BOARDS AND COMMISSIONS
Board of Dentistry
(Amended After Comments)

201 KAR 8:550. Anesthesia and sedation related to dentistry.

RELATES TO: KRS 313.035
STATUTORY AUTHORITY: KRS 313.035(1)
NECESSITY, FUNCTION, AND CONFORMITY: KRS 313.035(1) requires the board to promulgate administrative regulations related to anesthesia and sedation permits. The administration of local anesthesia, sedation, and general anesthesia is an integral part of dentistry and the foundation of pain control. This administrative regulation establishes requirements for permits to perform sedation or anesthesia associated with dentistry.

Section 1. Definitions.
(1) "Analgesia" means the diminution or elimination of pain.
(2) "ADA" means American Dental Association.
(3) "ASA" means American Society of Anesthesiologists.
(4) "Continual" means repeated regularly and frequently in steady succession.
(5) "Continuous" means prolonged without any interruption.
(6) "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 could be impaired. The patient might require assistance in maintaining a patent airway, and spontaneous ventilation could be inadequate. Cardiovascular function is usually maintained.
(7) "Enteral" means a technique of administration in which the agent is absorbed through the gastrointestinal (GI) tract or oral mucosa (oral, rectal, or sublingual).
(8) "General anesthesia" means a drug-induced loss of consciousness during which a patient is 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 could be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function might be impaired.
(9) "Immediately available" means onsite at the facility and available for immediate use.
(10) "Local anesthesia" means the elimination or diminution of sensation, especially pain, in one (1) part of the body by the topical application or regional injection of a drug.
(11) "Maximum Recommended Dose" or "MRD" means the maximum FDA-recommended dose of a drug for minimal sedation, as printed in FDA-approved labeling for unmonitored home use.
(12) "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 might be modestly impaired, ventilatory and cardiovascular functions are unaffected.
(13) "Moderate sedation" means a drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. Intervention is not required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained. This term includes the enteral administration of drugs exceeding the maximum recommended dose during a single appointment.
(14) "Nitrous oxide sedation" or "N2O sedation" means a technique of inhalation sedation with nitrous oxide and oxygen.

(15) "Operating dentist" means a licensed dentist with primary responsibility for providing dental care during a procedure.

(16) "Pediatric patient" means a patient twelve (12) years of age or younger.

(17) "Qualified anesthesia provider" means a licensed anesthesiologist, Certified Registered Nurse Anesthetist, or dentist with an applicable sedation permit.

(18) "Qualified dentist" means a licensed dentist with an applicable sedation permit. A qualified dentist can also be an operating dentist if they fulfill the requirement of subsection (15) of this section.

(19) "Time-oriented anesthesia record" means documentation at appropriate time intervals of drugs administered, doses of drugs administered, and physiologic patient data obtained during patient monitoring.

(20) "Trained individual" means personnel with an active certification in Basic Life Support for Healthcare Providers, who has been trained in monitoring EKG's, pulse oximetry, blood pressures, airway management, and capnography. Training, whether formal or internal, is documented in employee records.

Section 2. Scope and Applicability.

(1) The board shall be committed to the safe and effective use of sedation and anesthesia by licensed, educated, and trained dentists.

(2) Because large doses of local anesthetics, especially in combination with sedative agents, carry the risk of central nervous system depression, each licensed dentist shall be aware of the maximum, safe dosage limits for each patient.

(3) Level of sedation shall be independent of the route of administration. Moderate or deep sedation, or general anesthesia, may be achieved via any route of administration.

(4) Because sedation and general anesthesia are a continuum and it is not always possible to predict how an individual patient will respond, each licensed dentist intending to produce a given level of sedation shall be able to diagnose and manage the physiologic consequences for patients whose level of sedation becomes deeper than initially intended. For all levels of sedation, the qualified dentist shall have the training, skills, drugs, and equipment to identify and manage such an occurrence until either:

(a) Assistance arrives; or

(b) The patient returns to the intended level of sedation without airway or cardiovascular complications.

(5) Because new indications, agents, and techniques lead to changes in anesthesia and sedation practices, the board shall evaluate changes for safety, efficacy, and to what extent changes become accepted practice within the profession of dentistry.

Section 3. Nitrous Oxide Sedation.

(1) Nitrous oxide sedation may be used by a Kentucky-licensed dentist without a sedation permit or by a Kentucky-licensed dental hygienist who is registered to deliver nitrous oxide analgesia under the direct supervision of a dentist as per KRS 313.060(10).

(2) Equipment used in the administration of nitrous oxide sedation shall have functional safeguard measures that:

(a) Limit the minimum oxygen concentration to thirty (30) percent; and

(b) Provide for scavenger elimination of nitrous oxide gas.

(3) The dentist shall:

(a) Ensure that a patient receiving nitrous oxide is constantly monitored; and

(b) Be present in the office while nitrous oxide is being used.

