



Scott Walker, Governor
Laura Gutiérrez, Secretary

**DE 9 & 11 AD HOC COMMITTEE
DENTISTRY EXAMINING BOARD
Room 121A, 1400 E. Washington Avenue, Madison
Contact: Erin Karow (608) 266-2112
March 7, 2018**

The following agenda describes the issues that the Committee plans to consider at the meeting. At the time of the meeting, items may be removed from the agenda. Please consult the meeting minutes for a description of the actions of the Committee.

AGENDA

12:00 P.M.

(Or Immediately Following the Dentistry Examining Board Meeting)

OPEN SESSION – CALL TO ORDER – ROLL CALL

A. Adoption of Agenda (1)

B. Legislation and Rule Matters – Discussion and Consideration (2)

- 1) Proposals for Amending DE 9 & 11, Relating to Laboratories and Work Authorization and Anesthesia **(3-74)**

C. Public Comments

ADJOURNMENT

MEETINGS AND HEARINGS ARE OPEN TO THE PUBLIC, AND MAY BE CANCELLED WITHOUT NOTICE.

Times listed for meeting items are approximate and depend on the length of discussion and voting. All meetings are held at 1400 East Washington Avenue, Madison, Wisconsin, unless otherwise noted. In order to confirm a meeting or to request a complete copy of the board's agenda, please call the listed contact person. The board may also consider materials or items filed after the transmission of this notice. Times listed for the commencement of disciplinary hearings may be changed by the examiner for the convenience of the parties. Interpreters for the hearing impaired provided upon request by contacting the Affirmative Action Officer, 608-266-2112.

**State of Wisconsin
Department of Safety & Professional Services**

AGENDA REQUEST FORM

1) Name and Title of Person Submitting the Request: Sharon Henes Administrative Rules Coordinator		2) Date When Request Submitted: 28 February 2018 Items will be considered late if submitted after 12:00 p.m. on the deadline date: ▪ 8 business days before the meeting							
3) Name of Board, Committee, Council, Sections: Dentistry Examining Board Ad Hoc 9 and 11 Committee									
4) Meeting Date: 7 March 2018	5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? Legislation and Rule Matters – Discussion and Consideration 1. Proposals for Amending DE 9, 11 Relating to Laboratories and Work Authorizations and Anesthesia							
7) Place Item in: <input checked="" type="checkbox"/> Open Session <input type="checkbox"/> Closed Session	8) Is an appearance before the Board being scheduled? <input type="checkbox"/> Yes (Fill out Board Appearance Request) <input checked="" type="checkbox"/> No	9) Name of Case Advisor(s), if required:							
10) Describe the issue and action that should be addressed: Included in the packet are the following documents related to anesthesia & sedation: <ul style="list-style-type: none"> • Current Wisconsin DE 11 • 2016 American Dental Association Guidelines for the Use of Sedation and General Anesthesia by Dentists • Proposed Massachusetts Administrative Rules • Current Illinois, Iowa, Michigan and Minnesota Administrative Rules 									
11) Authorization <div style="text-align: center; font-size: 1.2em; font-family: cursive;"> <i>Sharon Henes</i> </div> <hr/> <table style="width: 100%; border: none;"> <tr> <td style="width: 70%; border: none;">Signature of person making this request</td> <td style="width: 30%; border: none;">Date</td> </tr> <tr> <td style="border: none;">Supervisor (if required)</td> <td style="border: none;">Date</td> </tr> <tr> <td style="border: none;">Executive Director signature (indicates approval to add post agenda deadline item to agenda)</td> <td style="border: none;">Date</td> </tr> </table>				Signature of person making this request	Date	Supervisor (if required)	Date	Executive Director signature (indicates approval to add post agenda deadline item to agenda)	Date
Signature of person making this request	Date								
Supervisor (if required)	Date								
Executive Director signature (indicates approval to add post agenda deadline item to agenda)	Date								
Directions for including supporting documents: <ol style="list-style-type: none"> 1. This form should be attached to any documents submitted to the agenda. 2. Post Agenda Deadline items must be authorized by a Supervisor and the Policy Development Executive Director. 3. If necessary, Provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting. 									

Chapter DE 11

ANESTHESIA

<p>DE 11.01 Authority and purpose. DE 11.02 Definitions. DE 11.025 Permit to administer anesthesia. DE 11.03 Requirements for nitrous oxide inhalation. DE 11.04 Requirements for anxiolysis. DE 11.05 Requirements for conscious sedation–enteral.</p>	<p>DE 11.06 Requirements for conscious sedation–parenteral. DE 11.07 Requirements for deep sedation and general anesthesia. DE 11.08 Office facilities and equipment. DE 11.09 Standards of care. DE 11.10 Reporting of adverse occurrences related to anesthesia administration.</p>
---	---

DE 11.01 Authority and purpose. The rules in this chapter are adopted under authority in ss. 15.08 (5) (b), 227.11 (2) (a) and 447.02 (2) (b), Stats., for the purpose of defining standards for the administration of anesthesia by dentists. The standards specified in this chapter shall apply equally to general anesthesia and sedation, regardless of the route of administration.

History: Cr. Register, August, 1985, No. 356, eff. 9–1–85; am. Register, October, 1988, No. 394, eff. 11–1–88; am. Register, August, 1991, No. 428, eff. 9–1–91.

DE 11.02 Definitions. In this chapter,

(1) “Analgesia” means the diminution or elimination of pain in a conscious patient.

(1m) “Anxiolysis” means the use of medication to relieve anxiety before or during a dental procedure which produces a minimally depressed level of consciousness, during which the patient’s eyes are open and the patient retains the ability to maintain an airway independently and to respond appropriately to physical and verbal command.

(1s) “Class I permit” means a sedation permit enabling a dentist to administer oral conscious sedation–enteral.

(1t) “Class II permit” means a sedation permit enabling a dentist to administer conscious sedation–parenteral and conscious sedation–enteral.

(1u) “Class III permit” means a sedation permit enabling a dentist to administer deep sedation, general anesthesia, conscious sedation–parenteral, and conscious sedation–enteral.

(2) “Conscious sedation” means a depressed level of consciousness during which the patient mimics physiological sleep, has vitals that are not different from that of sleep, has his or her eyes closed most of the time while still retaining the ability to independently and continuously maintain an airway and respond appropriately to physical stimulation and verbal command, produced by a pharmacologic or non–pharmacologic method, or a combination of pharmacologic and non–pharmacologic methods.

(3) “Deep sedation” means a controlled state of depressed consciousness, accompanied by partial loss of protective reflexes, including the ability to independently and continuously maintain an airway and to respond purposefully to verbal command, produced by a pharmacologic or non–pharmacologic method, or a combination of pharmacologic and non–pharmacologic methods.

(4) “General anesthesia” means a controlled state of unconsciousness accompanied by partial or complete loss of protective reflexes, including the ability to independently maintain an airway and respond purposefully to physical stimulation or verbal command, produced by a pharmacologic or non–pharmacologic method, or a combination of pharmacologic and non–pharmacologic methods.

(6) “Nitrous oxide inhalation” means analgesia by administration of a combination of nitrous oxide and oxygen in a patient.

(7) “Operative supervision” means the dentist is in the operating room performing procedures with the aid of qualified staff.

(8) “Qualified staff” means a person is certified in the administration of basic life support in compliance with the standards set forth by the American Heart Association, the American Red

Cross, or other organization approved by the board, and has training in how to monitor vital signs, and how to use a pulse oximeter, blood pressure cuff, and a precordial or a pretracheal stethoscope. If the dentist is administering deep sedation and general anesthesia under s. DE 11.07, a person shall also be trained in how to use an EKG.

(9) “Routes of administration” include the following:

(a) “Enteral” means administration by which the agent is absorbed through the gastrointestinal tract or through the oral, rectal or nasal mucosa.

(b) “Inhalation” means administration by which a gaseous or volatile agent is introduced into the pulmonary tree and whose primary effect is due to absorption through the pulmonary bed.

(c) “Parenteral” means administration by which the drug bypasses the gastrointestinal tract through either intramuscular (IM), intravenous (IV), intranasal (IN), submucosal (SM), subcutaneous (SC), or intraocular (IO) methods.

(d) “Transdermal or transmucosal” means administration by which the drug is administered by patch or iontophoresis.

(10) “Time–oriented anesthesia record” means documentation at appropriate intervals of drugs, doses and physiologic data obtained during patient monitoring.

History: Cr. Register, August, 1985, No. 356, eff. 9–1–85; r. and rec. Register, October, 1988, No. 394, eff. 11–1–88; r. (4), renum. (1) to (3) to be (2) to (4) and am., cr. (1) and (5), Register, August, 1991, No. 428, eff. 9–1–91; CR 04–095: am. (1) to (4), cr. (1m) and (6) to (10), r. (5) Register August 2006 No. 608, eff. 1–1–07; CR 13–061: cr. (1s) to (1u) Register June 2014 No. 702, eff. 7–1–14.

DE 11.025 Permit to administer anesthesia. (1) Dentists shall submit an application to administer anesthesia as specified in this chapter on a form prepared for and approved by the board. Each application shall be specific to the sedation permit class.

Note: Copies of the Application For Dental Permit to Administer Conscious Sedation are accessible from the department’s webpage at: <http://dsps.wi.gov/>.

(2) The board may grant a sedation permit and shall consider any of the following actions in developing their decision on an application:

(a) Defer a decision if the licensee has a pending investigation or has not met the conditions of a previous investigation.

(b) Defer a decision if any sedation permits held by the licensee have been temporally suspended.

(c) Defer a decision or recommend denial if any permits held by the licensee have been revoked or conditions of revocation have not been satisfactorily met.

(d) Recommend denial based on the severity of any investigations regarding noncompliance with ch. DE 5.

(e) Take any other action or actions necessary to maintain the health, welfare and safety of a patient or the public.

History: CR 13–061: cr. Register June 2014 No. 702, eff. 7–1–14.

DE 11.03 Requirements for nitrous oxide inhalation. (1) A dentist or a dental hygienist who holds a valid certificate under ch. DE 15 may use nitrous oxide inhalation on an outpatient basis for dental patients provided that he or she utilizes

adequate equipment with failsafe features and a 25% minimum oxygen flow.

(2) A dentist utilizing nitrous oxide inhalation shall be trained and certified in administering basic life support. This certification shall be renewed in compliance with the standards set forth by the American Heart Association, the American Red Cross, or other organization approved by the board.

History: CR 04-095: cr. Register August 2006 No. 608, eff. 1-1-07; CR 15-056: am. (1) Register February 2016 No. 722, eff. 3-1-16.

DE 11.04 Requirements for anxiolysis. A dentist utilizing anxiolysis shall be trained and certified in administering basic life support. This certification shall be renewed in compliance with the standards set forth by the American Heart Association, the American Red Cross, or any other organization approved by the board.

History: CR 04-095: cr. Register August 2006 No. 608, eff. 1-1-07.

DE 11.05 Requirements for conscious sedation—enteral. (1) No dentist may administer conscious sedation via an enteral route without having first obtained a class I permit from the board, unless a dentist has been granted a permit under s. DE 11.06 or 11.07. A class I permit enables a dentist to utilize conscious sedation enterally. The board may grant a class I permit to administer conscious sedation enterally to a dentist who submits a completed application for this sedation permit class and does all of the following:

(a) Provides proof of one of the following:

1. A board approved training course which includes:

a. Eighteen hours of didactic instruction which addresses physical evaluation of patients, conscious sedation—enteral, emergency management, and conforms to the principles in part one or part 3 of the American Dental Association's "Guidelines for Teaching the Comprehensive Control of Anxiety and Pain in Dentistry."

b. Twenty clinical cases utilizing an enteral route of administration to achieve conscious sedation, which may include group observation.

2. Graduate level training approved by the board that, at a minimum, includes the requirements as set forth in subd. 1. a. and b.

(b) Provides proof of certification in basic cardiac life support for the health care provider and a board approved training program in airway management or a course in advanced cardiac life support. If the dentist is sedating patients age 14 or younger, the dentist shall provide proof of certification in pediatric advanced life support. This certification shall be renewed in compliance with the standards set forth by the American Heart Association, the American Red Cross, or any other organization approved by the board.

(2) Any dentist who utilizes an enteral route of administration to achieve conscious sedation shall have qualified staff present throughout the dental procedure.

History: CR 04-095: cr. Register August 2006 No. 608, eff. 1-1-07; CR 13-061: am. (1) (intro.) Register June 2014 No. 702, eff. 7-1-14.

DE 11.06 Requirements for conscious sedation—parenteral. (1) No dentist may administer conscious sedation via a parenteral route without having first obtained a class II permit from the board, unless a dentist has been granted a permit under s. DE 11.07. A class II permit enables a dentist to utilize conscious sedation—enteral, and conscious sedation—parenteral. A dentist who holds a class II permit does not have to obtain a class I sedation permit. The board may grant a class II permit to administer conscious sedation—parenterally to a dentist who submits a completed application for this sedation permit class and does all the following:

(a) Provides proof of one of the following:

1. A board approved training course which includes:

a. A minimum of 60 hours of didactic instruction which addresses the physical evaluation of patients, IV sedation, and emergency management.

b. Twenty clinical cases of managing parenteral routes of administration.

2. Graduate level training approved by the board that, at a minimum, includes the requirements as set forth in subd. 1.

3. The utilization of conscious sedation administered parenterally on an outpatient basis for 5 years preceding January 1, 2007, by a dentist licensed under this chapter.

(b) Provides proof of certification in advanced cardiac life support. If the dentist is a pediatric specialist, the dentist is allowed to substitute certification in pediatric advanced life support. This certification shall be renewed in compliance with the standards set forth by the American Heart Association, or any other organization approved by the board.

(2) Any dentist who utilizes a parenteral route of administration to achieve conscious sedation shall have qualified staff present throughout the dental procedure.

History: CR 04-095: cr. Register August 2006 No. 608, eff. 1-1-07.; CR 13-061: am. (1) Register June 2014 No. 702, eff. 7-1-14.

DE 11.07 Requirements for deep sedation and general anesthesia. (1) No dentist may administer deep sedation or general anesthesia without having first obtained a class III permit from the board and submits a completed application for this sedation permit class. A class III permit enables a dentist to utilize conscious sedation—enteral, conscious sedation—parenteral, deep sedation, and general anesthesia. A dentist who holds class III sedation permit shall not have to obtain any other class of sedation permit. The board may grant a class III permit to administer deep sedation or general anesthesia to a dentist who does all of the following:

(a) Provides proof of one of the following:

1. Successful completion of a board approved postdoctoral training program in the administration of deep sedation and general anesthesia.

2. Successful completion of a postdoctoral training program in anesthesiology that is approved by the Accreditation Council for Graduate Medical Education.

3. Successful completion of a minimum of one year advanced clinical training in anesthesiology provided it meets the objectives set forth in part 2 of the American Dental Association's "Guidelines for Teaching the Comprehensive Control of Anxiety and Pain in Dentistry."

4. Has been a licensed dentist under this chapter who has been utilizing general anesthesia for 5 years prior to January 1, 2007.

(b) Provides proof of certification in advanced cardiac life support. If the dentist is a pediatric specialist, the dentist is allowed to substitute certification in pediatric advanced life support. This certification shall be renewed in compliance with the standards set forth by the American Heart Association, or any other organization approved by the board.

(2) Any dentist who administers deep sedation or general anesthesia shall have qualified staff present throughout the dental procedure.

(3) Nothing in this section may be construed to prevent a dentist from employing or working in conjunction with a certified registered nurse anesthetist, or with a licensed physician or dentist who is a member of the anesthesiology staff of an accredited hospital, provided that the anesthesia personnel must remain on the premises of the dental facility until the patient under general anesthesia or deep sedation regains consciousness.

History: CR 04-095: cr. Register August 2006 No. 608, eff. 1-1-07; CR 13-061: am. (1) (intro.) Register June 2014 No. 702, eff. 7-1-14.

DE 11.08 Office facilities and equipment. (1) A dental office shall have all of the following if a dentist is administering

conscious sedation–enteral, conscious sedation–parenteral, deep sedation, and general anesthesia:

- (a) An operating room containing all of the following:
 1. Oxygen and supplemental gas–delivery system capable of delivering positive pressure oxygen ventilation.
 2. Suction and backup system.
 3. Auxiliary lighting system.
 4. Gas storage facilities.
 5. An operating chair capable of withstanding cardiopulmonary resuscitation or a back board.
 6. Emergency equipment including a defibrillator, cardiopulmonary pocket mask, and appropriate emergency medications.
 7. Monitoring equipment including a pulse oximeter, blood pressure cuff, and precordial or pretracheal stethoscope.
 8. An EKG if administering deep sedation or general anesthesia.
- (b) A recovery room containing all of the following:
 1. Oxygen and supplemental gas–delivery system capable of delivering positive pressure oxygen ventilation.
 2. Suction and backup system.
 3. Auxiliary lighting system.
 4. Wheelchair.
 5. An operating chair capable of withstanding cardiopulmonary resuscitation or a back board.
 6. Emergency equipment including a defibrillator, cardiopulmonary pocket mask, and appropriate emergency medications.

