- (6) Requirements for Management of Recovery and Discharge of Patients.
- (a) The recovery and discharge procedures for a patient administered moderate sedation anesthesia shall include, but not be limited to:
 1. Immediate availability of oxygen and suction equipment;
 2. Continuous monitoring and documentation of the patient's blood pressure, heart rate, oxygenation, and level of consciousness;
 3. Determination and documentation that the level of consciousness, oxygenation, ventilation, and circulation are satisfactory for discharge; and
 4. Post-operative verbal and written instructions provided.
 - (b) If a reversal agent is administered before discharge criteria have been met, the patient must be monitored until recovery is assured.
- (7) Requirements for Management of Pediatric and Special Needs Patients. The Board adopts the American Academy of Pediatrics/American Academy of Pediatric Dentistry's *Guidelines for Monitoring and Management of Pediatric Patients During and After Sedation of Diagnostic and Therapeutic Procedures* and the American Dental Association's guidance on pediatric and special needs patients as contained in its policy statement on *The Use of Sedation and General Anesthesia by Dentists* (2007).

6.12: continued

(8) Requirements for Emergency Management. The qualified dentist is responsible for the sedative management, adequacy of the facility and staff, diagnosis and treatment of emergencies related to the administration of sedation, providing and maintaining the equipment, drugs and protocol for patient rescue and conducting and documenting emergency drills. If a patient enters a deeper level of sedation than the qualified dentist is permitted to provide, the dentist must stop the dental procedure until the patient returns to the intended level of sedation.

6.13: Individual Permit B-2: Administration of Minimal Sedation and/or Nitrous Oxide-oxygen in Conjunction with an Enteral Agent Dispensed or Administered in a Dental Facility

(1) Initial Application Requirements. An applicant shall submit an accurate and complete application on forms provided by the Board and accompanied by a fee established annually by the Executive Office of Administration and Finance, and includes documentation that demonstrates proof that the applicant:

- (a) Is a dentist licensed under M.G.L. c. 112, § 45 to practice in the Commonwealth;
- (b) Has current certification in ACLS or PALS;
- (c) Has successfully completed an education program that complies at a minimum with the *ADA Guidelines for Teaching Pain Control Sedation to Dentists and Dental Students, 2007*, at the time training was commenced; or
- (d) Is certified by the American Board of Oral and Maxillofacial Surgery (ABOMS); or
- (e) Is certified as a Fellow and/or has Board certification in Anesthesia issued by the American Dental Board of Anesthesiology.

(2) Auxiliary Personnel Required. A qualified dentist inducing minimum sedation must have at least one additional individual trained in BLS present during the administration of the anesthesia.

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

(4) Pre-operative Preparation Required. Pre-operative preparation for the administration of minimum sedation shall include:

- (a) The patient or legal representative shall be advised regarding the procedure associated with the delivery of any sedative or anesthetic agents and a signed informed consent shall be obtained pursuant to 234 CMR 5.15(3)(f) for the proposed sedation/anesthesia obtained prior to the administration of the anesthesia or sedative agent(s);
- (b) Determination of adequate oxygen supply and equipment necessary to deliver oxygen under positive pressure must be completed;
- (c) Baseline vital signs, including blood pressure, respiration, and heart rate, must be obtained and documented in the patient record. If the patient's behavior prohibits such determination, this must be documented in the patient record;
- (d) A medical history must be completed and problem focused physical evaluation must be performed where deemed appropriate;
- (e) Specific dietary instructions must be provided to the patient based upon the type of sedative/anesthetic technique prescribed and patient's physical status; and
- (f) Pre-operative verbal and written instructions must be given to the patient and responsible person.

(5) Patient Monitoring and Documentation Required.

- (a) A qualified dentist administering minimum sedation anesthesia must remain in the room with the patient to monitor the patient continuously until the patient meets the criteria for recovery and must not leave the facility until the patient meets the criteria for discharge and is discharged from the facility.
- (b) Monitoring and documentation of patient administered Minimum sedation anesthesia shall include, but not be limited to continuous monitoring and evaluation of:

6.13: continued

1. Color of mucosa, skin or blood (monitoring only);
 2. Oxygenation saturation by pulse oximetry;
 3. Level of consciousness (*e.g.* responsiveness to verbal command);
 4. Chest excursions;
 5. Ventilation either by auscultation of breath sounds, monitoring end-tidal CO₂ or by verbal communication with the patient; and
 6. ECG for patients with significant cardiovascular disease (may be considered).
- (c) Anesthesia Chart. The Anesthesia Chart shall contain documentation of all events related to the administration of the sedative or anesthetic agents, including but not limited to the following:
1. Time-oriented anesthetic record including the names of all drugs administered, including local anesthetics, dosages, and monitored physiologic parameters;
 2. Pulse oximetry, heart rate, respiratory rate, and blood pressure;
 3. The duration of the procedure; and
 4. The individuals present during the procedure.
- (6) Requirements for Management of Recovery and Discharge of Patients. The recovery and discharge procedures for a patient administered Minimum sedation anesthesia shall include, but not be limited to:
- (a) Immediate availability of oxygen and suction equipment;
 - (b) Continuous monitoring and documentation of the patient's blood pressure, heart rate, oxygenation, and level of consciousness;
 - (c) Determination and documentation that the level of consciousness, oxygenation, ventilation, and circulation are satisfactory for discharge;
 - (d) Post-operative verbal and written instructions provided; and
 - (e) If a reversal agent is administered before discharge criteria have been met, the patient must be monitored until recovery is assured.
- (7) Requirements for Management of Pediatric and Special Needs Patients. The Board adopts the American Academy of Pediatrics/American Academy of Pediatric Dentistry's *Guidelines for Monitoring and Management of Pediatric Patients During and After Sedation of Diagnostic and Therapeutic Procedures*, as may be amended and republished and the American Dental Association's guidance on pediatric and special needs patients as contained in its *Policy Statement on The Use of Sedation and General Anesthesia by Dentists* (234 CMR 6.02).
- (8) Requirements for Emergency Management. The qualified dentist is responsible for the sedative management, adequacy of the facility and staff, diagnosis and treatment of emergencies related to the administration of sedation, providing and maintaining the equipment, drugs and protocol for patient rescue, and conducting and documenting emergency drills. If a patient enters a deeper level of sedation than the qualified dentist is permitted to provide, the dentist must stop the dental procedure until the patient returns to the intended level of sedation.

6.14: Individual Permit C: Administration of Nitrous Oxide-oxygen Alone or in Conjunction with Local Anesthesia

- (1) Initial Application Requirements. An applicant shall submit an accurate and complete application on forms provided by the Board and accompanied by a fee established annually by the Executive Office of Administration and Finance, and includes documentation that demonstrates proof that the applicant:
- (a) Is a dentist licensed under M.G.L. c. 112, § 45 to practice in the Commonwealth;
 - (b) Has current certification in BLS, ACLS or PALS;
 - (c) Has successfully completed between 14 hours of didactic and clinical training in the administration of nitrous oxide-oxygen only; or
 - (d) An advanced education program accredited by the ADA Commission on Dental Accreditation that affords comprehensive and appropriate training necessary to administer and manage nitrous oxide-oxygen only.