(4) A Kentucky-registered dental assistant shall not independently administer nitrous oxide sedation, but may initiate nitrous oxide sedation if the dentist is in the office and gives the dental assistant specific instructions regarding the mode of administration and the titration, rate, and dosage of the anesthetic agent.

Section 4. Minimal Sedation.

(1) A sedation permit shall not be required for a Kentucky-licensed dentist to provide minimal sedation as defined by Section 1(12) of this administrative regulation.

(2) A patient whose only response is reflex withdrawal from repeated painful stimuli shall not be considered to be in a state of minimal sedation.

(3) The enteral administration of drugs exceeding the maximum recommended dose during a single appointment is considered to be moderate sedation, and Section 5 of this administrative regulation shall apply.

(4) Nitrous oxide, if used in combination with a sedative agent, may be considered to produce minimal, moderate, or deep sedation, or general anesthesia.

(5) If more than one (1) drug is administered enterally to achieve the desired sedation effect, with or without the concomitant use of nitrous oxide, Section 5 of this administrative regulation shall apply.

(6) A dentist who administers minimal sedation shall do so within a sufficient margin of safety to avoid an unintended loss of consciousness. The use of the MRD to guide dosing for minimal sedation is intended to create this margin of safety.

(7) If minimal sedation is administered to a patient who is taking another substance known to increase the sedative effects on the patient, Section 5 of this administrative regulation shall apply.

(8) An operating dentist shall not be required to complete additional training to administer minimal sedation.

(9) The administration of minimal sedation by another dentist or qualified anesthesia provider shall require the operating dentist to maintain current certification in Basic Life Support for Healthcare Providers.

(10) Clinical guidelines.

(a) Patient history and evaluation. Patients considered for minimal sedation shall be evaluated prior to the start of any sedative procedure. In healthy or medically stable individuals (ASA I, II), this evaluation shall consist of a review of the patient's current medical history and medication use. In addition, patients with significant medical considerations (ASA III, IV) shall, unless otherwise documented by the provider, require consideration of a consultation with their treating physician prior to being administered minimal sedation.

(b) Pre-operative evaluation and preparation.

1. The patient or the patient's parent, legal guardian, or caregiver, shall be advised regarding the planned procedure and any other anticipated possible procedures associated with the delivery of any sedative agents. Informed consent for the proposed sedation shall be obtained prior to its administration.

2. Adequate oxygen supply and the equipment necessary to deliver oxygen under positive pressure shall be determined prior to the administration of minimal sedation.

3. The patient shall be physically examined prior to the administration of minimal sedation. Baseline vital signs including body weight, height, blood pressure, and pulse rate shall be obtained unless rendered impractical by the nature of the patient, procedure, or equipment. Body temperature shall be measured if clinically indicated.

4. Preoperative dietary restrictions shall be considered based on the sedative technique prescribed.

5. The patient or the patient's parent, legal guardian, or caregiver, shall be given preoperative verbal and written instructions regarding the patient's sedation and procedure.

(c) Personnel and equipment requirements.

1. Personnel. All clinical staff participating in the care of a minimally sedated patient shall be certified in Basic Life Support for Healthcare Providers.

2. Equipment.

a. A positive-pressure oxygen delivery system suitable for the patient being treated shall be immediately available.

b. All equipment shall be examined for proper performance prior to each administration of sedation.

c. If inhalation equipment is used, it shall have a fail-safe system that shall be examined and calibrated and a functioning device that shall prohibit the delivery of less than thirty (30) percent oxygen, or a calibrated and functioning in-line oxygen analyzer with audible alarm.

d. A scavenging system shall be used if gases other than oxygen or air are delivered to a patient.

3. Monitoring and documentation.

a. Monitoring. The dentist or a trained individual chosen by the dentist, shall remain in the treatment room during active dental treatment to monitor the patient continuously until the patient meets the criteria for discharge to the recovery area. The following shall be monitored unless precluded or invalidated by the nature of the patient:

(i) Consciousness. The patient's level of sedation and responsiveness to verbal commands shall be continually assessed;

(ii) Oxygenation. Oxygen saturation by pulse oximetry shall be continually evaluated;

(iii) Ventilation. The patient's chest excursions shall be monitored and respirations shall be verified; and

(iv) Circulation. Blood pressure and heart rate shall be evaluated pre-operatively and postoperatively

b. Documentation. A sedative record shall be maintained for each patient to whom sedation is administered. The sedative record shall include the names of all drugs administered including local anesthetics, the time administered, the route of administration, dosages, and monitored physiological parameters.