(2) Nothing in this section shall be construed to prevent an operating room from also being used as a recovery room, nor shall it be construed to prevent the sharing of equipment between an operating room and a recovery room, provided all the required equipment is in the room being used.

History: CR 04–095: cr. Register August 2006 No. 608, eff. 1–1–07.

DE 11.09 Standards of care. (1) Before the administration of any type of sedation a complete written medical history shall be obtained from each patient. The medical history shall identify any medications a patient is taking and any allergies to medication a patient has.

(2) The recording of a time–oriented anesthesia record including appropriate vital signs, blood pressure, pulse, and oxygen saturation q 5 minutes, is required for conscious sedation–enteral, conscious sedation–parenteral, deep sedation, and general anesthesia.

(3) During the anesthesia period for conscious sedation–enteral, conscious sedation–parenteral, deep sedation, or general anesthesia, the oxygenation, ventilation, and circulation of the patient shall be continually evaluated, and any medications that are administered shall be documented in writing, including the dosages, time intervals, and the route of administration.

(4) A patient shall be continually observed during the anesthesia period for conscious sedation–enteral, conscious sedation–parenteral, deep sedation, and general anesthesia either by the treating dentist or by qualified staff. No permit holder shall have more

than one person in conscious sedation–enteral, conscious sedation–parenteral, deep sedation, or general anesthesia at one time, notwithstanding patients in recovery.

(5) Operative supervision is required for deep sedation and general anesthesia.

(6) Qualified staff shall continuously monitor post–treatment patients before final evaluation and discharge by the dentist. Written post–operative instructions shall be given to each patient or to a responsible adult who accompanies the patient for those individuals having undergone conscious sedation–enteral, conscious sedation–parenteral, deep sedation, or general anesthesia. Documentation of the post–operative instructions shall be noted in the patient’s chart.

(8) Any dentist whose patient lapses into conscious sedation–enteral from anxiety shall meet the requirements found in s. DE 11.05 and shall follow any applicable requirements in s. DE 11.09.

(9) Unless a dentist holds a class 3 permit, he or she shall not administer any drug that has a narrow margin for maintaining consciousness including, but not limited to, ultra–short acting barbiturates, propofol, ketamine, or any other similarly acting drugs.

(10) Dentists shall maintain verifiable records of the successful completion of any and all training of staff.

History: CR 04–095: cr. Register August 2006 No. 608, eff. 1–1–07.

Note: Section DE 11.09 (7) dealing with titration, has been removed from the rule in compliance with statutory restraints based on the objections by the Senate Committee on Health and the Joint Committee for Review of Administrative Rules. The Wisconsin Dentistry Examining Board intends to promulgate s. DE 11.09 (7) upon resolution of those objections.

DE 11.10 Reporting of adverse occurrences related to anesthesia administration. Dentists shall submit a report within 30 days to the board of any mortality or other incident which results in temporary or permanent physical or mental injury requiring hospitalization of a patient during, or as a result of, anesthesia administration under this chapter. The report shall be on a form approved by the board and shall include, at the minimum, responses to all of the following:

- (1) A description of the dental procedures.
- (2) The names of all participants in the dental procedure and any witnesses to the adverse occurrence.
- (3) A description of the preoperative physical condition of the patient.
- (4) A list of drugs and dosage administered before and during the dental procedures.
- (5) A detailed description of the techniques utilized in the administration of all drugs used during the dental procedure.
- (6) A description of the adverse occurrence, including the symptoms of any complications, any treatment given to the patient, and any patient response to the treatment.
- (7) A description of the patient’s condition upon termination of any dental procedures undertaken.

Note: Forms are available at the office of the Dentistry Examining Board located at 1400 East Washington Avenue, P.O. Box 8935, Madison, WI 53708.

History: CR 04–095: cr. Register August 2006 No. 608, eff. 1–1–07.

GUIDELINES

for the Use of Sedation and General Anesthesia by Dentists

Adopted by the ADA House of Delegates, October 2016

I. INTRODUCTION

The administration of local anesthesia, sedation and general anesthesia is an integral part of dental practice. The American Dental Association is committed to the safe and effective use of these modalities by appropriately educated and trained dentists. The purpose of these guidelines is to assist dentists in the delivery of safe and effective sedation and anesthesia.

Dentists must comply with their state laws, rules and/or regulations when providing sedation and anesthesia and will only be subject to Section III. Educational Requirements as required by those state laws, rules and/or regulations.

Level of sedation is entirely independent of the route of administration. Moderate and deep sedation or general anesthesia may be achieved via any route of administration and thus an appropriately consistent level of training must be established.

For children, the American Dental Association supports the use of the American Academy of Pediatrics/American Academy of Pediatric Dentistry Guidelines for Monitoring and Management of Pediatric Patients During and After Sedation for Diagnostic and Therapeutic Procedures.

TABLE OF CONTENTS

I. INTRODUCTION	1
II. DEFINITIONS	2
III. EDUCATIONAL REQUIREMENTS	6
IV. CLINICAL GUIDELINES	8
▶ MINIMAL SEDATION	8
▶ MODERATE SEDATION	10
▶ DEEP SEDATION OR GENERAL ANESTHESIA	12
ENDNOTES	15

II. DEFINITIONS

METHODS OF ANXIETY AND PAIN CONTROL



MINIMAL SEDATION (previously known as anxiolysis) – a minimally depressed level of consciousness, produced by a pharmacological method, that retains the patient’s ability to independently and continuously maintain an airway and respond normally to tactile stimulation and verbal command. Although cognitive function and coordination may be modestly impaired, ventilatory and cardiovascular functions are unaffected.¹

Patients whose only response is reflex withdrawal from repeated painful stimuli would not be considered to be in a state of minimal sedation.

The following definitions apply to administration of minimal sedation:

maximum recommended dose (MRD) – maximum FDA-recommended dose of a drug, as printed in FDA-approved labeling for unmonitored home use.

dosing for minimal sedation via the enteral route – minimal sedation may be achieved by the administration of a drug, either singly or in divided doses, by the enteral route to achieve the desired clinical effect, not to exceed the maximum recommended dose (MRD).

The administration of enteral drugs exceeding the maximum recommended dose during a single appointment is considered to be moderate sedation and the moderate sedation guidelines apply.

Nitrous oxide/oxygen when used in combination with sedative agent(s) may produce minimal, moderate, deep sedation or general anesthesia.

If more than one enteral drug is administered to achieve the desired sedation effect, with or without the concomitant use of nitrous oxide, the guidelines for moderate sedation must apply.

Note: In accord with this particular definition, the drug(s) and/or techniques used should carry a margin of safety wide enough never to render unintended loss of consciousness. The use of the MRD to guide dosing for minimal sedation is intended to create this margin of safety.



MODERATE SEDATION – 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.¹

Note: In accord with this particular definition, the drugs and/or techniques used should carry a margin of safety wide enough to render unintended loss of consciousness unlikely. Repeated dosing of an agent before the effects of previous dosing can be fully appreciated may result in a greater alteration of the state of consciousness than is the intent of the dentist. Further, a patient whose only response is reflex withdrawal from a painful stimulus is not considered to be in a state of moderate sedation.

The following definition applies to the administration of moderate or greater sedation:

titration – administration of incremental doses of an intravenous or inhalation drug until a desired effect is reached. Knowledge of each drug’s time of onset, peak response and duration of action is essential to avoid over sedation. Although the concept of titration of a drug to effect is critical for patient safety, when the intent is moderate sedation one must know whether the previous dose has taken full effect before administering an additional drug increment.



DEEP SEDATION AND GENERAL ANESTHESIA

deep sedation – a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.¹

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

Because sedation and general anesthesia are a continuum, it is not always possible to predict how an individual patient will respond. Hence, practitioners intending to produce a given level of sedation should be able to diagnose and manage the physiologic consequences (rescue) for patients whose level of sedation becomes deeper than initially intended.¹

For all levels of sedation, the qualified dentist must have the training, skills, drugs and equipment to identify and manage such an occurrence until either assistance arrives (emergency medical service) or the patient returns to the intended level of sedation without airway or cardiovascular complications.

ROUTES OF ADMINISTRATION

enteral – any technique of administration in which the agent is absorbed through the gastrointestinal (GI) tract or oral mucosa [i.e., oral, rectal, sublingual].

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), intraosseous (IO)].

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

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

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

TERMS

analgesia – the diminution or elimination of pain.

local anesthesia – the elimination of sensation, especially pain, in one part of the body by the topical application or regional injection of a drug.

Note: Although the use of local anesthetics is the foundation of pain control in dentistry and has a long record of safety, dentists must be aware of the maximum, safe dosage limits for each patient. Large doses of local anesthetics in themselves may result in central nervous system depression, especially in combination with sedative agents.

qualified dentist – a dentist providing sedation and anesthesia in compliance with their state rules and/or regulations.

operating dentist – dentist with primary responsibility for providing operative dental care while a qualified dentist or independently practicing qualified anesthesia healthcare provider administers minimal, moderate or deep sedation or general anesthesia.

competency – displaying special skill or knowledge derived from training and experience.

must/shall – indicates an imperative need and/or duty; an essential or indispensable item; mandatory.

should – indicates the recommended manner to obtain the standard; highly desirable.

may – indicates freedom or liberty to follow a reasonable alternative.

continual – repeated regularly and frequently in a steady succession.

continuous – prolonged without any interruption at any time.

time-oriented anesthesia record – documentation at appropriate time intervals of drugs, doses and physiologic data obtained during patient monitoring.

immediately available – on site in the facility and available for immediate use.

AMERICAN SOCIETY OF ANESTHESIOLOGISTS (ASA) PATIENT PHYSICAL STATUS CLASSIFICATION²

Classification	Definition	Examples, including but not limited to:
ASA I	A normal healthy patient	Healthy, non-smoking, no or minimal alcohol use
ASA II	A patient with mild systemic disease	Mild diseases only without substantive functional limitations. Examples include (but not limited to): current smoker, social alcohol drinker, pregnancy, obesity (30 < BMI < 40), well-controlled DM/HTN, mild lung disease
ASA III	A patient with severe systemic disease	Substantive functional limitations; One or more moderate to severe diseases. Examples include (but not limited to): poorly controlled DM or HTN, COPD, morbid obesity (BMI ≥40), active hepatitis, alcohol dependence or abuse, implanted pacemaker, moderate reduction of ejection fraction, *ESRD undergoing regularly scheduled dialysis, premature infant PCA < 60 weeks, history (>3 months) of MI, CVA, TIA, or CAD/stents.
ASA IV	A patient with severe systemic disease that is a constant threat to life	Examples include (but not limited to): recent (< 3 months) MI, CVA, TIA, or CAD/stents, ongoing cardiac ischemia or severe valve dysfunction, severe reduction of ejection fraction, sepsis, DIC, ARD or *ESRD not undergoing regularly scheduled dialysis
ASA V	A moribund patient who is not expected to survive without the operation	Examples include (but not limited to): ruptured abdominal/thoracic aneurysm, massive trauma, intracranial bleed with mass effect, ischemic bowel in the face of significant cardiac pathology or multiple organ/system dysfunction
ASA VI	A declared brain-dead patient whose organs are being removed for donor purposes	

*The addition of “E” denotes emergency surgery: (An emergency is defined as existing when delay in treatment of the patient would lead to a significant increase in the threat to life or body part)

AMERICAN SOCIETY OF ANESTHESIOLOGISTS’ FASTING GUIDELINES³

Ingested Material	Minimum Fasting Period
Clear liquids	2 hours
Breast milk	4 hours
Infant formula	6 hours
Nonhuman milk	6 hours
Light meal	6 hours
Fatty meal	8 hours

III. EDUCATIONAL REQUIREMENTS



A. Minimal Sedation

1. To administer minimal sedation the dentist must demonstrate competency by having successfully completed:
 - a. training in minimal sedation consistent with that prescribed in the *ADA Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students*;
 - or*
 - b. comprehensive training in moderate sedation that satisfies the requirements described in the Moderate Sedation section of the *ADA Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students* at the time training was commenced;
 - or*
 - c. an advanced education program accredited by the Commission on Dental Accreditation that affords comprehensive and appropriate training necessary to administer and manage minimal sedation commensurate with these guidelines;
 - and*
 - d. a current certification in Basic Life Support for Healthcare Providers.
2. Administration of minimal sedation by another qualified dentist or independently practicing qualified anesthesia healthcare provider requires the operating dentist and his/her clinical staff to maintain current certification in Basic Life Support for Healthcare Providers.



B. Moderate Sedation

1. To administer moderate sedation, the dentist must demonstrate competency by having successfully completed:
 - a. a comprehensive training program in moderate sedation that satisfies the requirements described in the Moderate Sedation section of the *ADA Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students* at the time training was commenced;
 - or*
 - b. an advanced education program accredited by the Commission on Dental Accreditation that affords comprehensive and appropriate training necessary to administer and manage moderate sedation commensurate with these guidelines;
 - and*
 - c. 1) A current certification in Basic Life Support for Healthcare Providers and
2) Either current certification in Advanced Cardiac Life Support (ACLS or equivalent) or completion of an appropriate dental sedation/anesthesia emergency management course on the same recertification cycle that is required for ACLS.

2. Administration of moderate sedation by another qualified dentist or independently practicing qualified anesthesia healthcare provider requires the operating dentist and his/her clinical staff to maintain current certification in Basic Life Support for Healthcare Providers.



C. Deep Sedation or General Anesthesia

1. To administer deep sedation or general anesthesia, the dentist must demonstrate competency by having completed:
 - a. An advanced education program accredited by the Commission on Dental Accreditation that affords comprehensive and appropriate training necessary to administer and manage deep sedation or general anesthesia, commensurate with Part IV.C of these guidelines;
and
 - b. 1) A current certification in Basic Life Support for Healthcare Providers and
2) either current certification in Advanced Cardiac Life Support (ACLS or equivalent) or completion of an appropriate dental sedation/anesthesia emergency management course on the same re-certification cycle that is required for ACLS.
2. Administration of deep sedation or general anesthesia by another qualified dentist or independently practicing qualified anesthesia healthcare provider requires the operating dentist and his/her clinical staff to maintain current certification in Basic Life Support (BLS) Course for the Healthcare Provider.

IV. CLINICAL GUIDELINES



A. Minimal sedation

1. Patient History and Evaluation

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

2. Pre-Operative Evaluation and Preparation

- The patient, parent, legal guardian or care giver must be advised regarding the procedure associated with the delivery of any sedative agents and informed consent for the proposed sedation must be obtained.
- Determination of adequate oxygen supply and equipment necessary to deliver oxygen under positive pressure must be completed.
- An appropriate focused physical evaluation should be performed.
- Baseline vital signs including body weight, height, blood pressure, pulse rate, and respiration rate must be obtained unless invalidated by the nature of the patient, procedure or equipment. Body temperature should be measured when clinically indicated.
- Preoperative dietary restrictions must be considered based on the sedative technique prescribed.
- Pre-operative verbal and written instructions must be given to the patient, parent, escort, legal guardian or care giver.

3. Personnel and Equipment Requirements

Personnel: At least one additional person trained in Basic Life Support for Healthcare Providers must be present in addition to the dentist.

Equipment:

- A positive-pressure oxygen delivery system suitable for the patient being treated must be immediately available.
- Documentation of compliance with manufacturers' recommended maintenance of monitors, anesthesia delivery systems, and other anesthesia-related equipment should be maintained. A pre-procedural check of equipment for each administration of sedation must be performed.
- When inhalation equipment is used, it must have a fail-safe system that is appropriately checked and calibrated. The equipment must also have either (1) a functioning device that prohibits the delivery of less than 30% oxygen or (2) an appropriately calibrated and functioning in-line oxygen analyzer with audible alarm.
- An appropriate scavenging system must be available if gases other than oxygen or air are used.



4. Monitoring and Documentation

Monitoring: A dentist, or at the dentist's direction, an appropriately trained individual, must remain in the operatory during active dental treatment to monitor the patient continuously until the patient meets the criteria for discharge to the recovery area. The appropriately trained individual must be familiar with monitoring techniques and equipment. Monitoring must include:

Consciousness: Level of sedation (e.g., responsiveness to verbal commands) must be continually assessed.

Oxygenation: Oxygen saturation by pulse oximetry may be clinically useful and should be considered.

Ventilation:

- The dentist and/or appropriately trained individual must observe chest excursions.
- The dentist and/or appropriately trained individual must verify respirations.

Circulation: Blood pressure and heart rate should be evaluated pre-operatively, post-operatively and intraoperatively as necessary (unless the patient is unable to tolerate such monitoring).

Documentation: An appropriate sedative record must be maintained, including the names of all drugs administered, time administered and route of administration, including local anesthetics, dosages, and monitored physiological parameters.

5. Recovery and Discharge

- Oxygen and suction equipment must be immediately available if a separate recovery area is utilized.
- The qualified dentist or appropriately trained clinical staff must monitor the patient during recovery until the patient is ready for discharge by the dentist.
- The qualified dentist must determine and document that level of consciousness, oxygenation, ventilation and circulation are satisfactory prior to discharge.
- Post-operative verbal and written instructions must be given to the patient, parent, escort, legal guardian or care giver.

