

Rule-Making Fact Sheet

(5 MRSA §8057-A)

AGENCY: Maine Board of Dental Practice (Affiliated with the Department of Professional and Financial Regulation)

NAME, ADDRESS, PHONE NUMBER, E-MAIL OF AGENCY CONTACT PERSON: Penny Vaillancourt, Executive Director, 143 State House Station, Augusta, ME 04333; 207-287-3333; penny.vaillancourt@maine.gov

CHAPTER NUMBER AND RULE TITLE:

Chapter 14 – “Rules for Use of Sedation and General Anesthesia”

STATUTORY AUTHORITY: 32 M.R.S. §§ 18324, 18379

TYPE OF RULE (*check one*): Routine Technical Major Substantive

DATE, TIME AND PLACE OF PUBLIC HEARING: No public hearing is scheduled. Written comments can be mailed to the Maine Board of Dental Practice, 143 State House Station with a physical location of 76 Northern Avenue, Gardiner, ME 04345; or can be emailed to Penny Vaillancourt, Executive Director at penny.vaillancourt@maine.gov

COMMENT DEADLINE: October 28, 2022 at 5:00 p.m.

PRINCIPAL REASON(S) OR PURPOSE FOR PROPOSING THIS RULE: [*see §8057-A(1)(A)&(C)*]:

1. Requires a dentist who applies for a permit to provide sedation and/or general anesthesia services to patients to obtain and maintain life support certification in basic life support (BLS), and advanced life support certification in Advanced Cardiac Life Support (ACLS). Advanced life support certification in Pediatric Advanced Life Support (PALS) is required when providing sedation services to pediatric patients and may be used in meeting the ACLS advanced life support certification requirements.
2. Requires an operating dentist who applies for a 14 Day Notification to utilize the services of a sedation provider to obtain and maintain life support certification in BLS, and advanced life support certification in Advanced Cardiac Life Support (ACLS). Advanced life support certification in Pediatric Advanced Life Support (PALS) is required when providing sedation services to pediatric patients and may be used in meeting the ACLS advanced life support certification requirements.
3. Clarifies that as part of the 14 Day Notification application requirements, a sedation provider must hold current life support certifications in BLS, ACLS and PALS. As noted in the previous sections, PALS certification is required only when providing sedation services to pediatric patients and may be used in meeting the ACLS advanced life support certification requirements.
4. Removes duplicative notification language when a dentist who holds a permit under Chapter 14 is part of a 14 Day Notification application. No additional application or notification is required by the dentist providing services as the sedation provider.

5. Other technical changes include clarification as follows:
- a. An operating dentist must file an application when utilizing a sedation provider as part of a 14 Day Notification requirement;
 - b. Life support certification requirements for a permit renewal;
 - c. Online life support/advanced life support certification training not accepted unless hands-on participation with the instructor as a component of the training is verified; and
 - d. Removing sections from the rule referencing dates for compliance after the rule was last amended in 2017.

IS MATERIAL INCORPORATED BY REFERENCE IN THE RULE? X YES NO [§8056(1)(B)]:

ANALYSIS AND EXPECTED OPERATION OF THE RULE: [see §8057-A(1)(B)&(D)]: The rule identifies the life support certification requirements when utilizing sedation and/or general anesthesia in a dental practice setting. The rule also identifies technical amendments to further streamline the sedation permitting process.

BRIEF SUMMARY OF RELEVANT INFORMATION CONSIDERED DURING DEVELOPMENT OF THE RULE (including up to 3 primary sources relied upon) [see §§8057-A(1)(E) & 8063-B]

- Title 32, Chapter 143 “Dental Professionals.”
- Board of Dental Practice Rules Chapter 14 “Rules for Use of Sedation and General Anesthesia”
- Board of Dental Practice Rules Chapter 12 “Practice Requirements”
- Public Comments received during comment period ending June 13, 2022 specific to a previous proposed rule change to Chapter 14
- Expertise of board members in their capacities as dental professionals training in managing patient emergencies

ESTIMATED FISCAL IMPACT OF THE RULE: [see §8057-A(1)(C)]: Most licensees are currently certified in basic life support and advanced life support training as outlined in the proposed rule. There may be a small financial impact to a limited number of licensees who need to obtain additional certification.

FOR EXISTING RULES WITH FISCAL IMPACT OF \$1 MILLION OR MORE, ALSO INCLUDE:

ECONOMIC IMPACT, WHETHER OR NOT QUANTIFIABLE IN MONETARY TERMS:
[see §8057-A(2)(A)]

INDIVIDUALS, MAJOR INTEREST GROUPS AND TYPES OF BUSINESSES AFFECTED AND HOW THEY WILL BE AFFECTED: [see §8057-A(2)(B)]

BENEFITS OF THE RULE: [see §8057-A(2)(C)]

Note: If necessary, additional pages may be used.

Notice of Agency Rule-making Proposal

AGENCY: Maine Board of Dental Practice (Affiliated with the Department of Professional and Financial Regulation)

TYPE OF RULE (*check one*): Routine Technical Major Substantive

CHAPTER NUMBER AND TITLE: Chapter 14 – “Rules for Use of Sedation and General Anesthesia”

PROPOSED RULE NUMBER (*leave blank; to be assigned by Secretary of State*):

BRIEF SUMMARY: This is an amendment to an existing rule that clarifies the advanced life support certification requirements when a dentist is utilizing sedation and/or general anesthesia as follows:

1. Requires a dentist who applies for a permit to provide sedation and/or general anesthesia services to patients to obtain and maintain life support certification in basic life support (BLS), and advanced life support certification in Advanced Cardiac Life Support (ACLS). Advanced life support certification in Pediatric Advanced Life Support (PALS) is required when providing sedation services to pediatric patients and may be used in meeting the ACLS advanced life support certification requirements.
2. Requires an operating dentist who applies for a 14 Day Notification to utilize the services of a sedation provider to obtain and maintain life support certification in BLS, and advanced life support certification in Advanced Cardiac Life Support (ACLS). Advanced life support certification in Pediatric Advanced Life Support (PALS) is required when providing sedation services to pediatric patients and may be used in meeting the ACLS advanced life support certification requirements.
3. Clarifies that as part of the 14 Day Notification application requirements, a sedation provider must hold current life support certifications in BLS, ACLS and PALS. As noted in the previous sections, PALS certification is required only when providing sedation services to pediatric patients and may be used in meeting the ACLS advanced life support certification requirements.
4. Removes duplicative notification language when a dentist who holds a permit under Chapter 14 is part of a 14 Day Notification application. No additional application or notification is required by the dentist providing services as the sedation provider.
5. Other technical changes include clarification as follows:
 - a. An operating dentist must file an application when utilizing a sedation provider as part of a 14 Day Notification requirement;
 - b. Life support certification requirements for a permit renewal;
 - c. Online life support/advanced life support certification training not accepted unless hands-on participation with the instructor as a component of the training is verified; and
 - d. Removing sections from the rule referencing dates for compliance after the rule was last amended in 2017.

Date, time and location of PUBLIC HEARING (*if any*): No public hearing is scheduled. Written comments can be mailed to the Maine Board of Dental Practice, 143 State House Station, Augusta, ME 04333; or can be emailed to Penny Vaillancourt, Executive Director at penny.vaillancourt@maine.gov

COMMENT DEADLINE: October 28, 2022 at 5:00 p.m.

CONTACT PERSON FOR THIS FILING (*include name, mailing address, telephone, fax, TTY, e-mail*): Penny Vaillancourt, Executive Director, Maine Board of Dental Practice, 143 State House Station, Augusta, ME 04333; 207-287-3333 (tel.); 207-287-8140 (fax); TTY 711; or email penny.vaillancourt@maine.gov

CONTACT PERSON FOR SMALL BUSINESS IMPACT STATEMENT (*if different*):

FINANCIAL IMPACT ON MUNICIPALITIES OR COUNTIES (if any): None known.

STATUTORY AUTHORITY FOR THIS RULE: 32 M.R.S. §§ 18324, 18379

SUBSTANTIVE STATE OR FEDERAL LAW BEING IMPLEMENTED (if different): N/A

AGENCY WEBSITE: www.maine.gov/dental

E-MAIL FOR OVERALL AGENCY RULE-MAKING LIAISON: penny.vaillancourt@maine.gov

* Check one of the following two boxes.

The summary provided above is for publication in both the newspaper and website notices.

The summary provided above is for the newspaper notice only. Title 5 §8053, sub-§5 & sub-§7, ¶D. A more detailed summary is attached for inclusion in the rule-making notice posted on the Secretary of State's website. Title 5 §8053, sub-§3, ¶D & sub-§6.

Please approve bottom portion of this form and assign appropriate AdvantageME number.

APPROVED FOR PAYMENT


(authorized signature)

DATE:

September 1, 2022

FUND	AGENCY	ORG	APP	OBJ	PROGRAM	FUNDING Profile JVC	FUND Pri JVC	FUND Line JVC
014	02D	0384	01	4946				

MAPA-3 revised 2-2016: additional summary information for web

Notice of Agency Rule-making Proposal

Additional Information for the Web (if any)

DETAILED SUMMARY:

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

313 MAINE STATE BOARD OF DENTAL PRACTICE

Chapter 14: RULES FOR USE OF SEDATION AND GENERAL ANESTHESIA

Summary: This rule prescribes the circumstances under which dentists may administer minimal sedation, moderate sedation, deep sedation, and general anesthesia, and circumstances under which operating dentists may use the services of a Maine licensed sedation provider to administer moderate sedation, deep sedation and general anesthesia in the State of Maine.

I. ADOPTION OF THE ADA GUIDELINES FOR THE USE OF SEDATION AND GENERAL ANESTHESIA BY DENTISTS.

The Board adopts and incorporates into this Chapter by reference the American Dental Association’s “Guidelines for the Use of Sedation and General Anesthesia by Dentists” (as adopted by the October 2007 ADA House of Delegates)[hereinafter referred to in these rules as “ADA Sedation Guidelines”]. All Dentists must comply with the “ADA Sedation Guidelines” in addition to any other requirement imposed by the Board pursuant to this Chapter. In the event of a conflict between a standard in the “ADA Sedation Guidelines” and a provision of this Chapter, the provision of this Chapter shall govern.

Copies of the ADA “Guidelines for the Use of Sedation and General Anesthesia by Dentists” (as adopted by the October 2007 ADA House of Delegates) are available at:

American Dental Association
211 East Chicago Ave.
Chicago, IL 60611-2678
312-440-2500

II. ADOPTION OF THE ADA GUIDELINES FOR TEACHING PAIN CONTROL AND SEDATION TO DENTISTS AND DENTAL STUDENTS

The Board adopts and incorporates into this Chapter by reference the American Dental Association’s “Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students” (as adopted by the October 2007 ADA House of Delegates). [hereinafter referred to in these rules as “ADA Teaching Guidelines”]. All Dentists must comply with the “ADA Teaching Guidelines” in addition to any other requirement imposed by the Board pursuant to this Chapter. In the event of a conflict between a standard in the “ADA Teaching Guidelines” and a provision of this Chapter, the provision of this Chapter shall govern.