4. Recovery and discharge.

a. Oxygen and suction equipment shall be immediately available if a separate recovery area is utilized.

b. The dentist or a trained individual chosen by the dentist shall monitor the patient during recovery until the patient is ready for discharge.

c. The dentist shall examine the patient and document the patient's level of consciousness, oxygenation, ventilation, and circulation prior to discharge.

d. The patient, parent, escort, legal guardian, or caregiver shall be given post-operative verbal and written instructions prior to or upon discharge.

(d) Emergency management.

1. If a patient enters a deeper level of sedation than the dentist is qualified to provide, the dentist shall stop the dental procedure until the patient is returned to the intended level of sedation.

2. The operating dentist shall be responsible for the sedative management, adequacy of the facility and staff, equipment, protocols, and diagnosis and treatment of emergencies related to the administration of minimal sedation and patient rescue.

Section 5. Moderate Sedation.

(1) A Moderate Sedation Permit issued by the board shall be required for a Kentucky-licensed dentist to administer moderate sedation as defined by Section 1(13) of this administrative regulation.

(2) A dentist who administers moderate sedation shall do so within a sufficient margin of safety to avoid an unintended loss of consciousness.

(3) A qualified dentist shall be aware that repeated dosing of an agent before the effects of previous dosing can be fully appreciated could result in a greater alteration of the state of consciousness than intended. A dentist who administers moderate sedation shall refrain from administering an additional drug increment before the previous dose has taken full effect.

(4) A patient whose only response is reflex withdrawal from a painful stimulus shall not be considered to be in a state of moderate sedation.

(5) To qualify for a Moderate Sedation Permit, a dentist shall:

(a) Submit an Application for Sedation or Anesthesia Permit;

(b) Pay the fee required by 201 KAR 8:520; and

(c) Provide documentation that the dentist meets the educational requirements of paragraphs~~[subsection]~~ (6)(a) and (b)~~[or (7)]~~of this section.

(6) Education requirements for moderate sedation.

(a) To administer moderate sedation to an adult patient, a dentist shall have current certifications in Basic Life Support for Healthcare Providers and Advanced Cardiac Life Support, and complete:

1. A comprehensive training program in moderate sedation that complies with the requirements established 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

2. An advanced education program accredited by the Commission on Dental Accreditation that provides comprehensive training necessary to administer and manage moderate sedation commensurate with this administrative regulation.

(b) To administer moderate sedation to a pediatric patient, a dentist shall have successfully completed:

1. An advanced education program accredited by the Commission on Dental Accreditation that provides comprehensive training necessary to administer and manage moderate sedation commensurate with this administrative regulation; and

2. Current certifications in Basic Life Support for Healthcare Providers and Pediatric Advanced Life Support.

(c) **If** ~~**[To]**~~ **authorizing** ~~**[authorize]**~~ a **third-party** qualified anesthesia provider to administer moderate sedation to an adult patient, the operating dentist shall **confirm that at least two (2) members of the onsite care team** maintain current certifications in Basic Life Support for Healthcare Providers and Advanced Cardiac Life Support. ~~[The operating dentist or the facility at which the moderate sedation is being administered shall maintain a current certification in Basic Life Support for Healthcare Providers in order for a qualified anesthesia provider to provide moderate sedation.]~~

(d) **If** ~~**[To]**~~ **authorizing** ~~**[authorize]**~~ a **third-party** qualified anesthesia provider to administer moderate sedation to a pediatric patient, the operating dentist shall **confirm that at least two (2) members of the onsite care team** maintain current certifications in Basic Life Support for Healthcare Providers and Pediatric Advanced Life Support.

(e) Any valid moderate sedation permits issued prior to this administrative regulation shall~~[remain active until their expiration date and shall comply with the requirements of this section, except that moderate adult enteral and parenteral permit holders shall]~~ have until December 31, 2023 to comply with subsection (6)(a)1. and 2. of this section.

(7) Clinical guidelines; patient history and evaluation.

(a) Patients considered for moderate sedation shall be evaluated prior to the start of any sedative procedure. In healthy or medically stable individuals (ASA I, II), this evaluation shall consist of a review of the patient's current medical history, medication use, body mass index, airway evaluation, and ASA status.

(b) Patients with significant medical considerations (ASA III, IV) shall, unless otherwise documented by the provider, require consideration of a consultation with

their treating physician prior to being administered moderate sedation.

(8) Pre-operative evaluation and preparation.

(a) The patient or the patient's parent, legal guardian, or caregiver, shall be advised regarding the planned procedure and any other anticipated possible procedures associated with the delivery of any sedative agents. Informed consent for the proposed sedation shall be obtained prior to its administration.

(b) Adequate oxygen supply and the equipment necessary to deliver oxygen under positive pressure shall be determined prior to the administration of moderate sedation.

(c) The patient shall be physically examined prior to the administration of minimal sedation. Baseline vital signs including body weight, height, blood pressure, and pulse rate shall be obtained unless rendered impractical by the nature of the patient, procedure, or equipment. Body temperature shall be measured if clinically indicated.