6. Emergency Management

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



B. Moderate Sedation

1. Patient History and Evaluation

Patients considered for moderate sedation must undergo an evaluation prior to the administration of any sedative. This should consist of at least a review at an appropriate time of their medical history and medication use and NPO (nothing by mouth) status. In addition, patients with significant medical considerations (e.g., ASA III, IV) should also require consultation with their primary care physician or consulting medical specialist. Assessment of Body Mass Index (BMI)⁴ should be considered part of a pre-procedural workup. Patients with elevated BMI may be at increased risk for airway associated morbidity, particularly if in association with other factors such as obstructive sleep apnea.

2. Pre-operative Evaluation and Preparation

- The patient, parent, legal guardian or care giver must be advised regarding the procedure associated with the delivery of any sedative agents and informed consent for the proposed sedation must be obtained.
- Determination of adequate oxygen supply and equipment necessary to deliver oxygen under positive pressure must be completed.
- An appropriate focused physical evaluation must be performed.
- Baseline vital signs including body weight, height, blood pressure, pulse rate, respiration rate, and blood oxygen saturation by pulse oximetry must be obtained unless precluded by the nature of the patient, procedure or equipment. Body temperature should be measured when clinically indicated.
- Pre-operative verbal or written instructions must be given to the patient, parent, escort, legal guardian or care giver, including pre-operative fasting instructions based on the ASA Summary of Fasting and Pharmacologic Recommendations.

3. Personnel and Equipment Requirements

Personnel: At least one additional person trained in Basic Life Support for Healthcare Providers must be present in addition to the dentist.

Equipment:

- A positive-pressure oxygen delivery system suitable for the patient being treated must be immediately available.
- Documentation of compliance with manufacturers' recommended maintenance of monitors, anesthesia delivery systems, and other anesthesia-related equipment should be maintained. A pre-procedural check of equipment for each administration of sedation must be performed.
- When inhalation equipment is used, it must have a fail-safe system that is appropriately checked and calibrated. The equipment must also have either (1) a functioning device that prohibits the delivery of less than 30% oxygen or (2) an appropriately calibrated and functioning in-line oxygen analyzer with audible alarm.
- The equipment necessary for monitoring end-tidal CO₂ and auscultation of breath sounds must be immediately available.



- An appropriate scavenging system must be available if gases other than oxygen or air are used.
- The equipment necessary to establish intravascular or intraosseous access should be available until the patient meets discharge criteria.

4. Monitoring and Documentation

Monitoring: A qualified dentist administering moderate sedation must remain in the operatory room to monitor the patient continuously until the patient meets the criteria for recovery. When active treatment concludes and the patient recovers to a minimally sedated level a qualified auxiliary may be directed by the dentist to remain with the patient and continue to monitor them as explained in the guidelines until they are discharged from the facility. The dentist must not leave the facility until the patient meets the criteria for discharge and is discharged from the facility. Monitoring must include:

Consciousness: Level of sedation (e.g., responsiveness to verbal command) must be continually assessed.

Oxygenation: Oxygen saturation must be evaluated by pulse oximetry continuously.

Ventilation:

- The dentist must observe chest excursions continually.
- The dentist must monitor ventilation and/or breathing by monitoring end-tidal CO₂ unless precluded or invalidated by the nature of the patient, procedure or equipment. In addition, ventilation should be monitored by continual observation of qualitative signs, including auscultation of breath sounds with a precordial or pretracheal stethoscope.

Circulation:

- The dentist must continually evaluate blood pressure and heart rate unless invalidated by the nature of the patient, procedure or equipment and this is noted in the time-oriented anesthesia record.
- Continuous ECG monitoring of patients with significant cardiovascular disease should be considered.

Documentation:

- Appropriate time-oriented anesthetic record must be maintained, including the names of all drugs, dosages and their administration times, including local anesthetics, dosages and monitored physiological parameters.
- Pulse oximetry, heart rate, respiratory rate, blood pressure and level of consciousness must be recorded continually.

5. Recovery and Discharge

- Oxygen and suction equipment must be immediately available if a separate recovery area is utilized.
- The qualified dentist or appropriately trained clinical staff must continually monitor the patient's blood pressure, heart rate, oxygenation and level of consciousness.
- 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, parent, escort, legal guardian or care giver.
- If a pharmacological reversal agent is administered before discharge criteria have been met, the patient must be monitored for a longer period than usual before discharge, since re-sedation may occur once the effects of the reversal agent have waned.

6. Emergency Management

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



C. Deep Sedation or General Anesthesia

1. Patient History and Evaluation

Patients considered for deep sedation or general anesthesia must undergo an evaluation prior to the administration of any sedative. This must consist of at least a review of their medical history and medication use and NPO (nothing by mouth) status. In addition, patients with significant medical considerations (e.g., ASA III, IV) should also require consultation with their primary care physician or consulting medical specialist. Assessment of Body Mass Index (BMI)⁴ should be considered part of a pre-procedural workup. Patients with elevated BMI may be at increased risk for airway associated morbidity, particularly if in association with other factors such as obstructive sleep apnea.

2. Pre-operative Evaluation and Preparation

- The patient, parent, legal guardian or care giver must be advised regarding the procedure associated with the delivery of any sedative or anesthetic agents and informed consent for the proposed sedation/anesthesia must be obtained.
- Determination of adequate oxygen supply and equipment necessary to deliver oxygen under positive pressure must be completed.
- A focused physical evaluation must be performed as deemed appropriate.
- Baseline vital signs including body weight, height, blood pressure, pulse rate, respiration rate, and blood oxygen saturation by pulse oximetry must be obtained unless invalidated by the patient, procedure or equipment. In addition, body temperature should be measured when clinically appropriate.
- Pre-operative verbal and written instructions must be given to the patient, parent, escort, legal guardian or care giver, including pre-operative fasting instructions based on the ASA Summary of Fasting and Pharmacologic Recommendations.
- An intravenous line, which is secured throughout the procedure, must be established except as provided in part IV. C.6., Special Needs Patients.



3. Personnel and Equipment Requirements

Personnel: A minimum of three (3) individuals must be present.

- A dentist qualified in accordance with part III. C. of these *Guidelines* to administer the deep sedation or general anesthesia.
- Two additional individuals who have current certification of successfully completing a Basic Life Support (BLS) Course for the Healthcare Provider.
- When the same individual administering the deep sedation or general anesthesia is performing the dental procedure, one of the additional appropriately trained team members must be designated for patient monitoring.

Equipment:

- A positive-pressure oxygen delivery system suitable for the patient being treated must be immediately available.
- Documentation of compliance with manufacturers' recommended maintenance of monitors, anesthesia delivery systems, and other anesthesia-related equipment should be maintained. A pre-procedural check of equipment for each administration must be performed.
- When inhalation equipment is used, it must have a fail-safe system that is appropriately checked and calibrated. The equipment must also have either (1) a functioning device that prohibits the delivery of less than 30% oxygen or (2) an appropriately calibrated and functioning in-line oxygen analyzer with audible alarm.
- An appropriate scavenging system must be available if gases other than oxygen or air are used.
- The equipment necessary to establish intravenous access must be available.
- Equipment and drugs necessary to provide advanced airway management, and advanced cardiac life support must be immediately available.
- The equipment necessary for monitoring end-tidal CO₂ and auscultation of breath sounds must be immediately available.
- Resuscitation medications and an appropriate defibrillator must be immediately available.

4. Monitoring and Documentation

Monitoring: A qualified dentist administering deep sedation or general anesthesia must remain in the operatory room to monitor the patient continuously until the patient meets the criteria for recovery. The dentist must not leave the facility until the patient meets the criteria for discharge and is discharged from the facility. Monitoring must include:

Oxygenation: Oxygenation saturation must be evaluated continuously by pulse oximetry.

Ventilation:

- Intubated patient: End-tidal CO₂ must be continuously monitored and evaluated.
- Non-intubated patient: End-tidal CO₂ must be continually monitored and evaluated unless precluded or invalidated by the nature of the patient, procedure, or equipment. In addition, ventilation should be monitored and evaluated by continual observation of qualitative signs, including auscultation of breath sounds with a precordial or pretracheal stethoscope.
- Respiration rate must be continually monitored and evaluated.

*Circulation:*

- The dentist must continuously evaluate heart rate and rhythm via ECG throughout the procedure, as well as pulse rate via pulse oximetry.
- The dentist must continually evaluate blood pressure.

Temperature:

- A device capable of measuring body temperature must be readily available during the administration of deep sedation or general anesthesia.
- The equipment to continuously monitor body temperature should be available and must be performed whenever triggering agents associated with malignant hyperthermia are administered.

Documentation:

- Appropriate time-oriented anesthetic record must be maintained, including the names of all drugs, dosages and their administration times, including local anesthetics and monitored physiological parameters.
- Pulse oximetry and end-tidal CO₂ measurements (if taken), heart rate, respiratory rate and blood pressure must be recorded continually.

5. Recovery and Discharge

- Oxygen and suction equipment must be immediately available if a separate recovery area is utilized.
- The dentist or clinical staff must continually monitor the patient's blood pressure, heart rate, oxygenation and level of consciousness.
- The 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** parent, escort, guardian or care giver.

6. Special Needs Patients

Because many dental patients undergoing deep sedation or general anesthesia are mentally and/or physically challenged, it is not always possible to have a comprehensive physical examination or appropriate laboratory tests prior to administering care. When these situations occur, the dentist responsible for administering the deep sedation or general anesthesia should document the reasons preventing the recommended preoperative management.

In selected circumstances, deep sedation or general anesthesia may be utilized without establishing an indwelling intravenous line. These selected circumstances may include very brief procedures or periods of time, which, for example, may occur in some patients; or the establishment of intravenous access after deep sedation or general anesthesia has been induced because of poor patient cooperation.

7. Emergency Management

The qualified dentist is responsible for sedative/anesthetic management, adequacy of the facility and staff, diagnosis and treatment of emergencies related to the administration of deep sedation or general anesthesia and providing the equipment, drugs and protocols for patient rescue.

ENDNOTES

- 1 Excerpted from *Continuum of Depth of Sedation: Definition of General Anesthesia and Levels of Sedation/ Analgesia*, 2014, of the American Society of Anesthesiologists. A copy of the full text can be obtained from ASA, 1061 American Lane Schaumburg, IL 60173-4973 or online at www.asahq.org.
- 2 Excerpted from *Continuum of Depth of Sedation: Definition of General Anesthesia and Levels of Sedation/ Analgesia*, 2014, of the American Society of Anesthesiologists. A copy of the full text can be obtained from ASA, 1061 American Lane Schaumburg, IL 60173-4973 or online at www.asahq.org.
- 3 Excerpted from American Society of Anesthesiologists: Practice Guidelines for preoperative fasting and the use of pharmacologic agents to reduce the risk of pulmonary aspiration: application to healthy patients undergoing elective procedures. *Anesthesiology*, 2011. A copy of the full text can be obtained from ASA, 1061 American Lane Schaumburg, IL 60173-4973 or online at www.asahq.org.
- 4 Standardized BMI category definitions can be obtained from the Centers for Disease Control and Prevention or the American Society of Anesthesiologists.

234 CMR: BOARD OF REGISTRATION IN DENTISTRY

234 CMR 6.00: ADMINISTRATION OF ANESTHESIA AND SEDATION

Section

- 6.01: Scope
- 6.02: Definitions
- 6.03: Facility Permit: Anesthesia Permits Required for Facilities
- 6.04: Facility Permit: D-A: Facility Requirements for Administration of General Anesthesia and Deep Sedation
- 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
- 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
- 6.07: Facility Permit D-C: Administration of Nitrous Oxide-oxygen Sedation Only
- 6.08: Mobile Facility Permit D-H: Facility Requirements for Dental Offices Using Mobile and/or Portable Anesthesia Services
- 6.09: Facility Permit D-P: Requirements for the Use and Provision of Portable and/or Mobile Anesthesia Services
- 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
- 6.11: Individual Permit A: Administration of General Anesthesia and/or Deep 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
- 6.13: Individual Permit B-2: 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
- 6.14: Individual Permit C: Administration of Nitrous Oxide-oxygen Alone or in Conjunction with Local Anesthesia
- 6.15: Administration of Local Anesthesia Only
- 6.16: Permit L: Administration of Local Anesthesia by a Dental Hygienist
- 6.17: Reporting of Adverse Occurrences
- 6.18: Penalty for Non-compliance

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).

6.01: continued

- (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.

6.02: continued

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.

6.02: continued

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-enteral 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.

6.02: continued

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.

6.03: continued

(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);

234 CMR: BOARD OF REGISTRATION IN DENTISTRY

6.04: continued

- (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;

6.06: continued

- (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:
- (a) 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;
 - (b) Determination of adequate oxygen supply and equipment necessary to deliver oxygen under positive pressure must be completed;
 - (c) 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;
 - (d) A focused physical evaluation must be performed as 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.
- (5) Requirements for Patient Monitoring and Documentation.
- (a) 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.
 - (b) 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. The color of mucosa, skin or blood (monitoring only);
 2. The qualified dentist and/or appropriately trained dental auxiliary must observe chest excursions continually;
 3. 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.
- (a) Oxygen and suction equipment must be immediately available;
 - (b) The qualified dentist or appropriately trained dental auxiliary must monitor the patient during recovery until the patient is ready for discharge;
 - (c) The qualified dentist must determine and document that level of consciousness, oxygenation, ventilation and circulation are satisfactory for discharge;
 - (d) 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.

ILLINOIS

Section 1220.500 Definitions

"Anesthesia Case" means a situation in which the permit holder is responsible for anesthesia care on a live patient.

"Deep Sedation" means a pharmacologically induced depressed state of consciousness, accompanied by partial loss of protective reflexes, including the inability to respond purposefully to oral commands. The purposeful response to painful stimulation is maintained.

"General Anesthesia" means a pharmacologically induced state of unconsciousness accompanied by a partial or complete loss of protective reflexes, including the inability to independently maintain an airway and respond purposefully to painful stimulation or oral commands.

"Minimal Sedation" means a minimally depressed level of consciousness, produced by a pharmacological method, that retains the patient's ability to independently and continually maintain an airway and respond normally to tactile stimulation and verbal command. Although cognitive function and coordination may be modestly impaired, ventilatory and cardiovascular functions are unaffected.

"Moderate Sedation" or "Conscious Sedation" means a pharmacologically induced depressed state of consciousness (altered consciousness; signs of sleep) under which an individual retains the ability to independently and continuously maintain an airway and respond appropriately to light tactile stimulation and oral commands.

(Source: Amended at 38 Ill. Reg. 15907, effective July 25, 2014)

Section 1220.505 Minimal Sedation in the Dental Office Setting

- a) Minimal sedation includes the prescription or administration of a pharmacologic anxiolytic either with or without concomitant use of nitrous oxide dental analgesia. The drugs and/or techniques used must carry a margin of safety wide enough to prevent a depressed level of consciousness.
- b) No permit is required beyond the D.D.S. or D.M.D. degrees.
- c) Minimal monitoring of the patient is to be by clinical observation and appropriately documented in the patient's record.