Copies of the “ADA Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students” (as adopted by the October 2007 ADA House of Delegates) are available at:

American Dental Association
211 East Chicago Ave.
Chicago, IL 60611-2678
312-440-2500

III. **ADOPTION OF THE ADA GUIDELINES FOR MONITORING AND MANAGEMENT OF PEDIATRIC PATIENTS DURING AND AFTER SEDATION FOR DIAGNOSTIC AND THERAPEUTIC PROCEDURES.**

The Board adopts and incorporates into this Chapter by reference 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” (developed and endorsed by the American Academy of Pediatrics and the American Academy of Pediatric Dentistry, 2006 and incorporated by reference into the ADA Sedation Guidelines) [hereinafter referred to in these rules as “Pediatric Sedation Guidelines”]. All Dentists must comply with the “Pediatric Sedation Guidelines” in addition to any other requirement imposed by the Board pursuant to this Chapter. In the event of a conflict between a standard in the “Pediatric Sedation Guidelines” and a provision of this Chapter, the provision of this Chapter shall govern.

Copies of the “Guidelines for Monitoring and Management of Pediatric Patients During and After Sedation for Diagnostic and Therapeutic Procedures” are available at:

American Academy of Pediatrics 141 Northwest Point Boulevard Elk Grove Village, IL 60007-1098	American Academy of Pediatric Dentistry 211 East Chicago Avenue, Suite 1600 Chicago, IL 60611-2637
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The electronic version may be accessed on line at:

http://www.aapd.org/media/policies_guidelines/g_sedation.pdf.

IV. **STANDARD OF CARE**

- A. **Minimal Sedation.** In addition to the provisions contained in this chapter, all dentists must comply with the generally accepted standards as established by the “ADA Sedation Guidelines” when administering minimal sedation.
- B. **Moderate Sedation.** In addition to the provisions contained in this chapter, all dentists administering moderate sedation:
- (1) Must comply with the generally accepted standards as established by the “ADA Sedation Guidelines” when administering moderate sedation; and
 - (2) Must not have more than one patient under moderate sedation simultaneously.

- C. **Deep Sedation/General Anesthesia.** In addition to the provisions contained in this chapter, all dentists must comply with the generally accepted standards as established by the “ADA Sedation Guidelines” when administering deep sedation/general anesthesia. In addition, each permitted dentist administering deep sedation/general anesthesia:
- (1) Must employ and document the use of continuous electrocardiograph monitoring for all patients to whom deep sedation/general anesthesia is administered; and
 - (2) Must not have more than one patient under deep sedation/general anesthesia and/or moderate sedation simultaneously.
- D. **Utilizing the Services of a Sedation Provider.** Any dentist who utilizes the services of a sedation provider to provide moderate sedation, deep sedation, and/or general anesthesia must comply with the generally accepted standards as established by the “ADA Sedation Guidelines” for the administration of sedation and general anesthesia, including the provisions of this chapter. In addition, any dentist who utilizes the service of a sedation provider must comply with the notification requirements in accordance with Section XIII of this chapter.
- V. **DENTIST RESPONSIBILITIES.** A dentist providing sedation services or an operating dentist utilizing the services of a sedation provider as outlined in this chapter must comply with the following:
- A. **Patient Recovery.** The operating dentist must ensure that the sedation provider remains at the location where services were provided until any patient given moderate or deep sedation/general anesthesia has been assessed for discharge in accordance with this chapter and the ADA Sedation guidelines. Patient assessment and discharge information such as level of consciousness, oxygenation, ventilation, and circulation must be documented in each patient record.
- B. **Levels of Anesthesia.** The dentist, the operating dentist and the sedation provider must be prepared to manage deeper than intended levels of anesthesia. If a patient enters a deeper level of sedation than the provider is qualified to provide, then the dental procedure must stop until the patient returns to the intended level of sedation.
- C. **Equipment Required When Administering Minimal Sedation, Moderate Sedation, Deep Sedation and/or General Anesthesia.** The dentist or operating dentist must ensure that that following requirements are met as it relates to the delivery of sedation:
- (1) A dentist whose practice includes the administration of minimal sedation must provide the following equipment, which is required to be functional at all times:
 - a. Emergency equipment, including:
 - i. An appropriate size bag-valve-mask apparatus or equivalent with an oxygen hook-up.
 - ii. Oral and nasopharyngeal airway device.
 - iii. Appropriate emergency medications.
 - iv. An external defibrillator - manual or automatic.
 - v. Broselow pediatric measuring tape.

- b. Equipment to monitor vital signs and oxygenation/ventilation, including:
 - i. A continuous pulse oximeter.
 - ii. A blood pressure cuff of appropriate size and stethoscope, or equivalent blood pressure monitoring devices.
 - c. Oxygen, suction, and a pulse oximeter must be immediately available during the recovery period.
- (2) A dentist or operating dentist whose practice includes the administration of moderate sedation must provide the following equipment, which is required to be functional at all times:
- a. Emergency equipment, including:
 - i. An appropriate size bag-valve-mask apparatus or equivalent with an oxygen hook-up.
 - ii. Oral and nasopharyngeal airway device.
 - iii. Appropriate emergency medications.
 - iv. An external defibrillator - manual or automatic.
 - v. ACLS algorithms card.
 - vi. Broselow pediatric measuring tape.
 - b. Equipment to monitor vital signs and oxygenation/ventilation, including:
 - i. A continuous pulse oximeter.
 - ii. A blood pressure cuff of appropriate size and stethoscope, or equivalent blood pressure monitoring devices.
 - c. Oxygen, suction, and a pulse oximeter must be immediately available during the recovery period.
 - d. Back-up suction equipment.
 - e. Back-up lighting system.
 - f. Equipment necessary to establish intravenous (IV), intraosseous (IO), or sublingual (SL) access.
 - g. Electrocardiograph if providing sedation services to patients with American Society of Anesthesiologists Physical Status Classification of ASA III or higher.
 - h. Ventilation monitoring system (e.g. color CO₂, auscultation of breath sounds). Permit holders are ~~will be~~ required to obtain and use an end-tidal carbon dioxide monitor (capnography) ~~by July 1, 2018.~~
- (3) A dentist or operating dentist whose practice includes the administration of deep sedation and/or general anesthesia must provide the following and equipment, which is required to be functional at all times:
- a. Emergency equipment, including:

- i. An appropriate size bag-valve-mask apparatus or equivalent with an oxygen hook-up.
 - ii. Oral and nasopharyngeal airways.
 - iii. Appropriate emergency medications.
 - iv. An external defibrillator - manual or automatic.
 - v. ACLS algorithms card.
 - vi. Broselow pediatric measuring tape.
- b. Equipment to monitor vital signs and oxygenation/ventilation, including:
 - i. A continuous pulse oximeter.
 - ii. A blood pressure cuff of appropriate size and stethoscope, or equivalent blood pressure monitoring devices.
 - c. Oxygen, suction, and a pulse oximeter must be immediately available during the recovery period.
 - d. Back-up suction equipment.
 - e. Back-up lighting system.
 - f. Equipment necessary to establish intravenous (IV), intraosseous (IO) or sublingual (SL) access.
 - g. Electrocardiograph.
 - h. Ventilation monitoring system (e.g. color CO₂, auscultation of breath sounds). Permit holders ~~are~~ will be required to obtain and use an end-tidal carbon dioxide monitor (capnography) ~~by July 1, 2018.~~
 - i. Additional emergency equipment to manage difficult airways, including:
 - i. Laryngeal mask airway, and/or endotracheal tubes and/or a LMA suitable for patients being treated.
 - ii. Laryngoscope with reserve batteries and bulbs.
 - iii. Endotracheal tube forceps (e.g. Magill).
 - iv. At least one additional airway management device.
 - v. Equipment to establish surgical airway.

(4) **Emergency Protocols:** A dentist or operating dentist whose practice includes the use of moderate sedation or general anesthesia must have written emergency protocols, and must provide training at least annually to familiarize office personnel in the treatment of the following clinical emergencies:

- a. Laryngospasm.
- b. Bronchospasm.
- c. Emesis and aspiration.
- d. Airway blockage by foreign body.
- e. Angina pectoris.
- f. Myocardial infarction.
- g. Hypertension/Hypotension.
- h. Allergic and toxicity reactions.
- i. Seizures.

- j. Syncope.
- k. Intra-arterial injection.
- l. Hyperventilation/Hypoventilation.
- m. Cardiac arrest.
- n. Cardiac arrhythmias.

A dentist or operating dentist must maintain for inspection a permanent record, which reflects the date, time, duration, names of attendees, and type of emergency protocol training provided.

- D. **Drugs.** A dentist or operating dentist must have the following drugs and/or categories of drugs with a current shelf life easily accessible from the operatory and recovery room when providing the services below:

(1) **Moderate Sedation Services**

a. **Level I (Enteral)**

i. **Cardiac Drugs**

1. Vasopressor (e.g. Epinephrine)
2. Nitroglycerin (spray or tablets)
3. Anticoagulant (aspirin)
4. Glucose (D50 or liquid glucose)

ii. **Reversal Agents** (required only for administration of benzodiazepines or narcotics)

1. Flumazenil (benzodiazepine reversal agent)
2. Narcan (narcotic reversal agent)

iii. **Other**

1. Antihistamine (e.g. Benadryl IV or PO)
2. Bronchodilator (e.g. Albuterol inhaler)

b. **Level II (Parenteral)**

i. **Cardiac Drugs**

1. Vasopressor (e.g. Epinephrine)
2. Nitroglycerin (spray or tablets)
3. Anticoagulant (aspirin)
4. Glucose (D50 or liquid glucose)
5. Lidocaine
6. Atropine
7. Adenosine
8. Diltiazem
9. Beta Blocker (e.g. Labetalol, Esmolol)

ii. **Reversal Agents** (required only for administration of benzodiazepines, narcotics, or triggering agents of malignant hypothermia)

1. Flumazenil (benzodiazepine reversal agent)
2. Narcan (narcotic reversal agent)

3. Dantrolene, Ryanodex (volatile gas reversal agent)

iii. **Other**

1. Antihistamine (e.g. Benadryl IV or PO)
2. Bronchodilator (e.g. Albuterol inhaler)
3. Corticosteroid (e.g. Solu-Medrol)
4. Muscle Relaxant (e.g. Succinylcholine)
5. Narcotics (e.g. morphine, fentanyl)
6. Antihypertensive drugs (e.g. Propranolol, Verapamil)

(2) **Deep Sedation and/or General Anesthesia Services**

a. **Cardiac Drugs**

- i. Vasopressor (e.g. Epinephrine)
- ii. Nitroglycerin (spray or tablets)
- iii. Anticoagulant (aspirin)
- iv. Glucose (D50 or liquid glucose)
- v. Lidocaine
- vi. Atropine
- vii. Adenosine
- viii. Diltiazem
- ix. Beta Blocker (e.g. Labetalol, Esmolol)

b. **Reversal Agents** (required only for administration of benzodiazepines, narcotics, or triggering agents of malignant hypothermia)

- i. Flumazenil (benzodiazepine reversal agent)
- ii. Narcan (narcotic reversal agent)
- iii. Dantrolene, Ryanodex (volatile gas reversal agent)

c. **Other**

- i. Antihistamine (e.g. Benadryl IV or PO)
- ii. Bronchodilator (e.g. Albuterol inhaler)
- iii. Corticosteroid (e.g. Solu-Medrol)
- iv. Muscle Relaxant (e.g. Succinylcholine)
- v. Narcotics (e.g. morphine, fentanyl)
- vi. Antihypertensive drugs (e.g. Propranolol, Verapamil)

E. **Anesthesia Gas Delivery Systems – must include all of the following:**

- (1) Capability to deliver oxygen to a patient under positive pressure, including a back-up oxygen system.
- (2) Gas outlets that meet generally accepted safety standards preventing accidental administration of inappropriate gases or gas mixture.
- (3) Fail-safe mechanisms for inhalation of nitrous oxide analgesia.
- (4) Inhalation equipment with an appropriate scavenging system.

- (5) Gas storage facilities, which meet generally accepted safety standards.
- (6) Engineering controls and maintenance procedures to ensure safety of inhalation equipment.