(d) Preoperative dietary restrictions shall be considered based on the sedative technique prescribed.

(e) The patient or the patient's parent, legal guardian, or caregiver, shall be given preoperative verbal and written instructions regarding the patient's sedation and procedure, including pre-operative fasting instructions based on the ADA Guidelines for the Use of Sedation and General Anesthesia by Dentist, adopted October 2016.

(9) Personnel and equipment requirements.

(a) Personnel. All clinical staff participating in the care of a moderately sedated patient shall be certified in Basic Life Support for Healthcare Providers.

(b) Equipment.

1. A positive-pressure oxygen delivery system suitable for the patient being treated shall be immediately available.

2. All equipment shall be examined for proper performance prior to each administration of sedation.

3. If inhalation equipment is used, it shall have a fail-safe system that shall be examined and calibrated and a functioning device that shall prohibit the delivery of less than thirty (30) percent oxygen, or a calibrated and functioning in-line oxygen analyzer with audible alarm.

4. A scavenging system shall be used if gases other than oxygen or air are delivered to a patient.

5. Equipment necessary to establish intravascular or intraosseous access and a defibrillator or automated external defibrillator shall be immediately available until the patient meets discharge criteria.

(10) Monitoring and documentation.

(a) Monitoring.

1. If leaving the room, a qualified dentist shall have at least one (1) month of general anesthesia training and shall select a trained individual to continuously monitor the patient; or

2. A qualified anesthesia provider shall remain in the treatment room during active treatment until the patient meets the criteria for discharge to the recovery area.

(b) The following shall be monitored:

1. Consciousness. The patient's level of sedation and responsiveness to verbal commands shall be continually assessed;

2. Oxygenation. Oxygen saturation by pulse oximetry shall be continually evaluated;

3. Ventilation: The qualified anesthesia provider shall be responsible for the observation of ventilation and breathing by monitoring end tidal CO2 unless precluded or invalidated by the nature of the patient. In addition, ventilation shall be monitored by continual observation of qualitative signs, which may include auscultation of breath sounds with a precordial or pretracheal stethoscope, or observation of chest excursions;

4. Circulation. The qualified anesthesia provider shall continually evaluate blood pressure and heart rate unless invalidated by the nature of the patient and noted in the time-oriented anesthesia record; and

5. The patient's pulse oximetry, heart rate, end tidal CO2, blood pressure, and level of consciousness shall be monitored continually and recorded at least every five (5) minutes.

(c) Documentation. A sedative record shall be maintained for each patient to whom sedation is administered. The sedation record shall include the names of all drugs administered including local anesthetics, the time administered, the route of administration, dosages, and monitored physiological parameters.

(11) Recovery and discharge.

(a) Oxygen and suction equipment shall be immediately available if a separate recovery area is utilized.

(b) When active treatment concludes and the patient recovers to a minimally sedated level, the qualified anesthesia provider or a trained individual chosen by the qualified anesthesia provider shall remain with and continue to monitor the patient until the patient is discharged from the facility. The qualified anesthesia provider shall not leave the facility until the patient is discharged.

(c) The qualified anesthesia provider or a trained individual chosen by the qualified anesthesia provider shall continually monitor the patient's blood pressure, heart rate, oxygenation, and level of consciousness during recovery.

(d) The qualified anesthesia provider shall determine and document the patient's level of consciousness, oxygenation, ventilation, and circulation prior to discharge.

(e) The patient, parent, escort, legal guardian, or caregiver shall be given post-operative verbal and written instructions prior to or upon discharge.

(f) Because re-sedation could occur after the effects of a reversal agent have waned, if a pharmacological reversal agent is administered before the patient's discharge criteria have been met, the patient's escort shall be notified of the risk of re-sedation.

(12) Emergency management.

(a) If a patient enters a deeper level of sedation than the qualified anesthesia provider is qualified to provide, the procedure shall stop until the patient is returned to the intended level of sedation.

(b) The qualified anesthesia provider shall be responsible for the sedative management, adequacy of the facility and staff, equipment, protocols, and diagnosis and treatment of emergencies related to the administration of moderate sedation and patient rescue.

Section 6. Deep Sedation and General Anesthesia.

(1) A Deep Sedation and General Anesthesia Permit issued by the board shall be required for a Kentucky-licensed dentist to administer "deep sedation" and "general anesthesia" as defined by Section 1(6) and (8) of this administrative regulation.

(2) To qualify for a deep sedation and general anesthesia permit, a dentist shall:

(a) Submit an Application for Sedation or Anesthesia Permit;

(b) Pay the fee required by 201 KAR 8:520; and

(c) Provide documentation that the dentist meets the educational requirements of paragraph~~[subsection]~~ (3)(a) of this section.

(3) Education requirements.