6.14: continued

- (2) Auxiliary Personnel Required. A qualified dentist inducing minimum sedation shall have at least one additional individual trained in BLS present during the administration of the anesthesia.
- (3) Patient Evaluation Required. Patients considered for nitrous oxide-oxygen sedation must be suitably evaluated prior to the start of any sedative procedure. In healthy or medically stable individuals (ASA I, II) this shall consist of at least a review of their current medical history and medication use. For patients with significant medical considerations (*e.g.*, ASA III, IV) may require consultation with their primary care physician or consulting medical specialist.
- (4) Pre-operative Preparation for Patients Required. Pre-operative preparation for the administration of nitrous oxide-oxygen sedation shall include the following:
- The patient or legal representative shall be advised regarding the procedure associated with the delivery of any sedative or anesthetic agents and signed informed consent pursuant to 234 CMR 5.15(3)(f) for the proposed sedation/anesthesia shall be obtained prior to the administration of nitrous oxide-oxygen;
 - Determination of adequate oxygen supply and equipment necessary to deliver oxygen under positive pressure must be completed;
 - Baseline vital signs must be obtained and documented in the patient record. If the patient's behavior prohibits such determination, this must be documented in the patient record;
 - A focused physical evaluation must be performed as deemed appropriate;
 - Specific dietary instructions must be provided to the patient based upon the type of sedative/anesthetic technique prescribed and patient's physical status; and
 - Pre-operative verbal and written instructions must be given to the patient.
- (5) Requirements for Patient Monitoring and Documentation.
- A qualified dentist, or at the qualified dentist's direction, an appropriately trained dental auxiliary, must remain in the operatory during active dental treatment to monitor the patient continuously until the patient meets the criteria for discharge to the recovery area. The appropriately trained dental auxiliary must be familiar with monitoring techniques and equipment.
 - Anesthesia Chart. The Anesthesia Chart shall contain documentation of all events related to the administration of the sedative or anesthetic agents, including but not limited to the following:
 - The color of mucosa, skin or blood (monitoring only);
 - The qualified dentist and/or appropriately trained dental auxiliary must observe chest excursions continually;
 - Blood pressure, respirations, and heart rate should be evaluated pre-operatively, post-operatively and intra-operatively as necessary. If the patient is uncooperative or cannot tolerate such monitoring, this must be documented in the patient record.
- (6) Requirements for Recovery and Discharge.
- Oxygen and suction equipment must be immediately available;
 - The qualified dentist or appropriately trained dental auxiliary must monitor the patient during recovery until the patient is ready for discharge;
 - The qualified dentist must determine and document that level of consciousness, oxygenation, ventilation and circulation are satisfactory for discharge;
 - Post-operative verbal and written instructions must be given to the patient and responsible person.
- (7) Requirements for Management of Pediatric Patients. The Board adopts the American Academy of Pediatrics/American Academy of Pediatric Dentistry's *Guidelines for Monitoring and Management of Pediatric Patients During and After Sedation of Diagnostic and Therapeutic Procedures*, and the American Dental Association's guidance on pediatric and special needs patients as contained in its *Policy Statement on The Use of Sedation and General Anesthesia by Dentists* (2007).

6.14: continued

(8) Requirements for Emergency Management for Patients. The qualified dentist is responsible for the sedative management, adequacy of the facility and staff, diagnosis and treatment of emergencies related to the administration of sedation and providing and maintenance of the equipment, drugs and protocol for patient rescue. If a patient enters a deeper level of sedation than the qualified dentist is permitted to provide, the dentist must stop the dental procedure until the patient returns to the intended level of sedation.

6.15: Administration of Local Anesthesia Only(1) Scope of Practice.

(a) A dentist licensed to practice dentistry may administer local anesthesia under the authority of his or her dental license. The administering dentist shall be currently certified in Basic Life Support (BLS).

(b) The Board may issue qualified dental hygienists, licensed pursuant to M.G.L. c. 112, § 51, a Permit L which authorizes the holder to administer local anesthesia under the direct supervision of a licensed dentist.

(2) Equipment and Supplies Required. The following equipment and drugs are required where local anesthesia is administered:

(a) Alternative light source for use during power failure;

(b) Automated External Defibrillator (AED);

(c) Disposable CPR masks (pediatric and adult);

(d) Disposable syringes, assorted sizes;

(e) Disposable pediatric and adult face masks or positive pressure ventilation with supplemental oxygen;

(f) Oxygen (portable Cylinder E tank) pediatric and adult masks capable of giving positive pressure ventilation (including bag-valve-mask system);

(g) Sphygmomanometer and stethoscope for pediatric and adult patients;

(h) Suction; and

(i) And any other equipment as may be required by the Board.

(3) Drugs Required. The following drugs and/or categories of drugs shall be provided and maintained in accordance with the *AHA/ACLS Guidelines* (234 CMR 6.02) or as determined by the Board for emergency use. All drugs shall be current and not expired

(a) Acetylsalicylic acid (readily absorbable form);

(b) Ammonia inhalants;

(c) Antihistamine;

(d) Antihypoglycemic agent;

(e) Bronchodilator;

(f) Epinephrine preloaded syringes (pediatric and adult);

(g) Two epinephrine ampules;

(h) Oxygen;

(i) Vasodilator; and

(j) Any other drugs or categories of drugs as may be required by the Board.

6.16: Permit L: Administration of Local Anesthesia by a Dental Hygienist

(1) No licensed dental hygienist shall administer local anesthesia unless he or she has been issued a Permit L by the Board. A dental hygienist who has been issued a Permit L may only administer local anesthesia under the direct supervision of a licensed dentist.