F. Patient Documentation – must include, but is not limited to, all of the following:

- (1) For administration of minimal sedation, moderate sedation, deep sedation or general anesthesia –
 - a. Medical History - current and comprehensive.
 - b. Height and Weight.
 - c. American Society of Anesthesiology (ASA) Classification.
 - d. Dental Procedure(s).
 - e. Informed Consent.
 - f. Time oriented anesthesia record, which includes:
 - i. Parenteral access site and method, if utilized.
 - ii. Medication(s) administered - medication (including oxygen), dosage, route, and time given.
 - iii. Vital signs before and after anesthesia is utilized.
 - iv. Intravenous fluids, if utilized.
 - v. Response to anesthesia - including any complications.
 - g. Condition of patient at discharge charted with objective data or scale such as the Modified Aldrete scoring system.
- (2) In addition, for administration of moderate sedation, deep sedation or general anesthesia -
 - a. Physical examination - airway assessment, baseline heart rate, blood pressure, respiratory rate, and oxygen saturation;
 - b. Time oriented anesthesia record, which includes:
 - i. Time anesthesia commenced and ended.
 - ii. At least every 5 minutes record blood pressure, heart rate, oxygen saturation (SpO₂), and respiratory rate.
 - iii. Continuous electrocardiograph (ECG) and documentation of changes in rhythm, if clinically indicated by patient history, medical condition(s), or age.

G. Patient Monitoring - Must include, but is not limited to the following:

- (1) For the administration of Minimal Sedation -
 - a. Continuous heart rate and respiratory status;

- b. Continuous oxygen saturation (SpO₂); and
 - c. Pre and post procedure blood pressure.
- (2) For the administration of Moderate Sedation -
- a. Continuous heart rate, respiratory status, and oxygen saturation;
 - b. Intermittent blood pressure, taken at least every 5 minutes;
 - c. Continuous electrocardiograph of patients with significant cardiovascular disease;
 - d. End-tidal carbon dioxide monitoring (capnography) ~~by July 1, 2018~~; and
 - e. Continuous monitoring of level of consciousness
- (3) For the administration of Deep Sedation or General Anesthesia -
- a. Continuous heart rate, respiratory status, and oxygen saturation;
 - b. Intermittent blood pressure, taken at least every 5 minutes;
 - c. Continuous electrocardiograph;
 - d. End-tidal carbon dioxide monitoring (capnography) ~~by July 1, 2018~~; and
 - e. Continuous monitoring of level of consciousness
- (4) When the level of cooperation in a pediatric or special needs patient does not reasonably allow for full compliance with some monitoring requirements, the dentist must use professional judgment regarding monitoring and must document the reasons preventing the recommended management.

H. Miscellaneous Requirements

- (1) **Life Support Certification(s)**
- a. Dentists must ensure that all dental personnel successfully complete Basic Life Support for Healthcare Providers (BLS) certification and maintain current BLS certification when utilizing, administering, or monitoring local anesthesia, nitrous oxide analgesia, minimal sedation, moderate sedation, deep sedation, or general anesthesia.
 - b. ~~Any dentist applying for or maintaining a Moderate Sedation Permit or a Deep Sedation/General Anesthesia Permit must have successfully completed current Advanced Cardiac Life Support (ACLS) or Pediatric Advanced Life Support (PALS), as appropriate for the dentist's practice, and maintain continuous certification~~ who files an application under this chapter for either a permit or a 14 Day Notification to utilize the services

of a sedation provider must obtain and maintain life support certification in BLS and advanced life support certification in Advanced Cardiac Life Support (ACLS). Advanced life support certification in Pediatric Advanced Life Support (PALS) is required when providing sedation services to pediatric patients and may be used in meeting the ACLS advanced life support certification requirements of this chapter.

- c. ~~Successful completion of PALS training and continuous certification are required for a dentist that provides pediatric sedation. Online life support certification training and online advanced life support certification training are not accepted unless hands-on participation with the instructor as a component of the training is verified.~~

(2) **Personnel**

- a. **Minimal/Moderate Sedation** – When providing minimal or moderate sedation at a dental practice location, the operating dentist and at least one other individual who is experienced in patient monitoring and documentation, and trained to handle emergency situations must be present.
- b. **Deep sedation/general anesthesia** - During the administration of deep sedation or general anesthesia, the operating dentist and at least two other individuals, one of whom is experienced in patient monitoring and documentation, and trained to handle emergency situations, must be present.

(3) **Monitoring and medication administration** - The dentist retains full accountability, but delegation as authorized by the **Maine Dental Practice Act** to dental personnel may occur under:

- a. Direct supervision by the dentist when a patient is being monitored, or
- b. Direct, continuous, and visual supervision by the dentist when medication, excluding local anesthetic, is being administered to a patient.

(4) **Discharge** - Patient discharge after sedation and/or general anesthesia must be specifically authorized by the dentist or sedation provider.

VI. SEDATION PERMITS; SCOPES OF PRACTICE. A dentist issued a Permit for Moderate Sedation Level II (Parenteral) by the Board may also perform Moderate Sedation Level I (Enteral) and Minimal Sedation. A dentist issued a Permit for Deep Sedation/ General Anesthesia by the Board may also perform any type of moderate or minimal sedation.

VII. USE OF MINIMUM AND MODERATE SEDATION; PERMIT REQUIREMENTS

A. Minimal Sedation

- (1) **General.** No dentist shall be required to obtain a permit in order to administer minimal sedation as defined by the “ADA Guidelines.”
- (2) **Exception.** Dentists who administer minimal sedation to patients age 12 and under must first obtain a Permit for Moderate Sedation if:
 - (a) The dentist prescribes a preoperative sedative to be administered to the child (Level I – Enteral); or
 - (b) The dentist administers a combination of minimal sedation methods (e.g. oral sedative and nitrous oxide) (Level I – Enteral).