(Source: Amended at 38 Ill. Reg. 15907, effective July 25, 2014)

Section 1220.510 Moderate Sedation (Conscious Sedation) in the Dental Office Setting

- a) Moderate sedation (conscious sedation) includes the prescription or administration of pharmacologic agents to be used for the purposes of moderate sedation. Moderate sedation (conscious sedation) must be administered by an individual qualified under this Section. (See Appendix D for characteristics of levels of anesthesia.) The drugs and/or techniques used must carry a margin of safety wide enough to render unintended loss of consciousness unlikely.
- b) A licensed dentist seeking a Permit A for moderate sedation (conscious sedation) administration privileges shall file an application with the Division, on forms provided by the Division, that shall include:
 - 1) Certification of completion of an anesthesiology training program that meets the following requirements:
 - A) Include a minimum of 75 hours of didactic and clinical study that includes training in moderate sedation (conscious sedation), physical evaluation, venipuncture, advanced airway management, technical administration, recognition and management of complications and emergencies, and monitoring with additionally supervised experience in providing moderate sedation to 20 or more patients; and
 - B) Be an organized sequence of study operated by one entity and completed in less than one calendar year;
 - 2) A signed affidavit certifying that:

- A) the dentist will practice in a facility properly equipped in accordance with subsection (g) for the administration of moderate sedation (conscious sedation);
 - B) the facility will be staffed with a team, supervised by the applicant, that will remain in the treatment room. For each patient, the anesthesia team will consist of at least:
 - i) the dentist who holds the Permit A;
 - ii) one dental hygienist or dental assistant who has completed the training prescribed in Section 1220.240(f) or 1220.245(c)(2) and is capable of assisting with procedures, problems and emergencies incident to the administration of sedation; and
 - iii) one additional hygienist or dental assistant;
 - C) the dentist permit holder will remain immediately available to the patient after being treated under moderate sedation. A dental hygienist or dental assistant trained to monitor a patient under moderate sedation will remain with the sedated patient until the patient is no longer sedated;
 - D) all members of the anesthesia team are capable of assisting with procedures, problems and emergencies incident to the administration of sedation and will maintain current certification in BLS; and
 - E) for the dentist permit holder, the BLS certification is in addition to the required 9 sedation technique CE hours (see subsection (k)) required per renewal cycle;
- 3) Proof of current ACLS certification or PALS certification; and
 - 4) The required fee set forth in Section 1220.415.
- c) Dentists who have a current valid permit for moderate sedation (conscious sedation) issued by the Division shall be permitted to administer without additional application.
 - d) In accordance with the standards set forth in this Section, the Division will:
 - 1) Issue a moderate sedation (conscious sedation) permit (Permit A).
 - 2) Re-issue a moderate sedation (conscious sedation) permit to Permit A holders who attest to completing continuing education.
 - e) Licensees qualified to administer deep sedation (Permit B) pursuant to Section 1220.520 may administer moderate sedation (conscious sedation) without a Permit A.
 - f) If the accuracy, relevance or sufficiency of any submitted documentation is questioned by the Division or the Board, because of discrepancies or conflicts in information, needing further clarification, and/or missing information, additional documentation may be required and/or an on-site evaluation of the facilities, equipment and personnel may be conducted by the Division or a member of the Board's Anesthesia Review Panel.
 - g) A properly equipped facility for the administration of moderate sedation (conscious sedation) shall include at minimum:
 - 1) Sphygmomanometer and stethoscope;
 - 2) An oxygen delivery system with full face masks and connectors appropriate to the patient population being served that is capable of delivering oxygen to the patient under positive pressure, with an emergency backup system;
 - 3) Emergency drugs and equipment appropriate to the medications administered;
 - 4) Suction equipment, including an emergency backup suction system;
 - 5) An emergency backup lighting system that will permit the completion of any operation underway;
 - 6) A pulse oximeter;
 - 7) Laryngoscope complete with selection of blades and spare batteries and bulbs in sizes appropriate to the patient population being served;
 - 8) Advanced airway devices that would isolate the trachea and facilitate positive pressure oxygen administration in sizes appropriate for the patient population being served (e.g., endotracheal tubes or laryngeal mask airway);
 - 9) Tonsillar or pharyngeal suction tips adaptable to all office outlets;

- 10) Nasal and oral airways in sizes appropriate to the patient population being served;
 - 11) Defibrillator (an automated external defibrillator is an acceptable defibrillator);
 - 12) Equipment for the establishment of an intravenous infusion;
 - 13) An operating table or an operating chair that permits appropriate access to the patient and provides a firm platform for the management of cardiopulmonary resuscitation; and
 - 14) A recovery area that has available oxygen, lighting, suction and electrical outlets. The Permit A holder shall remain with the patient until the patient retains the ability to independently and consciously maintain an airway and respond appropriately to physical stimulation and oral commands. The recovery area may be the operating theatre.
- h) The following records shall be kept during the administration of moderate sedation (conscious sedation):
- 1) Medical history of the patient and consent for administration of anesthesia prior to the performance of any procedure;
 - 2) Preoperative, intraoperative and pre-discharge monitoring of blood pressure, pulse, respiration and oxygen saturation. A time based record shall be entered into the patient's chart;
 - 3) Drugs and dosages of these drugs used during the operative procedure, including the identification of the person administering drugs and times of their administration over the course of the procedure.
- i) The dentist who holds the Permit A shall report adverse occurrences to the Division and the Board as required by Section 1220.405.
- j) A licensed dentist shall hold Permit A in order to perform dentistry while a licensed certified nurse anesthetist administers moderate sedation (conscious sedation). A nurse anesthetist for purposes of this Section is a licensed certified nurse anesthetist who holds a license as an advanced practice nurse under the Nurse Practice Act [225 ILCS 65]. The dentist shall enter into a written collaborative agreement with the nurse anesthetist in accordance with Section 65-35 of the Nurse Practice Act and 68 Ill. Adm. Code 1300.
- k) Proof of 9 hours of continuing education per renewal cycle in sedation techniques, including medications and recognition and management of complications and emergencies, is required for renewal of Permit A.
- l) A treating dentist does not need to hold Permit A to perform dentistry when another dentist, who holds Permit A or Permit B, or a physician assists the treating dentist by administering moderate sedation (conscious sedation). Physician for purposes of this Section means a physician who is licensed to practice medicine in all of its branches under the Medical Practice Act of 1987 [225 ILCS 60] and is authorized to provide anesthesia services in a licensed hospital or licensed ambulatory surgical treatment center or is a Board certified anesthesiologist.
- 1) The treating dentist shall be prepared to provide affidavits to the following if requested by the Division:
 - A) That the facility used for sedation meets the criteria of subsection (g) of this Section;
 - B) That the dentist shall staff the facility with a team, supervised by the permit holder or physician, that includes a minimum of 3 individuals per patient. The team shall be composed of either:
 - i) One dental hygienist or dental assistant who has completed the training prescribed in Section 1220.240(f) or 1220.245(c)(2) and is capable of assisting with procedures, problems and emergencies incident to the administration of the sedation; the treating dentist; and the dentist who holds a Permit A or B providing the anesthesia services; or
 - ii) One dental hygienist or dental assistant who has completed the training prescribed in Section 1220.240(f) or 1220.245(c)(2) and is capable of assisting with procedures, problems and emergencies incident to the administration of the sedation; the treating dentist; and a physician providing the anesthesia services.
 - C) That the permit holder or physician will remain immediately available to the patient after being treated under moderate sedation. A dental hygienist or dental assistant trained to

monitor a patient under moderate sedation will remain with the sedated patient until the patient is no longer sedated.

- 2) All members of the team, including the treating dentist (non-permit holder) must maintain current BLS certification or its equivalent.
 - 3) In addition, the dentist (non-permit holder) shall report adverse occurrences to the Division as set forth in Section 1220.405 and accept the responsibility to verify the certification and licensure of any licensed provider present during the moderate sedation (conscious sedation) of a patient who is receiving dental care.
- m) A dentist holding a Permit A shall maintain current ACLS or PALS certification. ACLS or PALS certification shall be in addition to the required 9 hours of anesthesia CE per renewal cycle.
 - n) A dentist holding a Permit A shall maintain a logbook indicating the sedation cases performed. The log shall include the patient name, date, route of sedation administration, drug name and dosage, and the names of anesthesia team members assisting. This information shall be supplied to the Division upon request.
 - o) A dentist holding a Permit A must also hold an active Illinois Controlled Substances License and current federal Drug Enforcement Administration registration.

(Source: Amended at 38 Ill. Reg. 15907, effective July 25, 2014)

Section 1220.520 Deep Sedation and General Anesthesia in the Dental Office Setting

Deep sedation and general anesthesia must be administered by an individual qualified under this Section. (See Appendix D for characteristics of levels of anesthesia.)

- a) A licensed dentist seeking a permit to administer deep sedation or general anesthesia shall make application to the Division, on forms provided by the Division, that shall include:
 - 1) Certification of meeting one or more of the following:
 - A) Completion of a minimum of 2 years of advanced training in anesthesiology beyond the pre-doctoral level, in a training program approved by the American Dental Association, Commission on Dental Education, as outlined in Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students, published by the American Dental Association, Commission on Dental Education (October 2012).
 - B) Be a diplomate of the American Board of Oral and Maxillofacial Surgery.
 - C) Have an active, approved application with the American Board of Oral and Maxillofacial Surgery to obtain diplomat status.
 - D) Have a specialty license in oral and maxillofacial surgery issued by the Division;
 - 2) A signed affidavit certifying that:
 - A) the dentist will practice in a facility properly equipped in accordance with subsection (d) for the administration of deep sedation and general anesthesia;
 - B) the facility will be staffed with an anesthesia team, supervised by the applicant, that will remain in the treatment room during the procedure on the patient. For each patient, the anesthesia team will consist of at least:
 - i) the dentist who holds the permit B;
 - ii) one dental hygienist or dental assistant who has completed the training prescribed in Section 1220.240(f) or 1220.245(c)(2) and is capable of assisting with procedures, problems and emergencies incident to the administration of the sedation; and
 - iii) one additional hygienist or dental assistant;
 - C) the dentist permit holder will remain immediately available to the patient after being treated under deep sedation or general anesthesia. A dental hygienist or dental assistant trained to monitor a patient under deep sedation or general anesthesia will remain with the sedated patient until the patient is no longer sedated;
 - D) all members of the anesthesia team are capable of assisting with procedures, problems and emergencies incident to the administration of sedation and will maintain current certification in BLS or its equivalent; and

- E) for the dentist permit holder, the BLS certification is in addition to the required 9 sedation technique CE hours (see subsection (h)) required per renewal cycle;
- 3) Proof of current ACLS or PALS certification; and
- 4) The required fee set forth in Section 1220.415.
- b) In accordance with the standards set forth in this Section, the Division will issue a deep sedation or general anesthesia permit (Permit B).
- c) If the accuracy, relevance or sufficiency of any submitted documentation is questioned by the Division or the Board because of discrepancies or conflicts in information needing further clarification, and/or missing information, additional documentation may be required and/or an on-site evaluation of the facilities, equipment and personnel may be conducted by the Division or a member of the Board's Anesthesia Review Panel.
- d) A properly equipped facility for the administration of deep sedation or general anesthesia shall include, at a minimum:
 - 1) Sphygmomanometer and stethoscope;
 - 2) An oxygen delivery system with full face masks and connectors appropriate to the patient population being served that is capable of delivering oxygen to the patient under positive pressure, with an emergency backup system;
 - 3) Emergency drugs and equipment appropriate to the medications administered;
 - 4) Suction equipment, including an emergency backup suction system;
 - 5) An emergency backup lighting system that will permit the completion of any operation underway;
 - 6) Laryngoscope complete with selection of blades and spare batteries and bulbs in sizes appropriate to the patient population being served;
 - 7) Endotracheal tubes and connectors in sizes appropriate for the patient population being served;
 - 8) Tonsillar or pharyngeal suction tips adaptable to all office outlets;
 - 9) Nasal and oral airways in sizes appropriate to the patient population being served;
 - 10) Device for monitoring temperature (e.g., temperature strips, thermometer);
 - 11) Electrocardioscope and defibrillator (an automated external defibrillator is an acceptable defibrillator);
 - 12) Pulse oximeter;
 - 13) Equipment for the establishment of an intravenous infusion;
 - 14) An operating table or an operating chair that permits appropriate access to the patient and provides a firm platform for the management of cardiopulmonary resuscitation; and
 - 15) A recovery area that has available oxygen, lighting, suction and electrical outlets. The Permit B holder shall remain with the patient until the patient retains the ability to independently and consciously maintain an airway and respond appropriately to physical stimulation and oral commands. The recovery area may be the operating theatre.
- e) The following records shall be kept when administering deep sedation and general anesthesia:
 - 1) Medical history and patient evaluation prior to the performance of any procedure;
 - 2) Preoperative, intraoperative, and pre-discharge monitoring of blood pressure, pulse, respiration and oxygen saturation. A time based record shall be entered into the patient's chart;
 - 3) EKG monitoring during the entire procedure;
 - 4) Drugs and dosages of agents used during the operative procedure, including nitrous oxide and oxygen, and including identification of the person administering drugs and times of their administration over the course of the procedure. Documentation of the anesthetic encounter will be consistent with currently accepted standards of anesthetic practice.
- f) The dentist who holds the Permit B shall report adverse occurrences to the Division and the Board as required by Section 1220.405.
- g) A licensed dentist shall hold a Permit B in order to perform dentistry while a licensed certified nurse anesthetist administers deep sedation or general anesthesia. A nurse anesthetist for purposes of this Section is a licensed certified nurse anesthetist who holds a license as an advanced practice nurse under

the Nurse Practice Act. The dentist shall enter into a written collaborative agreement with the nurse anesthetist in accordance with Section 65-35 of the Nurse Practice Act and 68 Ill. Adm. Code 1300.

- h) Proof of 9 hours of continuing education per renewal cycle in sedation techniques, including medications and recognition and management of complications and emergencies, is required for renewal of Permit B.
- i) A treating-dentist does not need to hold Permit B to perform dentistry when another dentist, who holds Permit B, or a physician assists the treating dentist by administering deep sedation or general anesthesia. Physician for purposes of this Section means a physician who is licensed to practice medicine in all of its branches under the Medical Practice Act of 1987 and is authorized to provide anesthesia services in a licensed hospital or licensed ambulatory surgical treatment center or is a Board certified anesthesiologist.
 - 1) The treating dentist shall be prepared to provide affidavits attesting to the following if requested by the Division:
 - A) That the facility used is equipped as specified in subsection (d);
 - B) That the dentist shall staff the facility with a team, supervised by the Permit B holder or physician, that includes a minimum of 3 individuals per patient. The team shall be composed of either:
 - i) One dental hygienist or dental assistant who has completed the training prescribed in Section 1220.240(f) or 1220.245(c)(2) capable of assisting with procedures, problems and emergencies incident to the administration of the sedation; the treating dentist; and the dentist who holds a Permit B providing the anesthesia services; or
 - ii) One dental hygienist or dental assistant who has completed the training prescribed in Section 1220.240(f) or 1220.245(c)(2) capable of assisting with procedures, problems and emergencies incident to the administration of the sedation; the treating dentist; and a physician.
 - C) That the Permit B holder will remain with the patient until the patient retains the ability to independently and consciously maintain an airway and respond appropriately to physical stimulation and oral commands. The recovery area may be the operating theatre.
 - 2) All members of the anesthesia team, including the treating dentist (non-Permit B holder) must maintain certification in BLS or its equivalent.
 - 3) In addition, the dentist shall report severe adverse occurrences to the Division as set forth in Section 1220.405 and accept the responsibility for verifying certification and licensure of any licensed provider present during the deep sedation or general anesthesia of a patient receiving dental care.
- j) A dentist holding a Permit B shall maintain current ACLS or PALS certification. ACLS or PALS certification shall be in addition to the required 9 hours of anesthesia CE per renewal cycle.
- k) A dentist holding a Permit B shall maintain a logbook indicating the sedation cases performed. The log shall include the patient name, date, route of sedation administration, drug name and dosage, and the names of anesthesia team members assisting. This information shall be supplied to the Division upon request.
- l) A dentist holding a Permit B must also hold an active Illinois Controlled Substances License and current federal Drug Enforcement Administration registration.

(Source: Amended at 38 Ill. Reg. 15907, effective July 25, 2014)

Section 1220.525 Renewal

- a) Beginning with the September 30, 2006 renewal, every anesthesia permit issued under the Act shall expire on September 30 every 3 years. The holder of a permit may renew the permit during the month preceding the expiration date by paying the required fee in Section 1220.415 and completing the following:
 - 1) 9 hours of continuing education as required in Section 1220.510(k) or 1220.520(h).
 - 2) Certification of the number of anesthesia cases that the renewal applicant has performed.

- 3) Certification that the renewal applicant has held at least semiannual emergency drills with staff that participates in Permit A or B related activities. These drills shall consist of the staff actively going through simulated emergencies that may occur during the administration of anesthesia. It is incumbent upon the permit holder to design the emergency drills to ensure adequate preparation of staff in the case of a real emergency. In addition, the staff shall assemble and review the necessary office emergency supplies and equipment intended for use in an actual office emergency, including verifying the expiration dates for emergency medications and checking that batteries for defibrillators and laryngoscopes are properly charged. Documentation of the semiannual drills shall be provided to the Division upon request.
- b) No anesthesia permit shall be renewed if the dental license of the permit holder is expired, revoked, suspended or otherwise subject to discipline under Section 23 of the Act.
- c) It is the responsibility of each licensee to notify the Division of any change of address. Failure to receive a renewal form from the Division shall not constitute an excuse for failure to pay the renewal fee or to renew one's license.
- d) Certification of Anesthesia Cases
 - 1) Each renewal applicant shall certify, on the renewal application, the number of anesthesia cases performed each year by the renewal applicant appropriate to the permit held.
 - 2) The licensee shall be required to maintain the logbooks required in Section 1220.510(n) or 1220.520(k) and shall provide the logbook to the Division upon request.
 - 3) The Division may conduct audits to verify compliance and/or competency. When a licensee is reviewed, the Division will provide notice to the licensee and request that the licensee's anesthesia logbook be submitted. Within 14 days after receipt of the notice, the licensee shall submit to the Division the records required to be kept pursuant to Section 1220.510(h) or 1220.520(e), as appropriate to the permit held, of all anesthesia cases performed during the renewal cycle.
 - 4) When the Division has reason to believe that there is a lack of competency or a lack of compliance, a licensee shall be notified in writing and may request a conference before the Division with a Board member present. When the Division finds a violation of the Act or this Part, it may recommend that steps be taken to begin formal disciplinary proceedings.

(Source: Amended at 34 Ill. Reg. 7205, effective May 5, 2010)

Section 1220.530 Anesthesia Review Panel

- a) The Director may appoint an Anesthesia Review Panel that shall consist of six members.
- b) The members shall meet the following minimum requirements:
 - 1) Each member shall be a licensed dentist in the State of Illinois whose license is active and in good standing;
 - 2) Three members shall hold an active Permit A;
 - 3) Three members shall hold an active Permit B.
- c) The Panel shall:
 - 1) Meet only at the direction of the Director;
 - 2) Be reimbursed for all legitimate, necessary and authorized expenses incurred in attending the meetings of the panel;
 - 3) Review Permit A and Permit B applications at the request of the Director;
 - 4) Recommend to the Director the eligibility of applicants;
 - 5) Recommend to the Director when an on-site inspection may be necessary and conduct an inspection with a Board member present;
 - 6) Evaluate results of on-site inspection and make recommendation to the Director as to eligibility of applicants; and
 - 7) Advise the Director in regard to anesthesiology related matters that include mortality and morbidity statistics.
- d) Each Panel member shall serve a 4 year term and may be appointed once.