(2) Application for Permit L by Examination. Application for a Permit L shall be on forms provided by the Board and shall be accompanied by the permit fee, to be determined annually by the Secretary of Administration and Finance, and documentation demonstrating proof of:

(a) Licensure as a dental hygienist in the Commonwealth;

(b) Current Basic Life Support (BLS) certification;

6.16: continued

(c) Successful completion of a training program or course of study, no more than two years prior to application for the permit, in a formal program in the administration of local anesthesia, which shall be a minimum of 35 hours of instruction, including no less than 12 hours of clinical training, and be conducted by an educational institution accredited by the Commission on Dental Accreditation of the American Dental Association; and

(d) Successful completion of a written examination in the administration of local anesthesia administered by the Northeast Regional Board of Dental Examiners (NERB) or any successor agency approved by the Board.

(3) Application for Permit L by Credentials. Application for local anesthesia permit by a dental hygienist qualified in another jurisdiction by virtue of successful completion of an examination to administer local anesthesia shall, at a minimum, be accompanied by the permit fee, to be determined annually by the Secretary of Administration and Finance and documentation demonstrating proof of:

(a) Licensure as a dental hygienist in the Commonwealth;

(b) Current BLS certification;

(c) Documentation of successful completion of a training program or course of study in a formal program in the administration of local anesthesia accredited by the American Dental Association and equivalent to the course of study described in 234 CMR 6.14(4); and

(d) A letter from a dentist who directly supervised the hygienist attesting to the hygienist's experience in administering local anesthesia within the previous two years.

(4) Requirements for Course of Study for Permit L.

(a) An applicant for a Permit L-Administration of Local Anesthesia shall have completed a minimum of 35 hours of instruction, which must include, but is not limited to:

1. Medical history evaluation procedures;

2. Physical evaluation of the dental patient;

3. Pharmacology of local anesthesia and vasoconstrictors; and

4. Local anesthesia, didactic and clinical courses, including the following:

a. Anatomy of head, neck, and oral cavity as it relates to administering local anesthetic agents;

b. Indications and contraindications for administration of local anesthesia;

c. Selection and preparation of the armamentaria and record-keeping for administering various local agents;

d. Medical and legal management of complication;

e. Recognition and management of post-injection complications;

f. Proper infection control techniques with regard to local anesthesia and proper disposal of sharps;

g. Methods of administering local anesthetic agents with emphasis on technique and minimum effective dosage; and

h. Management of diagnosis, prevention and treatment of medical emergencies.

(b) Instructors preparing students for certification to administer local anesthesia in Massachusetts shall be licensed to practice dentistry or dental hygiene in the Commonwealth.

(5) Renewal of Permit L. A permit to administer Local Anesthesia shall be renewed biennially at the same time the applicant's license to practice dental hygiene is renewed. The application for renewal of Permit L shall be accompanied by the permit fee, to be determined annually by the Executive Office of Administration and Finance; and an attestation confirming current BLS certification.

(6) Recording of Anesthesia Required.

(a) The dental hygienist shall obtain the local anesthesia only from the licensed dentist who is exercising direct supervision of the dental hygienist administering the local anesthesia.

(b) The dental hygienist shall sign and document in the patient record the date, type and amount of local anesthesia obtained from the supervising dentist.

(c) Upon completion of the treatment, any unused portion of the local anesthesia and armamentarium shall be returned to the supervising dentist and disposed of in accordance with M.G.L. c. 94C.

234 CMR: BOARD OF REGISTRATION IN DENTISTRY

6.17: Reporting of Adverse Occurrences

A qualified dentist who holds an anesthesia administration permit issued pursuant to 234 CMR 6.00 shall report to the Board any anesthesia, deep sedation and general anesthesia, moderate sedation, minimal sedation, nitrous oxide-oxygen only and local anesthetic related mortality which occurs during or as a result of treatment provided by the administration permit holder within 24 hours of the occurrence of any such mortality. Any morbidity which may result in permanent physical or mental injury as a result of the administration of general anesthetic agents, sedative agents or nitrous oxide-oxygen analgesia shall be reported to the Board by the anesthesia permit holder providing such treatment within 30 days of the occurrence of any such morbidity.

6.18: Penalty for Non-compliance

Non compliance with 234 CMR 6.00 shall subject a licensee's administration permit, facility permit and/or dental license to disciplinary action by the Board.

REGULATORY AUTHORITY

234 CMR 6.00: M.G.L. c. 112, §§ 43 through 53 and 61.