B. Moderate Sedation Permit

- (1) **General.** No dentist may administer moderate sedation without first obtaining a permit from by the board.
- (2) **Types of Permits for Moderate Sedation:** The Board may issue one of the following types of permits for moderate sedation:
 - (a) Permit for Moderate Sedation Level I (Enteral); and
 - (b) Permit for Moderate Sedation Level II (Parenteral).
- (3) **Qualifications for Initial Permits for Moderate Sedation:** In order to qualify, dentist applicants must submit an application, pay the required fees, and meet each of the following:
 - (a) **Permit for Moderate Sedation Level I (Enteral).** Dentist applicants for this type of permit must satisfy each of the following:
 - (i) Have successfully completed a Board-approved comprehensive training program of a minimum of twenty-four (24) hours duration, plus management of at least ten (10) adult case experiences by the enteral and/or enteral-nitrous oxide/oxygen route as described in the “ADA Teaching Guidelines.” The ten (10) cases must include at least three live clinical dental experiences managed by participants in groups no larger than five (5). The remaining cases may include simulations and/or video presentations, but must include one experience in returning (rescuing) a patient from deep to moderate sedation. Participants should be provided supervised opportunities for clinical experience to demonstrate competence in airway management. Clinical experience will be provided in managing healthy adult patients. This course in moderate enteral sedation is not designed for the management of children (aged 12 and under). Additional supervised clinical experience is necessary to prepare participants

to manage medically compromised adults and special needs patients. This course in moderate enteral sedation does not result in competency in moderate parenteral sedation;

- (ii) ~~Possess a current life support certifications in accordance with Section V(H)(1)(b) certification in: (a) Basic Life Support for Healthcare Providers (BLS); and (b) Advanced Cardiac Life Support (ACLS) or an appropriate dental sedation/anesthesia emergency management course that includes ACLS training;~~
- (iii) Have submitted to the Board a completed, signed certification form that attests to adhering to the equipment, personnel, procedures, techniques and documents as outlined in the “ADA Sedation Guidelines” and requirements in this chapter; and
- (iv) If providing sedation services to an operating dentist, agree to comply with the notification requirements in this chapter that requires the sedation provider to submit to the Board, fourteen (14) days prior to delivering services in this chapter, a signed, written agreement between the operating dentist and sedation provider identifying the location of which sedation services are to be administered and demonstrating compliance with the equipment, personnel, procedures, techniques and documents as outlined in the “ADA Sedation Guidelines” and requirements in this chapter. The agreement, at a minimum, must describe 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-operative, inter-operative, 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.

(b) **Permit for Moderate Sedation Level II (Parenteral).** Dentist applicants for this type of permit must satisfy each of the following:

- (i) Have successfully completed a Board-approved comprehensive training program of a minimum of sixty (60) hours of instruction, plus management of at least 20 patients by the intravenous route per participant as described in the “ADA Teaching Guidelines.” Clinical experience in managing a compromised airway is critical to the prevention of emergencies. Participants should be provided supervised opportunities for clinical experience to demonstrate competence in management of the airway. Typically, clinical experience will be provided in managing healthy adult patients. Additional supervised clinical experience is necessary to prepare participants to manage children (aged 12 and under) and medically compromised adults;

- (ii) ~~Possess a current life support certifications in accordance with Section V(H)(1)(b): (a) Basic Life Support for Healthcare Providers (BLS); and (b) Advanced Cardiac Life Support (ACLS) or an appropriate dental sedation/anesthesia emergency management course that includes ACLS training;~~
- (iii) Have submitted to the Board a completed, signed certification form that attests to adhering to the equipment, personnel, procedures, techniques and documents as outlined in the “ADA Sedation Guidelines” and requirements in this chapter; and
- (iv) If providing sedation services to an operating dentist, agree to comply with the notification requirements in this chapter that requires the sedation provider to submit to the Board, fourteen (14) days prior to delivering services in this chapter, a signed, written agreement between the operating dentist and sedation provider identifying the location of which sedation services are to be administered and demonstrating compliance with the equipment, personnel, procedures, techniques and documents as outlined in the “ADA Sedation Guidelines” and requirements in this chapter. The agreement, at a minimum, must describe 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-operative, inter-operative, 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.

VIII. USE OF DEEP SEDATION AND GENERAL ANESTHESIA; PERMITS REQUIRED

- A. **General.** No dentist may administer deep sedation or general anesthesia without first obtaining a permit from by the board.
- B. **Qualifications for Initial Permits for Deep Sedation/General Anesthesia:** In order to qualify, dentist applicants must submit an application, pay the required fees, and satisfy each of the following:
 - (1) Have successfully completed an advanced education program accredited by the ADA Commission on Dental Accreditation (CODA) that affords comprehensive and appropriate training necessary to administer and manage deep sedation or general anesthesia commensurate with Part IV.C of the “ADA Sedation Guidelines;”

- (2) ~~Possess a current life support certifications in accordance with Section V(H)(1)(b):-(a) Basic Life Support for Healthcare Providers (BLS); and (b) Advanced Cardiac Life Support (ACLS) or an appropriate dental sedation/anesthesia emergency management course that includes ACLS training;~~
- (3) Have submitted to the Board a completed, signed certification form that attests that the office is staffed with a supervised team of auxiliary personnel capable of reasonably handling procedures, problems, and emergencies as outlined in the “ADA Sedation Guidelines;”
- (4) Have submitted to the Board a completed, signed certification form that attests to adhering to the equipment, personnel, procedures, techniques and documents as outlined in the “ADA Sedation Guidelines” and requirements in this chapter; and
- (5) If providing sedation services to an operating dentist, agree to comply with the notification requirements in this chapter that requires the sedation provider to submit to the Board, fourteen (14) days prior to delivering services in this chapter, a signed, written agreement between the operating dentist and sedation provider identifying the location of which sedation and/or general anesthesia services are to be administered and demonstrating compliance with the equipment, personnel, procedures, techniques and documents as outlined in the “ADA Sedation Guidelines” and requirements in this chapter. The agreement, at a minimum, must describe 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-operative, inter-operative, 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.