(Source: Amended at 34 Ill. Reg. 7205, effective May 5, 2010)

Section 1220.560 Restoration of Permits

- a) A licensee seeking restoration of a permit after it has expired for 12 months or less shall have the permit restored upon payment of \$20 plus the current renewal fee. The licensee shall also submit certification of anesthesia cases as provided in Section 1220.525(d) and the records required to be kept pursuant to Section 1220.510(n) or 1220.520(k), as appropriate to the permit held, of all anesthesia cases performed since the permit was last renewed. The permit will be restored if the Division finds that the applicant is competent to provide anesthesia services appropriate to the permit for which restoration is sought.
- b) A licensee seeking restoration of a permit after it has expired for more than 12 months shall file an application, on forms supplied by the Division, together with the fees required by Section 1220.415. The licensee shall also submit:
 - 1) Sworn evidence of lawful active practice in another jurisdiction. Such evidence shall include a statement from the appropriate board or licensing authority in the other jurisdiction that the licensee was authorized to practice during the term of said active practice; or
 - 2) An affidavit attesting to military service as provided in Section 16 of the Act. If an applicant applies for restoration of the permit within 2 years after termination of such service, he/she shall have the permit restored without paying any lapsed renewal or restoration fees; or
 - 3) For Permit A restoration, proof of the training set forth in Section 1220.510(b)(1) taken 2 years prior to application; or
 - 4) For Permit B restoration, proof of the training set forth in Section 1220.520(a)(1) taken 2 years prior to application.
- c) When proof of remedial training is provided, the permit shall not be restored unless and until the Board has reviewed and approved the training. The Board may require the renewal applicant to obtain additional training when it finds that the training completed was not sufficient.

(Source: Amended at 34 Ill. Reg. 7205, effective May 5, 2010)

Section 1220.APPENDIX D Characteristics of Levels of Anesthesia*

Factors	Minimal Sedation (No Permit required)	Moderate/Conscious Sedation (Permit A)	Deep Sedation (Permit B)	General Anesthesia (Permit B)
Goal	Decrease anxiety; facilitate coping skills	Decrease or eliminate anxiety; facilitate coping skills	Eliminate anxiety; coping skills over- ridden	Eliminate cognitive, sensory and skeletal motor activity

Definition	Minimally depressed level of consciousness, produced by a pharmacological method, that retains the patient's ability to independently and continually maintain an airway and respond normally to tactile stimulation and verbal command. Although cognitive function and coordination may be modestly impaired, ventilatory and cardiovascular functions are unaffected	Pharmacologically induced depressed state of consciousness (altered consciousness, signs of sleep) under which an individual retains the ability to independently and continuously maintain an airway and respond appropriately to light tactile stimulation and oral commands	Pharmacologically induced controlled state of depressed consciousness, accompanied by partial loss of protective reflexes, including inability to respond purposefully to oral commands. The purposeful response to painful stimulation is maintained	Pharmacologically induced controlled state of unconsciousness accompanied by a partial or complete loss of protective reflexes, including inability to independently maintain an airway and respond purposefully to painful stimulation or oral commands
Personnel	1 (treating dentist)	3 (treating dentist with Permit A; trained person to monitor patient or nurse anesthetist; trained assistant) OR 3 (treating dentist w/o Permit A/B; physician or dentist with Permit A/B; trained assistant)	3 (treating dentist with Permit B; trained person to monitor patient or nurse anesthetist; trained assistant) OR 3 (treating dentist w/o Permit B; physician or dentist with Permit B; trained assistant)	3 (treating dentist with Permit B; trained person to monitor patient or nurse anesthetist, trained assistant) OR 3 (treating dentist w/o Permit B; physician or dentist with Permit B; trained assistant)
Monitoring	Clinical observation and monitoring as appropriate	Preoperative, intraoperative and pre-discharge monitoring of BP, pulse, respiration and oxygen saturation	Preoperative, intraoperative, and pre-discharge monitoring of BP, pulse, respiration and oxygen saturation, EKG monitoring. Defibrillator required	Preoperative, intraoperative, and pre-discharge monitoring of BP, pulse, respiration and oxygen saturation, EKG monitoring. Defibrillator required

* Chart adapted from American Academy of Pediatric Dentistry, Reference Manual 2000-2001, Templates of Definitions and Characteristics for Levels of Sedation and General Anesthesia and the American Dental Association, Guidelines for the Use of Sedation and General Anesthesia by Dentists (October 2012).

(Source: Amended at 38 Ill. Reg. 15907, effective July 25, 2014)

CHAPTER 29
SEDATION AND NITROUS OXIDE INHALATION ANALGESIA
[Prior to 5/18/88, Dental Examiners, Board of[320]]

650—29.1(153) Definitions. For the purpose of these rules, relative to the administration of deep sedation/general anesthesia, moderate sedation, minimal sedation, and nitrous oxide inhalation analgesia by licensed dentists, the following definitions shall apply:

“*Antianxiety premedication*” means minimal sedation. A dentist providing minimal sedation must meet the requirements of rule 650—29.7(153).

“*ASA*” refers to the American Society of Anesthesiologists Patient Physical Status Classification System. Category 1 means normal healthy patients, and category 2 means patients with mild systemic disease. Category 3 means patients with moderate systemic disease, and category 4 means patients with severe systemic disease that is a constant threat to life.

“*Board*” means the Iowa dental board established in Iowa Code section 147.14(1)“*d.*”

“*Capnography*” means the monitoring of the concentration of exhaled carbon dioxide in order to assess physiologic status or determine the adequacy of ventilation during anesthesia.

“*Committee*” or “*ACC*” means the anesthesia credentials committee of the board.

“*Conscious sedation*” means moderate sedation.

“*Deep sedation/general anesthesia*” is a controlled state of unconsciousness, produced by a pharmacologic agent, accompanied by a partial or complete loss of protective reflexes, including inability to independently maintain an airway and respond purposefully to physical stimulation or verbal command.

“*Facility*” means a dental office, clinic, dental school, or other location where sedation is used.

“*Hospitalization*” means in-patient treatment at a hospital or clinic. Out-patient treatment at an emergency room or clinic is not considered to be hospitalization for the purposes of reporting adverse occurrences.

“*Maximum recommended dose (MRD)*” means the maximum FDA-recommended dose of a drug as printed in FDA-approved labeling for unmonitored home use.

“*Minimal sedation*” means a minimally depressed level of consciousness, produced by a pharmacological method, that retains the patient’s ability to independently and continuously maintain an airway and respond normally to tactile stimulation and verbal command. Although cognitive function and coordination may be modestly impaired, ventilatory and cardiovascular functions are unaffected. The term “minimal sedation” also means “antianxiety premedication” or “anxiolysis.” A dentist providing minimal sedation shall meet the requirements of rule 650—29.7(153).

“*Moderate sedation*” means a drug-induced depression of consciousness, either by enteral or parenteral means, 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. Prior to January 1, 2010, moderate sedation was referred to as conscious sedation.

“*Monitoring nitrous oxide inhalation analgesia*” means continually observing the patient receiving nitrous oxide and recognizing and notifying the dentist of any adverse reactions or complications.

“*Nitrous oxide inhalation analgesia*” refers to 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.

“*Pediatric*” means patients aged 12 or under.

[ARC 8614B, IAB 3/10/10, effective 4/14/10; ARC 1194C, IAB 11/27/13, effective 11/4/13; ARC 3491C, IAB 12/6/17, effective 1/10/18]

650—29.2(153) Prohibitions.

29.2(1) Deep sedation/general anesthesia. Dentists licensed in this state shall not administer deep sedation/general anesthesia in the practice of dentistry until they have obtained a permit. Dentists shall

only administer deep sedation/general anesthesia in a facility that has successfully passed inspection as required by the provisions of this chapter.

29.2(2) Moderate sedation. Dentists licensed in this state shall not administer moderate sedation in the practice of dentistry until they have obtained a permit. Dentists shall only administer moderate sedation in a facility that has successfully passed inspection as required by the provisions of this chapter.

29.2(3) Nitrous oxide inhalation analgesia. Dentists licensed in this state shall not administer nitrous oxide inhalation analgesia in the practice of dentistry until they have complied with the provisions of rule 650—29.6(153).

29.2(4) Antianxiety premedication. Dentists licensed in this state shall not administer antianxiety premedication in the practice of dentistry until they have complied with the provisions of rule 650—29.7(153).

[ARC 8614B, IAB 3/10/10, effective 4/14/10; ARC 1194C, IAB 11/27/13, effective 11/4/13]

650—29.3(153) Requirements for the issuance of deep sedation/general anesthesia permits.

29.3(1) A permit may be issued to a licensed dentist to use deep sedation/general anesthesia on an outpatient basis for dental patients provided the dentist meets the following requirements:

- a. Has successfully completed an advanced education program accredited by the Commission on Dental Accreditation that provides training in deep sedation and general anesthesia; and
- b. Has formal training in airway management; and
- c. Has completed a minimum of one year of advanced training in anesthesiology and related academic subjects beyond the undergraduate dental school level in a training program approved by the board; and
- d. Has completed a peer review evaluation, as may be required by the board, prior to issuance of a permit.

29.3(2) A dentist using deep sedation/general anesthesia shall maintain a properly equipped facility at each facility where sedation is administered. The dentist shall maintain and be trained on the following equipment at each facility where sedation is provided: capnography to monitor end-tidal CO₂, pretracheal or precordial stethoscope to continually monitor auscultation of breath sounds, EKG monitor, positive pressure oxygen, suction, laryngoscope and blades, endotracheal tubes, magill forceps, oral airways, stethoscope, blood pressure monitoring device, pulse oximeter, emergency drugs, defibrillator. A licensee may submit a request to the board for an exemption from any of the provisions of this subrule. Exemption requests will be considered by the board on an individual basis and shall be granted only if the board determines that there is a reasonable basis for the exemption.

29.3(3) The dentist shall ensure that each facility where sedation services are provided is permanently equipped pursuant to subrule 29.3(2) and staffed with trained auxiliary personnel capable of reasonably handling procedures, problems and emergencies incident to the administration of general anesthesia. Auxiliary personnel shall maintain current certification in basic life support and be capable of administering basic life support.

29.3(4) A dentist administering deep sedation/general anesthesia must document and maintain current certification in Advanced Cardiac Life Support (ACLS). Current certification means certification by an organization on an annual basis or, if that certifying organization requires certification on a less frequent basis, evidence that the permit holder has been properly certified for each year covered by the renewal period. In addition, the course must include a clinical component.

29.3(5) A dentist who is performing a procedure for which deep sedation/general anesthesia was induced shall not administer the general anesthetic and monitor the patient without the presence and assistance of at least two qualified auxiliary personnel in the room who are qualified under subrule 29.3(3).

29.3(6) A dentist qualified to administer deep sedation/general anesthesia under this rule may administer moderate sedation and nitrous oxide inhalation analgesia provided the dentist meets the requirements of rule 650—29.6(153).

29.3(7) A licensed dentist who has been utilizing deep sedation/general anesthesia in a competent manner for the five-year period preceding July 9, 1986, but has not had the benefit of formal training

as outlined in this rule, may apply for a permit provided the dentist fulfills the provisions set forth in 29.3(2), 29.3(3), 29.3(4), and 29.3(5).

[ARC 8614B, IAB 3/10/10, effective 4/14/10; ARC 1194C, IAB 11/27/13, effective 11/4/13; ARC 3491C, IAB 12/6/17, effective 1/10/18]

650—29.4(153) Requirements for the issuance of moderate sedation permits.

29.4(1) A permit may be issued to a licensed dentist to use moderate sedation for dental patients provided the dentist meets the following requirements:

a. Has successfully completed a training program approved by the board that meets the American Dental Association Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students and that consists of a minimum of 60 hours of instruction and management of at least 20 patients; and

b. Has successfully completed a training program that includes rescuing patients from a deeper level of sedation than intended, including managing the airway, intravascular or intraosseous access, and reversal medications; or

c. Has submitted evidence of successful completion of an accredited residency program that includes formal training and clinical experience in moderate sedation, which is approved by the board; and

d. Has completed a peer review evaluation, as may be required by the board, prior to issuance of a permit.

29.4(2) A dentist utilizing moderate sedation shall maintain a properly equipped facility. The dentist shall maintain and be trained on the following equipment at each facility where sedation is provided: capnography to monitor end-tidal CO₂ unless precluded or invalidated by the nature of the patient, procedure or equipment, pretracheal or precordial stethoscope, EKG monitor, positive pressure oxygen, suction, laryngoscope and blades, endotracheal tubes, magill forceps, oral airways, stethoscope, blood pressure monitoring device, pulse oximeter, emergency drugs, defibrillator. A licensee may submit a request to the board for an exemption from any of the provisions of this subrule. Exemption requests will be considered by the board on an individual basis and shall be granted only if the board determines that there is a reasonable basis for the exemption.

29.4(3) The dentist shall ensure that each facility where sedation services are provided is permanently equipped pursuant to subrule 29.4(2) and staffed with trained auxiliary personnel capable of reasonably handling procedures, problems and emergencies incident to the administration of moderate sedation. Auxiliary personnel shall maintain current certification in basic life support and be capable of administering basic life support.

29.4(4) A dentist administering moderate sedation must document and maintain current certification in Advanced Cardiac Life Support (ACLS). A dentist administering moderate sedation to pediatric patients may maintain current certification in Pediatric Advanced Life Support (PALS) in lieu of ACLS. Current certification means certification by an organization on an annual basis or, if that certifying organization requires certification on a less frequent basis, evidence that the permit holder has been properly certified for each year covered by the renewal period. In addition, the course must include a clinical component.

29.4(5) A dentist who is performing a procedure for which moderate sedation is being employed shall not administer the pharmacologic agents and monitor the patient without the presence and assistance of at least one qualified auxiliary personnel in the room who is qualified under subrule 29.4(3).

29.4(6) Dentists qualified to administer moderate sedation may administer nitrous oxide inhalation analgesia provided they meet the requirement of rule 650—29.6(153).

29.4(7) If moderate sedation results in a general anesthetic state, the rules for deep sedation/general anesthesia apply.

29.4(8) A dentist utilizing moderate sedation on pediatric or ASA category 3 or 4 patients must have completed an accredited residency program that includes formal training in anesthesia and clinical experience in managing pediatric or ASA category 3 or 4 patients. A dentist who does not meet the

requirements of this subrule is prohibited from utilizing moderate sedation on pediatric or ASA category 3 or 4 patients.

[ARC 8614B, IAB 3/10/10, effective 4/14/10; ARC 1194C, IAB 11/27/13, effective 11/4/13; ARC 1810C, IAB 1/7/15, effective 2/11/15; ARC 3491C, IAB 12/6/17, effective 1/10/18]

650—29.5(153) Permit holders.

29.5(1) No dentist shall use or permit the use of deep sedation/general anesthesia or moderate sedation for dental patients, unless the dentist possesses a current permit issued by the board. No dentist shall use or permit the use of deep sedation/general anesthesia or moderate sedation for dental patients in a facility that has not successfully passed an equipment inspection pursuant to the requirements of subrule 29.3(2). A dentist holding a permit shall be subject to review and facility inspection at a frequency described in subrule 29.5(10).

29.5(2) An application for a deep sedation/general anesthesia permit must include the appropriate fee as specified in 650—Chapter 15, as well as evidence indicating compliance with rule 650—29.3(153).

29.5(3) An application for a moderate sedation permit must include the appropriate fee as specified in 650—Chapter 15, as well as evidence indicating compliance with rule 650—29.4(153).

29.5(4) If a facility has not been previously inspected, no permit shall be issued until the facility has been inspected and successfully passed.

29.5(5) Permits shall be renewed biennially at the time of license renewal following submission of proper application and may involve board reevaluation of credentials, facilities, equipment, personnel, and procedures of a previously qualified dentist to determine if the dentist is still qualified. The appropriate fee for renewal as specified in 650—Chapter 15 of these rules must accompany the application.

29.5(6) Upon the recommendation of the anesthesia credentials committee that is based on the evaluation of credentials, facilities, equipment, personnel and procedures of a dentist, the board may determine that restrictions may be placed on a permit.

29.5(7) The actual costs associated with the on-site evaluation of the facility shall be the primary responsibility of the licensee. The cost to the licensee shall not exceed the fee as specified in 650—Chapter 15.

29.5(8) Permit holders shall follow the American Dental Association's guidelines for the use of sedation and general anesthesia for dentists, except as otherwise specified in these rules.

29.5(9) A dentist utilizing moderate sedation on pediatric or ASA category 3 or 4 patients must have completed an accredited residency program that includes formal training in anesthesia and clinical experience in managing pediatric or ASA category 3 or 4 patients. A dentist who does not meet the requirements of this subrule is prohibited from utilizing moderate sedation on pediatric or ASA category 3 or 4 patients.