(a) To administer deep sedation or general anesthesia, a dentist shall have successfully completed:

1. An advanced education program accredited by the Commission on Dental Accreditation, which provides comprehensive training necessary to administer and manage deep sedation or general anesthesia; and

2. Current certifications in:

a. Basic Life Support for Healthcare Providers;

b. Advanced Cardiac Life Support if administering sedation to adult patients; and

c. Pediatric Advanced Life Support if administering sedation to pediatric patients.

(b) **If ~~[To]~~ authorizing ~~[authorize]~~** a **third-party** qualified anesthesia provider to administer deep sedation or general anesthesia, the operating dentist shall **confirm that at least two (2) members of the onsite care team** maintain current certifications in:

1. Basic Life Support for Healthcare Providers;

2. Advanced Cardiac Life Support if sedation is administered to adult patients; and

3. Pediatric Advanced Life Support if sedation is administered to pediatric patients.

~~[The operating dentist or the facility at which deep sedation or general anesthesia is being administered shall maintain a current certification in Basic Life Support for Healthcare Providers in order for a qualified anesthesia provider to provide deep sedation or general anesthesia.]~~

(4) Clinical guidelines; for patient history and evaluation. Each patient considered for deep sedation or general anesthesia shall be suitably evaluated prior to the start of any sedative procedure. In healthy or medically stable individuals (ASA I, II), this evaluation shall consist of a review of the patient's current medical history, medication use, body mass index, airway evaluation, nothing by mouth status, and ASA status. In addition, patients with significant medical considerations (ASA III, IV) shall, unless otherwise documented by the provider, require consideration of a consultation with their treating physician prior to being administered deep sedation or general anesthesia.

(5) Pre-operative evaluation and preparation.

(a) The patient or the patient's parent, legal guardian, or caregiver, shall be advised regarding the planned procedure and any other anticipated possible procedures associated with the delivery of any sedative agents. Informed consent for the proposed sedation shall be obtained prior to its administration.

(b) Adequate oxygen supply and the equipment necessary to deliver oxygen under positive pressure shall be confirmed prior to the administration of deep sedation or general anesthesia.

(c) The patient shall be physically examined prior to the administration of deep sedation or general anesthesia. Baseline vital signs including body weight, height, blood pressure, blood oxygen saturation, and pulse rate shall be obtained unless rendered impractical by the nature of the patient, procedure, or equipment. Body temperature shall be measured if clinically indicated.

(d) The patient or the patient's parent, legal guardian, or caregiver, shall be given preoperative verbal and written instructions regarding the patient's sedation and procedure, including pre-operative fasting instructions based on the ASA Summary of Fasting and Pharmacologic Recommendations.

(e) An intravenous line shall be established and secured throughout the procedure, except for patients with special needs as per subsection (9) of this section.

(6) Personnel and equipment requirements.

(a) Personnel. All clinical staff participating in the care of a deeply sedated patient or a patient who has been administered general anesthesia shall be certified in Basic Life Support for Healthcare Providers.

(b) A minimum of three (3) individuals shall be present while a patient is being treated with deep sedation or general anesthesia. If a pediatric patient is being treated with deep sedation or general anesthesia, in addition to the operating dentist, a separate qualified anesthesia provider shall manage the patient's anesthesia unless the anesthesia is performed by an oral and maxillofacial surgeon.

(c) Equipment.

1. A positive-pressure oxygen delivery system suitable for the patient being treated shall be immediately available.

2. All equipment shall be examined for proper performance prior to each administration of sedation.

3. If inhalation equipment is used, it shall have a fail-safe system that shall be examined and calibrated and a functioning device that shall prohibit the delivery of less than thirty (30) percent oxygen, or a calibrated and functioning in-line oxygen analyzer with audible alarm.

4. A scavenging system shall be used if gases other than oxygen or air are delivered to a patient.

5. Equipment necessary to establish intravenous access and to monitor end tidal CO2 and auscultation of breath sounds shall be immediately available.

6. Resuscitation medications, a defibrillator, equipment and drugs necessary to provide advanced airway management and advanced cardiac life support shall be immediately available.

(7) Monitoring and documentation.

(a) Monitoring.