IX. ITINERANT DENTAL SEDATION AND/OR GENERAL ANESTHESIA SERVICES; PERMIT REQUIRED

- A. **Qualifications for Initial Permits for Itinerant Dentist Sedation Permit:** In order to obtain a Permit for Itinerant Dental Sedation and/or General Anesthesia, dentist applicants must satisfy each of the following:
 - (1) Have successfully completed an advanced education program accredited by the ADA Commission on Dental Accreditation (CODA) that affords comprehensive and appropriate training necessary to administer and manage deep sedation or general anesthesia commensurate with Part IV.C of the “ADA Sedation Guidelines;”
 - (2) ~~Possess a current life support certifications in accordance with Section V(H)(1)(b):-(a) Basic Life Support for Healthcare Providers (BLS); and (b) Advanced Cardiac Life Support (ACLS) or an appropriate dental sedation/anesthesia emergency management course that includes ACLS training;~~

- (3) Have submitted to the Board a completed, signed certification form that attests to adhering to the equipment, personnel, procedures, techniques and documents as outlined in the “ADA Sedation Guidelines” and requirements in this chapter; and
- (4) Agree to comply with the notification requirements in this chapter that requires the sedation provider to submit to the Board, fourteen (14) days prior to delivering services in this chapter, a signed, written agreement between the operating dentist and sedation provider identifying location of which sedation and/or general anesthesia services are to be administered and demonstrating compliance with the equipment, personnel, procedures, techniques and documents as outlined in the “ADA Sedation Guidelines” and requirements in this chapter. The agreement, at a minimum, must describe 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.

X. PERMIT RENEWAL REQUIREMENTS

- A. **Renewal Requirements.** The Board may renew a permit if the dentist applicant files the application on or before the date of expiration, pays the required fees, and meets each of the following criteria:
- (1) The dentist applicant attests to adhering to the equipment, personnel, procedures, techniques and documents as outlined in the “ADA Sedation Guidelines” and notification requirements in this chapter;
 - (2) The dentist applicant possesses a current life support certifications in accordance with Section V(H)(1)(b) in: (a) Basic Life Support for Healthcare Providers (BLS); and (b) Advanced Cardiac Life Support (ACLS) or an appropriate dental sedation/anesthesia emergency management course that includes ACLS training; and
 - (3) There are no other grounds to deny the renewal of the permit.

XI. LATE RENEWAL; REINSTATEMENT OF PERMIT.

- A. **Late Renewal Requirements.** The Board may renew a permit if the dentist applicant files the application no later than 90 days after the date of expiration and meets the following criteria:
- (1) Payment of the renewal and late fees; and
 - (2) Meets all the requirements pursuant to Section X(A)(1) through (3).
- B. **Reinstatement Requirements.** The Board may reinstate a permit if the dentist applicant files the application between 91 days and 2 years from the date of expiration and meets the following criteria:

- (1) The Board receives an application and applicable fees to reinstate the permit;
 - (2) The dentist applicant meets the qualifications for the permit as outlined in this chapter; and
 - (3) The dentist applicant attests to adhering to the equipment, personnel, procedures, techniques and documents as outlined in the “ADA Sedation Guidelines” and notification requirements in this chapter ;
- C. **Permit expiration date beyond two (2) years.** A dentist whose permit expired more than two years from the date of expiration must file a new application and meet the qualifications for a permit under this chapter.

XII. EXEMPTIONS TO INSPECTION REQUIREMENTS

A dentist who applies for a sedation permit under this chapter is exempt from the inspection requirement if the sedation services are provided in hospitals licensed by the State of Maine or provided in clinical settings of educational institutional programs accredited by CODA.

XIII. NOTIFICATION REQUIREMENTS WHEN UTILIZING THE SERVICES OF A SEDATION PROVIDER ~~OR WHEN PROVIDING SEDATION AND/OR GENERAL ANESTHESIA SERVICES WITH A SEDATION PERMIT.~~ Failure to comply with the requirements of this section may result in disciplinary action against the operating dentist utilizing the services of a sedation provider, or disciplinary action against the dentist with a sedation permit issueds under this chapter when providing sedation services for an operating dentist.

- A. **The following requirements must be met when an operating dentist intends to utilize the services of a sedation provider (a licensed dentist who holds a sedation permit issued under this chapter, a licensed physician or anesthesiologist, or a certified registered nurse anesthetist):**
- (1) **Notification requirements when the Sedation Provider is a Dentist.** Fourteen (14) days prior to utilizing the services of a dentist as a sedation provider, the operating dentist must submit to the Board for approval an application that meets the following requirements:
 - (a) A certification form, ~~approved by the Board,~~ that is signed by the operating dentist and attests to the following:
 - i. The sedation provider holds an active dentist license in good standing and holds an active sedation permit in good standing from the Board to provide moderate or deep sedation/general anesthesia services;
 - ii. The sedation provider holds ~~a current life support certifications in advanced cardiac life support~~ current life support certifications in advanced cardiac life support in accordance with Section V(H)(1)(b); and

- (b) A signed, written agreement between the operating dentist and sedation provider identifying the location at which sedation and/or general anesthesia services are to be administered by the sedation provider and demonstrating compliance with the equipment, personnel, procedures, techniques and documents as outlined in the “ADA Sedation Guidelines” and requirements in this chapter. The agreement, at a minimum, must describe 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-operative, inter-operative, 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.