29.5(10) Frequency of facility inspections.

a. The board office will conduct ongoing facility inspections of each facility every five years, with the exception of the University of Iowa College of Dentistry.

b. The University of Iowa College of Dentistry shall submit written verification to the board office every five years indicating that it is properly equipped pursuant to this chapter.

29.5(11) Use of capnography and pretracheal or precordial stethoscope.

a. Consistent with the practices of the American Association of Oral and Maxillofacial Surgeons (AAOMS), all general anesthesia/deep sedation permit holders shall use capnography at all facilities where they provide sedation beginning January 1, 2014.

b. All general anesthesia/deep sedation permit holders shall use a pretracheal or precordial stethoscope to continually monitor auscultation of breath sounds beginning January 1, 2018.

29.5(12) Use of capnography or pretracheal/precordial stethoscope required for moderate sedation permit holders. Beginning January 1, 2018, all moderate sedation permit holders shall use capnography to monitor end-tidal CO₂ unless precluded or invalidated by the nature of the patient, procedure or equipment. In cases where the use of capnography is precluded or invalidated for the reasons listed

previously, a pretracheal or precordial stethoscope must be used to continually monitor the auscultation of breath sounds at all facilities where permit holders provide sedation.

[ARC 8614B, IAB 3/10/10, effective 4/14/10; ARC 0265C, IAB 8/8/12, effective 9/12/12; ARC 1194C, IAB 11/27/13, effective 11/4/13; ARC 1810C, IAB 1/7/15, effective 2/11/15; ARC 3491C, IAB 12/6/17, effective 1/10/18]

650—29.6(153) Nitrous oxide inhalation analgesia.

29.6(1) A dentist may use nitrous oxide inhalation analgesia sedation on an outpatient basis for dental patients provided the dentist:

- a. Has completed a board approved course of training; or
- b. Has training equivalent to that required in 29.6(1) “a” while a student in an accredited school of dentistry, and
- c. Has adequate equipment with fail-safe features and minimum oxygen flow which meets FDA standards.
- d. Has routine inspection, calibration, and maintenance on equipment performed every two years and maintains documentation of such, and provides documentation to the board upon request.
- e. Ensures the patient is continually monitored by qualified personnel while receiving nitrous oxide inhalation analgesia.

29.6(2) A dentist utilizing nitrous oxide inhalation analgesia shall be trained and capable of administering basic life support, as demonstrated by current certification in a nationally recognized course in cardiopulmonary resuscitation.

29.6(3) A licensed dentist who has been utilizing nitrous oxide inhalation analgesia in a dental office in a competent manner for the 12-month period preceding July 9, 1986, but has not had the benefit of formal training outlined in paragraph 29.6(1) “a” or 29.6(1) “b,” may continue the use provided the dentist fulfills the requirements of paragraphs 29.6(1) “c” and “d” and subrule 29.6(2).

29.6(4) A dental hygienist may administer nitrous oxide inhalation analgesia provided the administration of nitrous oxide inhalation analgesia has been delegated by a dentist and the hygienist meets the following qualifications:

- a. Has completed a board-approved course of training; or
- b. Has training equivalent to that required in 29.6(4) “a” while a student in an accredited school of dental hygiene.

29.6(5) A dental hygienist or registered dental assistant may monitor a patient under nitrous oxide inhalation analgesia provided all of the following requirements are met:

- a. The hygienist or registered dental assistant has completed a board-approved course of training or has received equivalent training while a student in an accredited school of dental hygiene or dental assisting;
- b. The task has been delegated by a dentist and is performed under the direct supervision of a dentist;
- c. Any adverse reactions are reported to the supervising dentist immediately; and
- d. The dentist dismisses the patient following completion of the procedure.

29.6(6) A dentist who delegates the administration of nitrous oxide inhalation analgesia in accordance with 29.6(4) shall provide direct supervision and establish a written office protocol for taking vital signs, adjusting anesthetic concentrations, and addressing emergency situations that may arise.

29.6(7) If the dentist intends to achieve a state of moderate sedation from the administration of nitrous oxide inhalation analgesia, the rules for moderate sedation apply.

[ARC 8369B, IAB 12/16/09, effective 1/20/10; ARC 8614B, IAB 3/10/10, effective 4/14/10]

650—29.7(153) Minimal sedation.

29.7(1) The term “minimal sedation” also means “antianxiety premedication” or “anxiolysis.”

29.7(2) If a dentist intends to achieve a state of moderate sedation from the administration of minimal sedation, the rules for moderate sedation shall apply.

29.7(3) A dentist utilizing minimal sedation and the dentist’s auxiliary personnel shall be trained in and capable of administering basic life support.

29.7(4) Minimal sedation for adults.

a. Minimal sedation for adults is limited to a dentist's prescribing or administering a single enteral drug that is no more than 1.0 times the maximum recommended dose (MRD) of a drug that can be prescribed for unmonitored home use. A single supplemental dose of the same drug may be administered, provided the supplemental dose is no more than one-half of the initial dose and the dentist does not administer the supplemental dose until the dentist has determined the clinical half-life of the initial dose has passed.

b. The total aggregate dose shall not exceed 1.5 times the MRD on the day of treatment.

c. For adult patients, a dentist may also utilize nitrous oxide inhalation analgesia in combination with a single enteral drug.

d. Combining two or more enteral drugs, excluding nitrous oxide, prescribing or administering drugs that are not recommended for unmonitored home use, or administering any intravenous drug constitutes moderate sedation and requires that the dentist must hold a moderate sedation permit.

29.7(5) Minimal sedation for ASA category 3 or 4 patients or pediatric patients.

a. Minimal sedation for ASA category 3 or 4 patients or pediatric patients is limited to a dentist's prescribing or administering a single dose of a single enteral drug that can be prescribed for unmonitored home use and that is no more than 1.0 times the maximum recommended dose.

b. A dentist may administer nitrous oxide inhalation analgesia for minimal sedation of ASA category 3 or 4 patients or pediatric patients provided the concentration does not exceed 50 percent and is not used in combination with any other drug.

c. The use of one or more enteral drugs in combination with nitrous oxide, the use of more than a single enteral drug, or the administration of any intravenous drug in ASA category 3 or 4 patients or pediatric patients constitutes moderate sedation and requires that the dentist must hold a moderate sedation permit.

29.7(6) A dentist providing minimal sedation shall not bill for non-IV conscious or moderate sedation.

29.7(7) A dentist shall ensure that any advertisements related to the availability of antianxiety premedication, anxiolysis, or minimal sedation clearly reflect the level of sedation provided and are not misleading.

[ARC 8614B, IAB 3/10/10, effective 4/14/10]

650—29.8(153) Noncompliance. Violations of the provisions of this chapter may result in revocation or suspension of the dentist's permit or other disciplinary measures as deemed appropriate by the board.

650—29.9(153) Reporting of adverse occurrences related to sedation, nitrous oxide inhalation analgesia, and antianxiety premedication.

29.9(1) Reporting. All licensed dentists in the practice of dentistry in this state must submit a report within a period of seven days to the board office of any mortality or other incident which results in temporary or permanent physical or mental injury requiring hospitalization of the patient during, or as a result of, antianxiety premedication, nitrous oxide inhalation analgesia, or sedation. The report shall include responses to at least the following:

- a.* Description of dental procedure.
- b.* Description of preoperative physical condition of patient.
- c.* List of drugs and dosage administered.
- d.* Description, in detail, of techniques utilized in administering the drugs utilized.
- e.* Description of adverse occurrence:
 1. Description, in detail, of symptoms of any complications, to include but not be limited to onset, and type of symptoms in patient.
 2. Treatment instituted on the patient.
 3. Response of the patient to the treatment.
- f.* Description of the patient's condition on termination of any procedures undertaken.

29.9(2) Failure to report. Failure to comply with subrule 29.9(1), when the occurrence is related to the use of sedation, nitrous oxide inhalation analgesia, or antianxiety premedication, may result in the dentist's loss of authorization to administer sedation, nitrous oxide inhalation analgesia, or antianxiety premedication or in any other sanction provided by law.

[ARC 8614B, IAB 3/10/10, effective 4/14/10; ARC 1194C, IAB 11/27/13, effective 11/4/13]

650—29.10(153) Anesthesia credentials committee.

29.10(1) The anesthesia credentials committee is a peer review committee appointed by the board to assist the board in the administration of this chapter. This committee shall be chaired by a member of the board and shall include at least six additional members who are licensed to practice dentistry in Iowa. At least four members of the committee shall hold deep sedation/general anesthesia or moderate sedation permits issued under this chapter.

29.10(2) The anesthesia credentials committee shall perform the following duties at the request of the board:

a. Review all permit applications and make recommendations to the board regarding those applications.

b. Conduct site visits at facilities under rule 650—29.5(153) and report the results of those site visits to the board. The anesthesia credentials committee may submit recommendations to the board regarding the appropriate nature and frequency of site visits.

c. Perform professional evaluations and report the results of those evaluations to the board.

d. Other duties as delegated by the board or board chairperson.

[ARC 1194C, IAB 11/27/13, effective 11/4/13]

650—29.11(153) Review of permit applications.

29.11(1) Review by board staff. Upon receipt of a completed application, board staff will review the application for eligibility. Following staff review, a public meeting of the ACC will be scheduled.

29.11(2) Review by the anesthesia credentials committee (ACC). Following review and consideration of an application, the ACC may at its discretion:

a. Request additional information;

b. Request an investigation;

c. Request that the applicant appear for an interview;

d. Recommend issuance of the permit;

e. Recommend issuance of the permit under certain terms and conditions or with certain restrictions;

f. Recommend denial of the permit;

g. Refer the permit application to the board for review and consideration without recommendation;

or

h. Request a peer review evaluation.

29.11(3) Review by executive director. If, following review and consideration of an application, the ACC recommends issuance of the permit with no restrictions or conditions, the executive director as authorized by the board has discretion to authorize the issuance of the permit.

29.11(4) Review by board. The board shall consider applications and recommendations from the ACC. The board may take any of the following actions:

a. Request additional information;

b. Request an investigation;

c. Request that the applicant appear for an interview;

d. Grant the permit;

e. Grant the permit under certain terms and conditions or with certain restrictions; or

f. Deny the permit.

29.11(5) Right to defer final action. The ACC or board may defer final action on an application if there is an investigation or disciplinary action pending against an applicant who may otherwise meet the requirements for permit until such time as the ACC or board is satisfied that issuance of a permit to the applicant poses no risk to the health and safety of Iowans.

29.11(6) Appeal process for denials. If a permit application is denied, an applicant may file an appeal of the final decision using the process described in rule 650—11.10(147).
[ARC 1194C, IAB 11/27/13, effective 11/4/13]

650—29.12(153) Renewal. A permit to administer deep sedation/general anesthesia or moderate sedation shall be renewed biennially at the time of license renewal. Permits expire August 31 of every even-numbered year.

29.12(1) To renew a permit, a licensee must submit the following:

- a. Evidence of renewal of ACLS certification.
- b. A minimum of six hours of continuing education in the area of sedation. These hours may also be submitted as part of license renewal requirements.
- c. The appropriate fee for renewal as specified in 650—Chapter 15.

29.12(2) Failure to renew the permit prior to November 1 following its expiration shall cause the permit to lapse and become invalid for practice.

29.12(3) A permit that has been lapsed may be reinstated upon submission of a new application for a permit in compliance with rule 650—29.5(153) and payment of the application fee as specified in 650—Chapter 15.

[ARC 8614B, IAB 3/10/10, effective 4/14/10; ARC 1194C, IAB 11/27/13, effective 11/4/13]

650—29.13(147,153,272C) Grounds for nonrenewal. A request to renew a permit may be denied on any of the following grounds:

29.13(1) After proper notice and hearing, for a violation of these rules or Iowa Code chapter 147, 153, or 272C during the term of the last permit renewal.

29.13(2) Failure to pay required fees.

29.13(3) Failure to obtain required continuing education.

29.13(4) Failure to provide documentation of current ACLS certification.

29.13(5) Failure to provide documentation of maintaining a properly equipped facility.

29.13(6) Receipt of a certificate of noncompliance from the college student aid commission or the child support recovery unit of the department of human services in accordance with 650—Chapter 33 or 650—Chapter 34.

[ARC 1194C, IAB 11/27/13, effective 11/4/13]

650—29.14(153) Record keeping.

29.14(1) Minimal sedation. An appropriate sedative record must be maintained and must contain the names of all drugs administered, including local anesthetics and nitrous oxide, dosages, time administered, and monitored physiological parameters, including oxygenation, ventilation, and circulation.

29.14(2) Moderate or deep sedation. The patient chart must include preoperative and postoperative vital signs, drugs administered, dosage administered, anesthesia time in minutes, and monitors used. Pulse oximetry, heart rate, respiratory rate, and blood pressure must be recorded continually until the patient is fully ambulatory. The chart should contain the name of the person to whom the patient was discharged.

29.14(3) Nitrous oxide inhalation analgesia. The patient chart must include the concentration administered and duration of administration, as well as any vital signs taken.

[ARC 8369B, IAB 12/16/09, effective 1/20/10; ARC 8614B, IAB 3/10/10, effective 4/14/10; ARC 1194C, IAB 11/27/13, effective 11/4/13]

These rules are intended to implement Iowa Code sections 153.33 and 153.34.

[Filed 5/16/86, Notice 3/26/86—published 6/4/86, effective 7/9/86]

[Filed 1/23/87, Notice 12/17/86—published 2/11/87, effective 3/18/87]

[Filed 4/28/88, Notice 3/23/88—published 5/18/88, effective 6/22/88]

[Filed 3/17/89, Notice 1/25/89—published 4/5/89, effective 5/10/89]

[Filed 1/29/92, Notice 11/13/91—published 2/19/92, effective 3/25/92]

[Filed 10/17/97, Notice 8/13/97—published 11/5/97, effective 12/10/97]

[Filed 5/1/98, Notice 2/11/98—published 5/20/98, effective 6/24/98¹]

[Filed emergency 7/24/98—published 8/12/98, effective 7/24/98]
 [Filed 7/23/99, Notice 5/19/99—published 8/11/99, effective 9/15/99²]
 [Filed 1/21/00, Notice 12/15/99—published 2/9/00, effective 3/15/00]
 [Filed 1/19/01, Notice 11/15/00—published 2/7/01, effective 3/14/01][◇]
 [Filed 3/30/01, Notice 2/7/01—published 4/18/01, effective 5/23/01]
 [Filed 1/16/04, Notice 9/17/03—published 2/4/04, effective 3/10/04]
 [Filed 1/27/06, Notice 9/28/05—published 2/15/06, effective 3/22/06]
 [Filed 2/5/07, Notice 9/27/06—published 2/28/07, effective 4/4/07]
 [Filed 2/5/07, Notice 11/22/06—published 2/28/07, effective 4/4/07]
 [Filed ARC 8369B (Notice ARC 8044B, IAB 8/12/09), IAB 12/16/09, effective 1/20/10]
 [Filed ARC 8614B (Notice ARC 8370B, IAB 12/16/09), IAB 3/10/10, effective 4/14/10]
 [Filed ARC 0265C (Notice ARC 0128C, IAB 5/16/12), IAB 8/8/12, effective 9/12/12]
 [Filed Emergency After Notice ARC 1194C (Notice ARC 1008C, IAB 9/4/13), IAB 11/27/13, effective
 11/4/13]
 [Filed ARC 1810C (Notice ARC 1658C, IAB 10/1/14), IAB 1/7/15, effective 2/11/15]
 [Filed ARC 3491C (Notice ARC 3261C, IAB 8/16/17), IAB 12/6/17, effective 1/10/18]

◇ Two or more ARCs

¹ Effective date of 29.6(4) to 29.6(6) delayed 70 days by the Administrative Rules Review Committee at its meeting held June 9, 1998.

² Effective date of 29.6(4) to 29.6(6) delayed until the end of the 2000 Session of the General Assembly by the Administrative Rules Review Committee at its meeting held September 15, 1999. Subrules 29.6(4) and 29.6(5) were rescinded IAB 2/9/00, effective 3/15/00; delay on subrule 29.6(6) lifted by the Administrative Rules Review Committee at its meeting held January 4, 2000, effective January 5, 2000.

MICHIGAN

PART 1. GENERAL PROVISIONS

R 338.11101 Definitions.

Rule 1101. As used in these rules:

(a) “Analgesia” means the diminution or elimination of pain in the conscious patient as a result of the administration of an agent including, but not limited to, local anesthetic, nitrous oxide, and pharmacological and non-pharmacological methods.

(e) “Conscious sedation” means a minimally depressed level of consciousness that retains a 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 a non-pharmacological method or a combination of both.

(g) “Combination inhalation-enteral conscious sedation” means conscious sedation using inhalation and enteral agents. Nitrous oxide/oxygen when used in combination with sedative agents may produce conscious or deep sedation or general anesthesia.

(k) “Enteral” means any technique of administration in which the agent is absorbed through the gastrointestinal or oral mucosa.

(l) “General anesthesia” means the elimination of all sensations accompanied by a state of unconsciousness and loss of reflexes necessary to maintain a patent airway.