1. If leaving the room, a qualified dentist shall have at least one (1) month of general anesthesia training and shall select a trained individual to continuously monitor the patient; or

2. A qualified anesthesia provider shall remain in the treatment room during active treatment until the patient meets the criteria for discharge to the recovery area. The following shall be monitored:

3. Oxygenation. Oxygen saturation by pulse oximetry shall be continually evaluated;

4. Ventilation. For an intubated patient, end-tidal CO2 shall be continually monitored and evaluated. For a non-intubated patient, end-tidal CO2 shall be continually monitored and evaluated unless precluded or invalidated by the nature of the patient. In addition, ventilation shall be monitored by continual observation of qualitative signs, which may include auscultation of breath sounds with a precordial or pretracheal stethoscope, or observation of chest excursions;

5. Circulation. The qualified anesthesia provider shall continually evaluate heart rate and rhythm by ECG throughout the procedure, as well as the patient's pulse rate by pulse oximetry;

6. Temperature. A device capable of measuring body temperature shall be readily available during the administration of deep sedation or general anesthesia. Equipment necessary to continually monitor body temperature shall be available and used if triggering agents associated with malignant hyperthermia are administered; and

7. The patient's pulse oximetry, heart rate, end tidal CO2, blood pressure, and level of consciousness shall be monitored continually and recorded at least every five (5) minutes.

(b) Documentation. A sedative record shall be maintained for each patient to whom sedation is administered. The sedative record shall include the names of all drugs administered, including local anesthetics, the time administered, the route of administration, dosages, and monitored physiological parameters.

(8) Recovery and discharge.

(a) Oxygen and suction equipment shall be immediately available if a separate recovery area is utilized.

(b) When active treatment concludes and the patient recovers to a minimally sedated level, the qualified anesthesia provider or a trained individual chosen by the qualified anesthesia provider shall remain with and continue to monitor the patient until the patient is discharged from the facility. The qualified anesthesia provider shall not leave the facility until the patient is discharged.

(c) The qualified anesthesia provider or a trained individual chosen by the qualified anesthesia provider shall continually monitor the patient's blood pressure, heart rate, oxygenation, and level of consciousness during recovery.

(d) The qualified anesthesia provider shall determine and document the patient's level of consciousness, oxygenation, ventilation, and circulation prior to discharge.

(e) The patient, parent, escort, legal guardian, or caregiver shall be given post-operative verbal and written instructions prior to or upon discharge.

(9) Patients with special needs.

(a) Because many dental patients undergoing deep sedation or general anesthesia are mentally or physically challenged, it is not always possible to administer a comprehensive physical examination or appropriate laboratory tests prior to sedation. In this circumstance, the dentist responsible for administering the deep sedation or general anesthesia shall document the reasons preventing the examination of the patient in the patient's medical record.

(b) Deep sedation or general anesthesia may be administered without first establishing an indwelling intravenous line if the establishment of intravenous access after deep sedation or general anesthesia is rendered necessary because of poor patient cooperation.

(10) Emergency management. The qualified anesthesia provider shall be responsible for the sedative management, adequacy of the facility and staff, equipment, protocols, and diagnosis and treatment of emergencies related to the administration of patient rescue and deep sedation or general anesthesia.

Section 7. Multiple Application Levels. A dentist with the required education and training to provide more than one (1) level of sedation may mark **all**~~**[the]**~~ levels of qualification on the Application for Sedation or Anesthesia Permit **without paying additional application fees**.

Section 8. Renewal of a Sedation or Anesthesia Permit.

(1) A qualified dentist applying for renewal of an active permit to administer moderate sedation, or deep sedation or general anesthesia shall:

(a) Submit an Application for Renewal of Sedation or Anesthesia Permit;

(b) Pay the fee required by 201 KAR 8:520;

(c) Complete at least four (4) hours of clinical continuing education related to sedation or anesthesia in a classroom setting during the two (2) year term of the permit; and

(d) Maintain Advanced Cardiac Life Support~~[ACLS]~~ or Pediatric Advanced Life Support~~[PALS]~~ certification as required by Sections 5 and 6 of this administrative regulation.

(2) The continuing education requirements of this section shall be in addition to the license renewal requirements of 201 KAR 8:532.

(3) Unless properly renewed, each permit issued under this administrative regulation shall expire on December 31 of odd-number years.

Section 9. Location Requirement. A dentist holding a permit in accordance with this administrative regulation shall advise the board of the name and address of each facility where the dentist intends to or has ceased to administer anesthesia and sedation by submitting the Sedation or Anesthesia Permit Location Notification Form within ten (10) business days of the change.

Section 10. Facility Certificates.

(1) The owner or operator of a facility shall obtain an Anesthesia or Sedation Facility Certificate from the board for any location at which a dentist holding a sedation or general anesthesia permit provides moderate sedation, deep sedation, or general

anesthesia. A facility certificate shall not be required for minimal sedation or nitrous oxide sedation alone.

(2) A facility certificate shall also be required if a dentist allows an independently practicing qualified anesthesia provider to administer sedation or general anesthesia in a dental office.

(3) A facility owner or operator desiring to obtain an Anesthesia or Sedation Facility Certificate shall:

(a) Submit an Application for Sedation or Anesthesia Facility Certificate;**and**~~[and]~~

(b) Pay the fee required by 201 KAR 8:520**.**~~[; and]~~

~~[(c)]~~ ~~[Hold an active sedation permit issued by the board]~~ ~~[.]~~

(4) The owner or operator of a facility shall not allow an individual to administer anesthesia or sedation unless the individual is permitted to do so as established by this administrative regulation.