(2) **Notification requirements when the Sedation Provider is an Anesthesiologist.** Fourteen (14) days prior to utilizing the services of an anesthesiologist as a sedation provider, the operating dentist must submit to the Board for approval an application that meets the following requirements:

- (a) A certification form, ~~approved by the Board,~~ that is signed by the operating dentist and attests to the following:
- i. The sedation provider holds an active medical license in good standing and has successfully completed graduate medical education in the field of anesthesiology, as defined by the Maine Board of Licensure in Medicine or the Maine Board of Osteopathic Licensure;
 - ii. The sedation provider holds a current life support certifications in BLS, ACLS and PALS. PALS certification is required only when providing sedation services to pediatric patients and may be used in meeting the ACLS requirement in advanced cardiac life support; and
- (b) A signed, written agreement between the operating dentist and sedation provider identifying the location at which sedation and/or general anesthesia services are to be administered by the sedation provider and demonstrating compliance with the equipment, personnel, procedures, techniques and documents as outlined in the “ADA Sedation Guidelines” and requirements in this chapter. The agreement, at a minimum, must describe 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-operative, inter-operative, 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.

- (3) **Notification requirements when the Sedation Provider is a Certified Registered Nurse Anesthetist.** Fourteen (14) days prior to utilizing the services of a certified registered nurse anesthetist, the operating dentist must submit to the Board for approval an application that meets the following requirements:
- (a) A certification form, ~~approved by the Board,~~ that is signed by the operating dentist and attests to the following:
 - i. The sedation provider holds an active license in good standing as a certified registered nurse anesthetist as defined by the Maine State Board of Nursing;
 - ii. The sedation provider holds a current life support certifications in BLS, ACLS and PALS. PALS certification is required only when providing sedation services to pediatric patients and may be used in meeting the ACLS requirement in advanced cardiac life support; and
 - (b) A signed, written agreement between the operating dentist and sedation provider identifying the location at which sedation and/or general anesthesia services are to be administered by the sedation provider and demonstrating compliance with the equipment, personnel, procedures, techniques and documents as outlined in the “ADA Sedation Guidelines” and requirements in this chapter. The agreement, at a minimum, must describe 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-operative, inter-operative, 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.

~~B. The following requirements must be met when a dentist who holds a sedation permit under this chapter and provides sedation and/or general anesthesia for an operating dentist:~~

~~(1) Notification requirements when a Dentist who holds a sedation permit under this chapter and provides sedation and/or general anesthesia services for an operating dentist. Fourteen (14) days prior to providing sedation services to an operating dentist, the dentist who holds a sedation permit must submit to the Board:~~

- ~~(a) A signed, written agreement between the dentist providing the sedation and/or general anesthesia services and the operating dentist identifying the location at which the sedation and/or general anesthesia services are to be administered and demonstrating compliance with the equipment, personnel, procedures, techniques and documents as outlined in the “ADA Sedation Guidelines” and requirements in this chapter. The agreement, at a minimum, must describe 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-operative, inter-operative, 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.~~

XIV. Prohibited Conduct

- A. No dentist may administer minimal sedation as described in Section VII(A)(2) to a patient 12 and under without first obtaining a moderate sedation permit from the Board.
- B. No dentist may administer moderate sedation or deep sedation/general anesthesia to any person without first obtaining a permit by the Board.
- C. No operating dentist may utilize the services of a sedation provider without notifying the Board in writing fourteen (14) days in advance and submitting a copy of the written agreement in accordance with the requirements of this chapter.
- ~~D. No dentist may provide sedation and/or general anesthesia services for an operating dentist without first obtaining the proper sedation permit and submitting a written agreement to the Board in accordance with the requirements in this chapter.~~

XV. PENALTIES FOR VIOLATIONS. A violation of this chapter pertaining to the use of sedation or general anesthesia shall constitute unprofessional conduct and may result in disciplinary action.

XVI. DURATION OF PERMITS; NON-TRANSFERABLE; EXCEPTION.

- A. Permits issued by the Board pursuant to this rule expire on December 31st of odd-numbered years, and must be renewed prior to that date by the dentist. Dentists holding such permits shall be subject to review of their education, training, and office equipment and procedures at the discretion of the Board.
- B. Permits issued pursuant this chapter are site specific and cannot be used at or extended to another site without a new permit issued by the Board, with the exception of itinerant permits.
- C. Itinerant permits issued pursuant to this chapter are not site specific.

XVII. BOARD AUTHORITY

- A. **Board Access to Dental Practice.** By applying for and obtaining a sedation permit from the Board, or by filing a notification with the Board of utilizing the services of a sedation provider, a dentist agrees to allow the Board or its agent(s) access to his/her dental practice in order to inspect and evaluate the equipment, personnel, procedures, techniques and documents to ensure that they comply with the “ADA Sedation Guidelines” and this Chapter. The Board, in its discretion, may perform quality assurance audits, which may include, but are not limited to, a review of documentation of pre-sedation evaluations, sedation and recovery records, and documentation of appropriateness for discharge.

- B. **Board Action Upon Receipt of Adverse Event Report.** In the event that the Board receives a report regarding any mortality or morbidity occurring in the out-patient facilities of a dentist, the Board may, in its discretion, investigate the circumstances surrounding the mortality or morbidity, including but not limited to a review of the dentist's documentation of pre-sedation evaluations, and sedation and recovery records.

TRANSITION LANGUAGE:

Permits issued after the effective date of this new rule will be issued as a fixed, biennial permit with an expiration date of December 31st of odd-numbered years.

A holder of a current temporary permit who meet the requirements for a full permit will be issued a fixed, biennial permit with an expiration date of December 31st of 2019.

A holder of a current five year permit will transition to a fixed, biennial permit with an expiration date of December 31st of odd-numbered years no sooner than the current expiration date of the existing permit, and may be extended to align with the fixed, biennial date of December 31st of odd-numbered years.

STATUTORY AUTHORITY: 32 M.R.S.A. §§ 18324, 18379

EFFECTIVE DATE:

June 7, 1995

EFFECTIVE DATE (ELECTRONIC CONVERSION):

October 14, 1996

AMENDED:

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REPEALED AND REPLACED:

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