(n) “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.

(v) “Sedation” means the calming of a nervous, apprehensive individual, without inducing loss of consciousness, through the use of systemic drugs. Agents may be given orally, parenterally, or by inhalation.

(w) “Titration” means the administration of small incremental doses of a drug until a desired clinical effect is observed. In accordance with this definition, titration of oral medication for the purposes of sedation is unpredictable. Repeated dosing of orally administered sedative agents may result in an alteration of the state of consciousness beyond the intent of the practitioner. The maximum recommended dose (mrd) of an oral medication shall not be exceeded. Facilities, personnel, and standards for enteral sedation are the same as those for parental sedation.

PART 6. GENERAL ANESTHESIA AND INTRAVENOUS CONSCIOUS SEDATION AND ENTERAL SEDATION

R 338.11601 General anesthesia; conditions; violation.

Rule 1601. (1) A dentist shall not administer general anesthesia to a dental patient or delegate and supervise the performance of any act, task, or function involved in the administration of General anesthesia to a dental patient, unless all of the following conditions are satisfied:

(a) The dentist has completed a minimum of 1 year of advanced training in general anesthesia and pain control in a program which meets the standards adopted in R 338.11603(l). This subdivision takes effect 1 year after the effective date of this amendatory rule.

(b) The dentist and the delegatee, if any, maintain current certification in basic and advanced cardiac life support from an agency or organization that grants such

certification pursuant to standards substantially equivalent to the standards adopted in R 338.11603(2).

(c) The facility in which the anesthesia is administered meets the equipment standards adopted in R 338.11603(3).

(d) The dentist shall be physically present with the patient who is given any general anesthesia until he or she regains consciousness and the dentist shall remain on the premises until such patient is capable of being discharged.

(2) A dentist who does not meet the requirements of subrule (1) of this rule shall not offer general anesthesia services for dental patients unless all of the following conditions are met:

(a) General anesthesia services are directly provided through association with, and by, either of the following individuals:

(i) A physician who is licensed under the provisions of part 170 or 175 of the act and who is a member in good standing on the anesthesiology staff of a hospital accredited by the Joint Commission.

(ii) A dentist who meets the requirements of subrule (1)(a) and (b) of this rule.

(b) A person who administers anesthesia, as authorized by the provisions of subdivision (a) of this subrule, shall be physically present with the patient who is given any general anesthesia until he or she regains consciousness and the dentist shall remain on the actual premises where the general anesthesia is administered until the patient anesthetized is capable of being discharged.

(c) The provisions of subrule (1)(b) and (c) of this rule shall be complied with.

(3) A dentist is in violation of section 16221(l)(h) of the code, MCL 333.16221(1)(h), if he or she administers general anesthesia to a dental patient or delegates and supervises the performance of any act, task, or function involved in the administration of general anesthesia to a dental patient or offers general anesthesia services for dental patients without being in compliance with subrules (1) and (2) of this rule.

History: 1990 AACCS; 2011 AACCS; 2017 MR 1, Eff. Jan. 6, 2017.

R 338.11602 Intravenous conscious sedation; conditions; violations.

Rule 1602. (1) A dentist shall not administer intravenous conscious sedation to a dental patient or delegate and supervise the performance of any act or function involved in the administration of intravenous conscious sedation to a dental patient unless 1 of the following conditions is satisfied:

(a) The dentist complies with R 338.11601(1) or (2).

(b) The dentist complies with both of the following provisions:

(i) The dentist has completed a minimum of 60 hours of training in intravenous conscious sedation and related academic subjects, including a minimum of 40 hours of supervised clinical instruction in which the individual has sedated not less than 20 cases in a course that is in compliance with the standards adopted in R 338.11603(1).

(ii) The dentist and the delegatee, if any, maintains current certification in basic or advanced cardiac life support from an agency or organization that grants such certification under standards substantially equivalent to the standards adopted in R 338.11603(2).

(c) The facility in which the anesthesia is administered complies with the equipment standards adopted in R 338.11603(3).

(2) A dentist is in violation of section 16221(1)(h) of the code, MCL 333.16221(1)(h), if he or she administers intravenous conscious sedation to a dental patient or delegates and supervises the performance of any act, task, or function involved in the administration of intravenous conscious sedation to a dental patient without complying with the provisions of subrule (1) of this rule. History: 1990 AACCS; 1997 AACCS; 2011 AACCS; 2017 MR 1, Eff. Jan. 6, 2017.

R 338.11603 Adoption of standards; effect of certification of programs.

Rule 1603. (1) The board adopts the standards for advanced training in anesthesia and pain control and training in intravenous conscious sedation and related subjects set forth by the Commission on Dental Education of the American Dental Association in the publication entitled "Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students" October 2012 edition. The guidelines may be obtained at no cost from the Commission on Dental Education, American Dental Association, 211 E. Chicago Avenue, Chicago, IL 60611, or on the association's website at <http://www.ada.org>. A copy of the standards is available for inspection and distribution at cost from the Michigan Board of Dentistry, Department of Licensing and Regulatory Affairs, 611 West Ottawa, P.O. Box 30670, Lansing, MI 48909. Certification of programs by the Council on Dental Education as meeting the standards adopted constitutes a prima facie showing that the program is in compliance with the standards.

(2) The board adopts the standards for credentialing in basic and advanced life support set forth by the American Heart Association in the guidelines for cardiopulmonary resuscitation and emergency cardiac care for professional providers and published in "2015 AHA Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care." (Circulation, Volume 132, Issue 18 Supplement 2, November 3, 2015.) A copy of the guidelines for cardiopulmonary resuscitation and emergency cardiac care may be obtained from the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231 or at no cost from the association's website site at <http://circahajournals.org>. A copy of this document is available for inspection and distribution at cost from the Michigan Board of Dentistry, Department of Licensing and Regulatory Affairs, 611 West Ottawa, P.O. Box 30670, Lansing, MI 48909.

(3) The board adopts the standards regarding the equipment within a facility set forth by the American Association of Oral and Maxillofacial Surgeons in the publication entitled "Office Anesthesia Evaluation Manual," eighth edition. A copy of this manual may be obtained from the American Association of Oral and Maxillofacial Surgeons, 9700 West Bryn Mawr Avenue, Rosemont, IL 60018, or at the association's website at <http://www.aaoms.org> at a cost of \$285 as of the adoption of these rules. A copy of this document is available for inspection and distribution at cost from the Michigan Board of Dentistry, Department of Licensing and Regulatory Affairs, 611 West Ottawa, P.O. Box 30670, Lansing, MI 48909.

History: 1990 AACCS; 1997 AACCS; 2006 AACCS; 2011 AACCS; 2014 AACCS; 2017 MR 1, Eff. Jan. 6, 2017.

R 338.11604 "Morbidity" and "Mortality" defined; reporting requirements.

Rule 1604. (1) As used in this rule:

(a) "Morbidity" means an incident that results in mental or physical impairment which is related to or results from the administration of general anesthesia or intravenous conscious sedation by a dentist, under the delegation and supervision of a dentist, or in a dental facility.

(b) "Mortality" means an incident that results in death related to the administration of general anesthesia or intravenous conscious sedation by a dentist, under the delegation and supervision of a dentist, or in a dental facility.

(2) A dentist shall file a morbidity report with the board within 30 days after the occurrence of an incident.

(3) A dentist shall file a mortality report with the board within 5 days after the occurrence of an incident.

(4) A dentist who fails to file a report as required by this rule is in violation of section 6221(1)(g) of the act.

History: 1990 AACCS; 2011 AACCS.

R 338.11605 Enteral sedation; requirements for approval of course and instructor.

Rule 1605. (1) A course in enteral sedation shall be approved by the board of dentistry and shall, at a minimum, be consistent with the enteral sedation course as outlined in the American Dental Association's educational guidelines "Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students," 2012, whose guidelines are adopted by the board. Such a course must provide training in patient assessment, recognition of emergencies and airway management, including the ability to manage an unconscious airway. Part 3 of the guidelines may be obtained at no cost from the American Dental Association, 211 E. Chicago Avenue, Chicago, IL 60611 or on the association's website at <http://www.ada.org>. A copy of the guidelines is available for inspection and distribution at cost from the Michigan Board of Dentistry, Department of Licensing and Regulatory Affairs, 611 West Ottawa, P.O. Box 30670, Lansing, MI 48909.

(2) An instructor of a course in enteral sedation shall be approved by the board of dentistry and shall have at least 3 years of experience which includes his or her formal postdoctoral training in anxiety and pain control.

(3) An instructor of an approved enteral sedation course shall certify the competency of a participant upon a participant's satisfactorily completing training in each conscious sedation technique, including instruction, clinical experience, and airway management.

History: 2006 AACCS; 2011 AACCS; 2014 AACCS; 2017 MR 1, Eff. Jan. 6, 2017.

MINNESOTA

3100.3600 ADMINISTRATION OF GENERAL ANESTHESIA, DEEP SEDATION, MODERATE SEDATION, MINIMAL SEDATION, AND NITROUS OXIDE INHALATION ANALGESIA.

Subpart 1.

Prohibitions.

A dental therapist, dental hygienist, or licensed dental assistant may not administer general anesthesia, deep sedation, moderate sedation, or minimal sedation.

Subp. 2.

General anesthesia or deep sedation; educational training requirements.

A dentist may administer general anesthesia or deep sedation only pursuant to items A to C.

A. A dentist must complete either subitem (1) or (2) and subitems (3) and (4):

(1) a didactic and clinical program at a dental school, hospital, or graduate medical or dental program accredited by the Commission on Dental Accreditation, resulting in the dentist becoming clinically competent in the administration of general anesthesia. The program must be equivalent to a program for advanced specialty education in oral and maxillofacial surgery; or

(2) a one-year residency in general anesthesia at an institution certified by the American Society of Anesthesiology, the American Medical Association, or the Joint Commission on Hospital Accreditation, resulting in the dentist becoming clinically competent in the administration of general anesthesia. The residency must include a minimum of 390 hours of didactic study, 1,040 hours of clinical anesthesiology, and 260 cases of administration of general anesthesia to an ambulatory outpatient; and

(3) the ACLS or PALS course and maintain current advanced certification thereafter; and

(4) a CPR certification course and maintain current CPR certification thereafter.

B. A dentist shall be prepared and competent to diagnose, resolve, and reasonably prevent any untoward reaction or medical emergency that may develop any time after the administration of general anesthesia or deep sedation. A dentist shall apply the current standard of care to continuously monitor and evaluate a patient's blood pressure, pulse, respiratory function, and cardiac activity. The current standard of care to assess respiratory function requires the monitoring of tissue oxygenation or the use of a superior method of monitoring respiratory function.

C. A dentist shall administer general anesthesia or deep sedation only by application of the appropriate systems and drugs for the delivery of general anesthesia or deep sedation. Prior to discharge, the dentist or the person administering the general anesthesia or deep sedation shall assess the patient to ensure the patient is no longer at risk for cardiorespiratory depression. The patient must be discharged into the care of a responsible adult.

Subp. 3.

Moderate sedation; educational training requirements.

A dentist may administer moderate sedation only pursuant to items A to C.

A. A dentist must complete subitems (1) to (3):

- (1) a course of education resulting in the dentist becoming clinically competent for administration of moderate sedation, to include a minimum of 60 hours of didactic education in both enteral and parenteral administration, personally administering and managing at least ten individual supervised cases of parenteral moderate sedation of which a maximum of five cases may be performed on a patient-simulated manikin, and submit to the board original documentation from the instructor of successful completion of the course;
- (2) the ACLS or PALS course and maintain current advanced certification thereafter; and
- (3) a CPR certification course and maintain current CPR certification thereafter.

B. A dentist shall be prepared and competent to diagnose, resolve, and reasonably prevent any untoward reaction or medical emergencies that may develop any time after rendering a patient in the state of moderate sedation. The dentist shall apply the current standard of care to continuously monitor and evaluate a patient's blood pressure, pulse, respiratory function, and cardiac activity. The current standard of care to assess respiratory function shall require the monitoring of tissue oxygenation or the use of a superior method of monitoring respiratory function.

C. A dentist shall administer moderate sedation by application of the appropriate systems and drugs for the delivery of moderate sedation. Prior to discharge, the dentist or the person administering the moderate sedation shall assess the patient to ensure the patient is no longer at risk for cardiorespiratory depression. The patient must be discharged into the care of a responsible adult.

Subp. 4.

Nitrous oxide inhalation analgesia; educational training requirements.

A dentist may administer nitrous oxide inhalation analgesia only according to items A to D and subpart 5, items A and C. A dental therapist may administer nitrous oxide inhalation analgesia only according to items C to F. A dental hygienist may administer nitrous oxide inhalation analgesia only according to items C to F and subpart 5, item D. A licensed dental assistant may administer nitrous oxide inhalation analgesia only after a maximum dosage has been prescribed by a dentist for a specific patient, and it is administered according to items C to F and subpart 5, item D.

A. Prior to January 1, 1993, a licensed dentist who is currently administering nitrous oxide inhalation analgesia may register that fact with the board according to subpart 5, item A. Such registered dentists may continue to administer nitrous oxide inhalation analgesia and need not comply with item B.

B. A dentist who has not previously registered with the board pursuant to subpart 5, item A, may administer nitrous oxide inhalation analgesia only after satisfactorily completing a course on the administration of nitrous oxide inhalation analgesia from an institution accredited by the Commission on Dental Accreditation, and submitting to the board original documentation from the institution of successful completion of the course. The course must be a minimum of 12 hours total comprised of didactic instruction, personally administering and managing at least three individual supervised cases of analgesia, and supervised clinical experience using fail-safe anesthesia equipment capable of positive pressure respiration.

C. A dentist, dental therapist, dental hygienist, or licensed dental assistant must complete CPR training and maintain current CPR certification thereafter.

D. A dentist, dental therapist, dental hygienist, or licensed dental assistant must only use fail-safe anesthesia equipment capable of positive pressure respiration.

E. A dental therapist, dental hygienist, or licensed dental assistant may administer nitrous oxide inhalation analgesia only after satisfactorily completing a course on the administration of nitrous oxide inhalation analgesia from an institution accredited by the Commission on Dental Accreditation, and submitting to the board original documentation from the institution of successful completion of the course. The course must be a minimum of 12 hours total comprised of didactic instruction, personally administering and managing at least three individual supervised cases of analgesia, and supervised clinical experience using fail-safe anesthesia equipment capable of positive pressure respiration.

F. A dental therapist, dental hygienist, or licensed dental assistant may administer nitrous oxide inhalation analgesia under the appropriate level of supervision by a dentist who is current with the requirements to administer nitrous oxide inhalation analgesia according to items A to D and subpart 5, items A to C.

Subp. 5.

Notice to board.

A. A dentist who is administering general anesthesia, deep sedation, or moderate sedation or who is administering nitrous oxide inhalation analgesia shall inform the board of that fact on forms provided by the board.

B. A dentist may administer general anesthesia, deep sedation, or moderate sedation only if the dentist has submitted the following information to the board on forms provided by the board: the name, address, and telephone number of the institution at which the dentist took the program or residency that complies with subparts 2, item A, subitem (1) or (2); and 3, item A, subitem (1), a certified copy of the dentist's transcript and other official record from the institution verifying that the dentist satisfactorily completed the program, residency, or course; and the name, address, and telephone number of the institution or other agency at which the dentist successfully completed the ACLS or PALS required by subparts 2, item A, subitem (3); and 3, item A, subitem (2). After this initial submission, dentists shall submit on a license renewal application or other form provided by the board a statement of the most recent course completed in ACLS or PALS.

C. A dentist not previously registered with the board according to item A or who graduated from an institution in Minnesota accredited by the Commission on Dental Accreditation prior to April 15, 2008, may administer nitrous oxide inhalation analgesia only after the dentist has submitted the information in subitems (1) and (2) to the board on forms provided by the board:

(1) the name, address, and telephone number of the institution at which the dentist took the course that complies with subpart 4, item B; and

(2) a certified copy of the dentist's transcript and other official record from the institution verifying that the dentist has successfully completed CPR as required by subpart 4, item C. After the initial submission, a dentist must attest to maintaining consecutive and current CPR certification at the time of each license renewal.

D. A dental hygienist or licensed dental assistant who graduated from an institution in Minnesota accredited by the Commission on Dental Accreditation or received licensure by credentials prior to September 2, 2004, may administer nitrous oxide inhalation analgesia only after the dental hygienist or licensed dental assistant has submitted the information in subitems (1) and (2) to the board on forms provided by the board:

(1) the name, address, and telephone number of the institution at which the dental hygienist or licensed dental assistant successfully completed the course required by subpart 4, item E; and

(2) a certified copy of the dental hygienist's or licensed dental assistant's transcript and other official record from the institution verifying that the dental hygienist or licensed dental assistant has successfully completed CPR as required by subpart 4, item C. After the initial submission, a dental hygienist or licensed dental assistant must attest to maintaining consecutive and current CPR certification at the time of each license renewal.