(5) The owner or operator of a facility shall maintain for at least seven (7) years, for inspection by the board, the name and license number of each dentist or independently practicing qualified anesthesia provider who has administered anesthesia or moderate sedation at that location.

(6) The owner or operator of a facility shall ensure that the facility remains equipped and staffed for the duration of time that moderate sedation, deep sedation, or general anesthesia is provided at the facility.

(7) The owner or operator of a facility shall ensure that the facility has nonexpired emergency and sedation medications.

Section 11. Renewal of Facility Certificate.

(1) All active facility certificates shall expire on December 31 of odd-numbered years.

(2) ~~[Any valid facility certificates issued prior to this administrative regulation shall remain active until their original expiration date, at which time the requirements of this regulation shall have to be met prior to renewal.]~~

~~[(3)]~~ To renew a facility certificate, the owner or operator shall:

(a) Submit an Application for Renewal of Sedation or Anesthesia Facility Certificate; **and**~~[and]~~

(b) Pay the fee required by 201 KAR 8:520~~[; and]~~

~~[(c)]~~ ~~[Maintain an active sedation permit issued by the board]~~.

Section 12. Facility Criteria.

(1) To qualify for a facility certificate, the owner or operator of a facility shall attest in the Application for Sedation or Anesthesia Facility Certificate that the facility has:

(a) An oxygen and gas delivery system with fail-safe backup;

(b) A safety indexed gas system;

(c) A suction and backup system;

(d) An auxiliary lighting system;

(e) An operating room to include:

1. At a minimum, ten (10) feet by eight (8) feet or eighty (80) square feet in size;
2. An operating primary light source and secondary portable back-up source, unless a backup generator is available; and
3. Accessibility by emergency medical staff;

(f) A recovery area, including oxygen, suction, and electronic monitoring, which may be a part of the operating room;

(g) Preoperative medical history and physical evaluation form; and

(h) Anesthesia and monitoring equipment checked to ensure working order and calibration, if applicable.

(2) The following shall be maintained in working order by the facility or by the qualified individual administering sedation or anesthesia at or on behalf of the facility:

(a) Drugs for each procedure, all of which shall be unexpired, including reversal agents and emergency medications;
(b) Devices to maintain an airway with positive pressure ventilation;
(c) Anesthesia records, including monitoring and discharge records;
(d) Monitoring equipment, including pulse oximeter, blood pressure monitor, and end tidal CO2 monitor. An electrocardiogram (EKG) shall be required for facilities providing deep sedation or general anesthesia;
(e) Defibrillator or automated external defibrillator (AED); and
(f) Precordial stethoscope or pretracheal stethoscope for deep sedation or general anesthesia in pediatric patients.

Section 13. Morbidity and Mortality Incident Reports.
(1) A dentist shall report to the board, in writing, any death caused by or resulting from the ~~[dentist's]~~administration of minimal sedation, moderate sedation, deep sedation, or general anesthesia within seven (7) days after the death.
(2) A dentist shall report to the board, in writing, any incident that occurred at a facility operating under a Sedation or Anesthesia Facility permit that resulted in hospital inpatient admission or emergency room visit caused by or resulting from the ~~[dentist's]~~administration of minimal sedation, moderate sedation, deep sedation, or general anesthesia within thirty (30) days after the hospitalization or emergency room visit.
(3) The written report to the board required in subsections (1) and (2) of this section shall include:
(a) The date of the incident;
(b) The name, age, and address of the patient;
(c) The patient's original complete dental records;
(d) The name and permit number of the dentist and the name and address of all other persons present during the incident;
(e) The address where the incident took place;
(f) The preoperative physical condition of the patient;
(g) The type of anesthesia and dosages of drugs administered to the patient;
(h) The techniques used in administering the drugs;
(i) Any adverse occurrence including:
1. The patient's signs and symptoms;
2. The treatment instituted in response to adverse occurrences;
3. The patient's response to the treatment; and
4. The patient's condition on termination of any procedures undertaken; and
(j) A narrative description of the incident including approximate times and evolution of symptoms.
(4) The duties established in this section shall apply to every dentist who administers any type of sedation or anesthesia.

Section 14. Registered Dental Assistant Duties while Working with Sedation Permit Holders. A registered dental assistant working with a qualified dentist administering sedation or anesthesia in accordance with this administrative regulation may, under direct supervision:
(1) Apply noninvasive monitors on the patient;
(2) Perform continuous observation of patients and noninvasive monitors appropriate to the level of sedation, during the pre-operative, intra-operative, and post-operative (recovery) phases of treatment;
(3) Report monitoring parameters at pre-determined intervals, and if changes in monitored parameters occur;
(4) Record vital sign measurements in the sedation record;

(5) Establish and remove intravenous lines if the registered dental assistant has completed training in intravenous access;
(6) Assist in the management of a patient emergency; and
(7) Administer medications into an existing intravenous line upon the verbal order and direct supervision of a qualified dentist in accordance with this administrative regulation.