E. A dental therapist who graduated from a board-approved dental therapy program in Minnesota prior to August 1, 2013, may administer nitrous oxide inhalation analgesia only after the dental therapist has submitted the information in subitems (1) and (2) to the board on forms provided by the board:

(1) the name, address, and telephone number of the institution where the dental therapist successfully completed the course required by subpart 4, item E; and

(2) a certified copy of the dental therapist's transcript and other official records from the institution verifying that the dental therapist has successfully completed CPR as required by subpart 4, item C. After the initial submission, a dental therapist must attest to maintaining consecutive and current CPR certification at the time of each license renewal.

Subp. 6.

Analgesia.

A dentist who has a current license to practice dentistry in Minnesota may administer analgesia.

Subp. 7.

Minimal sedation.

A dentist who has a current license to practice dentistry in Minnesota may administer minimal sedation.

Subp. 8.

Reporting of incidents required.

A dentist, dental therapist, dental hygienist, or licensed dental assistant must report to the board any incident that arises from the administration of nitrous oxide inhalation analgesia, general anesthesia, deep sedation, moderate sedation, local anesthesia, analgesia, or minimal sedation that results in:

A. a serious or unusual outcome that produces a temporary or permanent physiological injury, harm, or other detrimental effect to one or more of a patient's body systems; or

B. minimal sedation unintentionally becoming moderate sedation, deep sedation, or general anesthesia when the licensee does not have a certificate for administering general anesthesia or moderate sedation described in subparts 9 and 9b.

The report must be submitted to the board on forms provided by the board within ten business days of the incident by the dentist, dental therapist, dental hygienist, or licensed dental assistant, even when another licensed health care professional who, under contract or employment with the dentist, was the actual person administering the analgesia or pharmacological or nonpharmacological method. A licensee who fails to comply with reporting of incidents is

subject to disciplinary proceedings on grounds specified in parts [3100.6100](#) and [3100.6200](#) and Minnesota Statutes, section [150A.08, subdivision 1](#).

Subp. 9.

General anesthesia or moderate sedation certificate.

A. The board may contract with advisory consultants as necessary for advice and recommendations to the board on requirements for general anesthesia or moderate sedation certification and approval of an applicant and facility.

B. A dentist shall not administer general anesthesia, deep sedation, or moderate sedation in the practice of dentistry unless the dentist possesses a general anesthesia or moderate sedation certificate issued by the board according to this subpart. For certification, the dentist shall meet all applicable requirements of this part, including the educational training requirements in subparts 2 and 3, the practice and equipment requirements in subpart 10, and the on-site inspection requirements in subpart 11. Failure by a dentist to obtain a general anesthesia or moderate sedation certificate subjects the dentist to disciplinary proceedings on the grounds specified in parts [3100.6100](#) and [3100.6200](#) and Minnesota Statutes, section [150A.08](#), subdivision 1. Certificates shall be issued by the board in the following titles:

- (1) general anesthesia, which authorizes a dentist to administer general anesthesia, deep sedation, or moderate sedation, or to provide dental services to patients under general anesthesia, deep sedation, or moderate sedation when a dentist employs or contracts another licensed health care professional with the qualified training and legal qualification to administer general anesthesia, deep sedation, or moderate sedation; and
- (2) moderate sedation, which authorizes a dentist to administer moderate sedation, or to provide dental services to patients under moderate sedation when a dentist employs or contracts another licensed health care professional with the qualified training and legal qualification to administer moderate sedation.

C. All certificates described in item B are issued and governed by subitems (1) to (9).

- (1) A board-approved application form to obtain an initial general anesthesia or moderate sedation certificate must be filled out completely and submitted to the board along with the applicable nonrefundable fee described in Minnesota Statutes, section [150A.091](#), subdivision 11. An application form must include, but not be limited to, information on office facilities, support staff training, emergency protocols, monitoring equipment, and record-keeping procedures.
- (2) A dentist is not required to possess an additional certificate for deep or moderate sedation if the dentist possesses a valid certificate for general anesthesia.
- (3) A dentist holding a current general anesthesia or moderate sedation certificate on March 19, 2007, is considered by the board to be in compliance with this subpart until the expiration and required renewal of the certificate described in subitem (5).
- (4) Upon receipt of an application for an initial general anesthesia or moderate sedation certificate, the board shall require that the dentist undergo an on-site inspection described in subpart 11 or further review of the dentist's anesthesia/sedation credentials. The board may direct an anesthesia consultant or qualified anesthetic practitioner who has been approved by the board and provided with board-established guidelines to assist in the inspection or review.
- (5) For renewal of a general anesthesia or moderate sedation certificate, a board-approved application form must be obtained from the board and completed by the dentist

whenever the dentist is subject to license renewal described in part [3100.1700](#), subpart 2. An application form must include, but not be limited to, information on office facilities, support staff training, emergency protocols, monitoring equipment, and record-keeping procedures. A dentist's general anesthesia or moderate sedation certificate expires if the completed application and the nonrefundable fee described in Minnesota Statutes, section [150A.091](#), subdivision 11, are not received by the board by the application deadline. Immediately upon expiration of a certificate, the dentist is prohibited from administering general anesthesia, deep sedation, or moderate sedation in the practice of dentistry until the board issues a current general anesthesia or moderate sedation certificate to the dentist described in subpart 9a. After 60 days from the renewal application deadline, the board will terminate the dentist's general anesthesia or moderate sedation certificate and send a notice of termination to the dentist.

(6) Upon receipt of an application for renewal of a general anesthesia or moderate sedation certificate, the board may require that the dentist undergo an on-site inspection described in subpart 11 or further review of the dentist's anesthesia/sedation credentials. The board may direct an anesthesia consultant or qualified anesthetic practitioner who has been approved by the board and provided with board-established guidelines to assist in the inspection or review.

(7) Upon granting an application, receiving payment of the required fee, and, if required, receiving notice of having successfully passed an on-site inspection and evaluation, the board shall issue a general anesthesia or moderate sedation certificate to the dentist.

(8) A dentist shall submit with a request for issuance of a duplicate of the general anesthesia or moderate sedation certificate the applicable nonrefundable fee described in Minnesota Statutes, section [150A.091](#), subdivision 12.

(9) A certificate issued by the board must be conspicuously displayed in plain sight of patients in every office in which the dentist administers general anesthesia, deep sedation, or moderate sedation.

Subp. 9a.

Expiration or termination of general anesthesia or moderate sedation certificate; requirements.

A dentist requesting renewal or recertification of a general anesthesia or moderate sedation certificate following expiration or termination must comply with the requirements for the applicable interval specified in item A or B. After successful completion of all requirements, the board shall issue a general anesthesia or moderate sedation certificate to the dentist.

A. A dentist whose anesthesia/sedation certificate has expired as described in subpart 9, item C, subitem (5), or who voluntarily terminated the anesthesia/sedation certificate, within 60 calendar days after the renewal application deadline, must comply with subitems (1) to (6):

- (1) submit to the board a completed board-approved renewal application form for a general anesthesia or moderate sedation certificate;
- (2) submit with the renewal application the applicable nonrefundable renewal fee described in Minnesota Statutes, section [150A.091, subdivision 11](#);
- (3) submit payment of the nonrefundable late fee to the board described in Minnesota Statutes, section [150A.091, subdivision 11a](#);
- (4) provide official documentation as proof of current certification in ACLS or PALS;
- (5) provide required documentation of current CPR certification; and

- (6) not administer general anesthesia, deep sedation, or moderate sedation until the board issues a general anesthesia or moderate sedation certificate to the dentist.
- B. A dentist whose anesthesia/sedation certificate has been terminated by the board according to subpart 9, item C, subitem (5), or who voluntarily terminated the anesthesia/sedation certificate, more than 60 calendar days after the renewal application deadline, must comply with subitems (1) to (6):
- (1) submit to the board a completed board-approved recertification application form for a general anesthesia or moderate sedation certificate;
 - (2) submit with the recertification application the applicable nonrefundable recertification fee described in Minnesota Statutes, section [150A.091, subdivision 11b](#);
 - (3) provide official documentation from the institution verifying successful completion of the educational requirements for either general anesthesia described in subpart 2 or moderate sedation described in subpart 3;
 - (4) provide official documentation of current certification in ACLS or PALS;
 - (5) provide required documentation of current CPR certification; and
 - (6) not administer general anesthesia, deep sedation, or moderate sedation until the board issues a general anesthesia or moderate sedation certificate to the dentist.
- C. Upon receipt of a recertification application for general anesthesia or moderate sedation, the board may require that the dentist undergo an on-site inspection described in subpart 11 or further review of the dentist's anesthesia/sedation credentials.

Subp. 9b.

Certificate to provide dentistry with contracted sedation provider.

A. A dentist shall not provide dental services to a patient who is under general anesthesia, deep sedation, or moderate sedation, at any location other than a hospital, unless the dentist possesses the applicable contracted sedation provider certificate for general anesthesia or moderate sedation issued by the board according to this subpart. For certification, the dentist shall meet all applicable requirements of this subpart, including the practice and equipment requirements in subpart 10 and the on-site inspection requirements in subpart 11. Failure by a dentist to obtain the applicable certificate subjects the dentist to disciplinary proceedings on grounds specified in parts [3100.6100](#) and [3100.6200](#), and Minnesota Statutes, section [150A.08, subdivision 1](#).

Certificates shall be issued by the board in the following titles:

- (1) dentistry with contracted sedation provider-general anesthesia, which authorizes a dentist to provide dental services to patients under general anesthesia, deep sedation, or moderate sedation when a dentist employs or contracts another licensed health care professional with the qualified training and legal authority to administer general anesthesia, deep sedation, or moderate sedation; and
 - (2) dentistry with contracted sedation provider-moderate sedation, which authorizes a dentist to provide dental services to patients under moderate sedation when a dentist employs or contracts another licensed health care professional with the qualified training and legal qualification to administer moderate sedation.
- B. Certificates in item A are issued and governed by subitems (1) to (7).
- (1) To obtain an initial contracted sedation provider certificate, a board-approved application form must be filled out completely and submitted to the board along with the applicable nonrefundable fee in Minnesota Statutes, section [150A.091](#), subdivision 11. A completed application form will provide information on the employed or contracted

licensed health care professional, office facilities, emergency protocols, monitoring equipment, record-keeping procedures, and other information reasonably needed by the board to assess the certificate application.

(2) For renewal of a contracted sedation provider certificate, a board-approved application form must be completed and submitted to the board along with the applicable nonrefundable fee in Minnesota Statutes, section [150A.091](#), subdivision 11, whenever the dentist is subject to license renewal in part [3100.1700](#), subpart 2. A completed application form will provide information on the employed or contracted licensed health care professional, office facilities, emergency protocols, monitoring equipment, record-keeping procedures, and other information reasonably needed by the board to assess the certificate application. A dentist's contracted sedation provider certificate expires if the completed application and nonrefundable fee are not received by the board by the application deadline. Immediately upon expiration of a certificate, the dentist is prohibited from providing dental services to patients under general anesthesia, deep sedation, or moderate sedation until the board issues a current contracted sedation provider certificate to the dentist as described in item C. Absent a timely renewal, after 60 days from the renewal application deadline, the board will terminate the dentist's contracted sedation provider certificate and send a notice of termination to the dentist.

(3) The dentist must comply with the practice and equipment requirements in subpart 10.

(4) The dentist must comply with having an on-site inspection described in subpart 11.

(5) If a dentist possesses a moderate sedation certificate described in subpart 9 and desires to provide dental services to a patient under general anesthesia or deep sedation, at any location other than a hospital, the dentist must obtain a contracted sedation provider certificate for general anesthesia.

(6) A request for issuance of a duplicate contracted sedation provider certificate must be accompanied by the applicable nonrefundable fee specified in Minnesota Statutes, section

(7) A certificate issued by the board must be conspicuously displayed in plain sight of patients in every office in which the dentist provides dental services to patients under general anesthesia, deep sedation, or moderate sedation.

C. A dentist desiring renewal of a contracted sedation provider certificate following expiration or termination by the board under item B, subitem (2), or who voluntarily terminated the certificate must comply with subitems (1) to (5). The dentist must:

(1) submit to the board a completed board-approved renewal application form for an appropriate contracted sedation provider certificate;

(2) submit with the renewal application the applicable nonrefundable renewal fee described in Minnesota Statutes, section [150A.091, subdivision 11](#);

(3) submit payment to the board of the nonrefundable late fee specified in Minnesota Statutes, section [150A.091, subdivision 11a](#);

(4) provide required documentation of current CPR certification; and

(5) not provide dental services to patients under general anesthesia, deep sedation, or moderate sedation until the board issues an appropriate contracted sedation provider certificate to the dentist.

After successful completion of all requirements, the board shall issue an appropriate contracted sedation provider certificate to the dentist.

Subp. 10.

Practice and equipment requirements.

A. Dentists who administer general anesthesia, deep sedation, or moderate sedation or who provide dental services to patients under general anesthesia, deep sedation, or moderate sedation must ensure that the practice requirements in subitems (1) to (3) are followed.

(1) A dentist who employs or contracts another licensed health care professional, such as a dentist, nurse anesthetist, or physician anesthesiologist, with the qualified training and legal qualification to administer general anesthesia, deep sedation, or moderate sedation must notify the board that these services are being provided in the office facility. The dentist is also responsible for maintaining the appropriate facilities, equipment, emergency supplies, and a record of all general anesthesia, deep sedation, or moderate sedation procedures performed in the facility.

(2) An individual qualified to administer general anesthesia, deep sedation, or moderate sedation, who is in charge of the administration of the anesthesia or sedation, must remain in the operatory room to continuously monitor the patient once general anesthesia, deep sedation, or moderate sedation is achieved and until all dental services are completed on the patient. Thereafter, an individual qualified to administer anesthesia or sedation must ensure that the patient is appropriately monitored and discharged as described in subparts 2, items B and C, and 3, items B and C.

(3) A dentist administering general anesthesia, deep sedation, or moderate sedation to a patient must have in attendance personnel who are currently certified in CPR.

B. Dentists who administer general anesthesia, deep sedation, or moderate sedation or who provide dental services to patients under general anesthesia, deep sedation, or moderate sedation must ensure that the offices in which it is conducted have the following equipment:

- (1) an automated external defibrillator or full function defibrillator that is immediately accessible;
- (2) a positive pressure oxygen delivery system and a backup system;
- (3) a functional suctioning device and a backup suction device;
- (4) auxiliary lighting;
- (5) a gas storage facility;
- (6) a recovery area;
- (7) a method to monitor respiratory function; and
- (8) a board-approved emergency cart or kit that must be available and readily accessible and includes the necessary and appropriate drugs and equipment to resuscitate a nonbreathing and unconscious patient and provide continuous support while the patient is transported to a medical facility. There must be documentation that all emergency equipment and drugs are checked and maintained on a prudent and regularly scheduled basis.

Subp. 11.

On-site inspection; requirements and procedures.

All offices in which general anesthesia, deep sedation, or moderate sedation is conducted under the terms of this part must be in compliance with items A to C. Besides these requirements, each office must be in compliance with the practice and equipment requirements in subpart 10. The dentist is responsible for all costs associated with an on-site inspection.

A. Requirements for on-site inspections are described in subitems (1) to (3).

(1) A dentist who applies for an initial general anesthesia or moderate sedation certificate or who provides dental services to patients under general anesthesia, deep sedation, or moderate sedation must have an on-site inspection conducted at one primary office facility within 12 months following receipt of a certificate from the board. Thereafter, a dentist must have an on-site inspection conducted at one primary office facility at least once every five years.

(2) A dentist who holds an existing certificate must have an on-site inspection conducted at one primary office facility or provide proof to the board of having an inspection conducted within two years of March 19, 2010. Thereafter, each dentist must have an on-site inspection conducted at one primary office facility at least once every five years.

(3) A dentist must have an on-site inspection conducted at one primary office facility if the board receives a complaint alleging violation of this part and the board finds the complaint warrants further investigation.

B. If a dentist fails to meet the on-site inspection requirements because of extenuating circumstances, the dentist may apply for an extension of time to complete the requirements by making a written request to the board. The written request must include a complete explanation of the circumstances and the dentist's plan for completing the on-site inspection requirement. If an extension is granted after review, the board shall establish the length of the extension to obtain the on-site inspection requirements.

C. On-site inspection procedures are described in subitems (1) to (3).

(1) The dentist must be notified in writing by the board if an on-site inspection is required and provided with the name of an anesthesia consultant or qualified anesthetic practitioner who is qualified to coordinate the inspection. The dentist may have an on-site inspection performed by another individual or organization or agency that has been approved by the board. The dentist must make arrangements for the scheduling or completion of the inspection within 30 calendar days of the date the notice is mailed.

(2) Within 30 calendar days following an on-site inspection, the dentist must direct the individual or organization or agency conducting the inspection to provide the board with the written results of the inspection.

(3) A dentist who fails an on-site inspection shall have the general anesthesia or moderate sedation certificate suspended or be subject to disciplinary proceedings.

Statutory Authority:

MS s [150A.04](#); [150A.06](#); [150A.08](#); [150A.10](#)

History:

[16 SR 2314](#); [20 SR 1196](#); [27 SR 1836](#); [29 SR 306](#); [31 SR 1238](#); [35 SR 459](#); [36 SR 738](#); [37 SR 1849](#); [39 SR 1455](#); [42 SR 226](#)

Published Electronically:

August 30, 2017