Section 15. Administration by Qualified Anesthesia Provider.
(1) An operating dentist may authorize the administration of sedation or anesthesia by a qualified anesthesia provider.
(2) The administration of anesthesia or sedation by an individual established in subsection (1) of this section shall:
(a) Comply with the requirements of this administrative regulation; and
(b) Not require board review prior to the administration of sedation or anesthesia.
(3) Nothing in this section shall preclude a dentist from working with a qualified anesthesia provider to provide care in an ambulatory care center or hospital.

Section 16. Incorporation by Reference.
(1) The following material is incorporated by reference:
(a) "Application for Sedation or Anesthesia Permit", March 2020;
(b) "Application for Sedation or Anesthesia Facility Certificate", March 2020; and
(c) "Sedation or Anesthesia Permit Location Notification Form", March 2020.
(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Kentucky Board of Dentistry, 312 Whittington Parkway, Suite 101, Louisville, Kentucky 40222, Monday through Friday 8 a.m. through 4:30 p.m. This material is also available on the board's Web site at http://dentistry.ky.gov.

JEFF ALLEN, Executive Director

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REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact Person:Jeff Allen

(1) Provide a brief summary of:

(a) What this administrative regulation does:
This regulation establishes requirements for dentist to receive permits to perform sedation or anesthesia.

(b) The necessity of this administrative regulation:
KRS 313.035(1) requires the board to promulgate administrative regulations related to anesthesia and sedation permits

(c) How this administrative regulation conforms to the content of the authorizing statutes:
This administrative regulation establishes requirements for permits to perform sedation or anesthesia.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes:
This administrative regulation establishes requirements for permits to perform sedation or anesthesia in conformity with its authorizing statute.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation:
This amendment includes minor clarifications of the existing requirements for dental sedation and anesthesia.

(b) The necessity of the amendment to this administrative regulation:
This amendment is necessary in order to clarify some reporting and training requirements in the existing regulation.

(c) How the amendment conforms to the content of the authorizing statutes:
The amendment updates the requirements for permits to perform sedation or anesthesia in conformity with its authorizing statute.

(d) How the amendment will assist in the effective administration of the statutes:
The amendment clarifies the requirements to perform sedation and anesthesia, thereby reducing non-compliance and improving public safety.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation:
This regulation will primarily affect the approximately 400 dentists with a moderate or deep sedation permit in Kentucky. (4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it an amendment, including:

(4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment:
Each entity will be required to administer sedation or anesthesia in accordance with applicable law and administrative regulations.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3):

No additional costs are likely to be accrued as a result of the amendment.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3):

The amendment will result in a healthier patient population and the avoidance of potentially costly violations of applicable law and administrative regulations.

(5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:

(a) Initially:

No additional cost.

(b) On a continuing basis:

No additional cost.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation:

? Licensure fees.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment:

No increase in fees or funding is needed

(8) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees:

This amendment does not establish any new fees.

(9) TIERING: Is tiering applied?

No; this amendment impacts all similarly situated practitioners equally.

FISCAL NOTE

(1) What units, parts, or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation?

None, other than the Board of Dentistry itself.

(2) Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation.

KRS 313.035

(3) Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year?

This amendment will not generate any new revenue for state or local government.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years?

This amendment will not generate any new revenue for state or local government.

(c) How much will it cost to administer this program for the first year?

This amendment will not require additional costs to administer.

(d) How much will it cost to administer this program for subsequent years?

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-):None

Expenditures (+/-):None

Other Explanation:

This amendment will not generate or require additional funding.

(4) Estimate the effect of this administrative regulation on the expenditures and cost savings of regulated entities for the first full year the administrative regulation is to be in effect.

(a) How much cost savings will this administrative regulation generate for the regulated entities for the first year?

None

(b) How much cost savings will this administrative regulation generate for the regulated entities for subsequent years?

None

(c) How much will it cost the regulated entities for the first year?

None

(d) How much will it cost the regulated entities for subsequent years?

None

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Cost Savings (+/-):None

Expenditures (+/-):None

Other Explanation:

This amendment will not generate additional costs.

(5) Explain whether this administrative regulation will have a major economic impact, as defined below.

"Major economic impact" means an overall negative or adverse economic impact from an administrative regulation of five hundred thousand dollars ($500,000) or more on state or local government or regulated entities, in aggregate, as determined by the promulgating administrative bodies. [KRS 13A.010(13)] This amendment will not have a major economic impact.