GENERAL GOVERNMENT CABINET
Kentucky Board of Dentistry
(Amendment)

201 KAR 8:550. Anesthesia and sedation.

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 [conscious] anesthesia and sedation permits. This administrative regulation establishes requirements for permits to perform [conscious] sedation or anesthesia.

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) "Competency" means displaying special skill or knowledge derived from training and experience.
(5) "Continual" means repeated regularly and frequently in steady succession.
(6) "Continuous" means prolonged without any interruption.
(7) "Advanced Cardiac Life Support" or "ACLS" means a certification that an individual has successfully completed an advanced cardiac life support course that meets or exceeds the standards established by the American Heart Association and incorporated by reference in 201 KAR 8:532.
(8) "Anesthesia" means an artificially induced insensibility to pain usually achieved by the administration of gases or drugs.
(9) "Anesthesia and sedation" means:
(a) Minimal sedation;
(b) Moderate sedation;
(c) Deep sedation; and
(d) General anesthesia.
(10) "Board" means the Kentucky Board of Dentistry.
(11) "Certified registered nurse anesthetist" means a registered nurse who is currently certified to practice nurse anesthesia in Kentucky.
(12) "Conscious sedation permit" means a permit that was issued by the board prior to February 1, 2011, that authorized the dentist to whom the permit was issued to administer parenteral sedation for the practice of dentistry.
(13) "Deep sedation" means a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. The patient may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.
(14) "Enteral" means a technique of administration in which the agent is absorbed through the gastrointestinal (GI) tract or oral mucosa (oral, rectal, or sublingual).
(15) "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 may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be...
impaired.

(10) "Immediately available" means onsite at the facility and available for immediate use.

(11) "Independently practicing qualified anesthesia provider" means an individual with a valid Kentucky license or permit to provide sedation.

(12) "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.

(13) "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.

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

(15) "Facility" means a location in which anesthesia or sedation is administered for the practice of dentistry.

(10) "Facility inspection" means an on-site inspection by the board or its designee to determine if a facility where the applicant proposes to provide anesthesia and sedation is adequately supplied, equipped, staffed, and maintained in a condition to support the provision of anesthesia and sedation services in a manner that meets the requirements of this administrative regulation.

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

(12) "General anesthesia permit" means a permit that was issued by the board prior to February 1, 2011, that authorized the dentist to whom the permit was issued to administer general anesthesia for the practice of dentistry.

(13) "Incident" means dental treatment performed on a patient under minimal sedation, moderate sedation, deep sedation, or general anesthesia with unforeseen complications.

(14) "Incremental dosing" means administration of multiple doses of a drug until a desired effect is reached.

(15) "Minimal sedation" means a drug-induced state, with or without nitrous oxide to decrease anxiety, in which patients respond normally to tactile stimulation and verbal commands. Although cognitive function and coordination may be impaired, ventilatory and cardiovascular functions are maintained and do not require assistance.

(16) "Moderate enteral sedation" means a drug-induced depression of consciousness through the gastrointestinal tract or oral mucosa 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.

(17) "Moderate parenteral sedation" means a drug-induced depression of consciousness that bypasses the gastrointestinal tract or oral mucosa 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.

(15) "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.

(16) "Nitrous oxide sedation" or "N2O sedation" means a technique of inhalation seda-
tion with nitrous oxide and oxygen.

(17) "Operating dentist" means a dentist with primary responsibility for providing dental care
while a separate qualified dentist or independently practicing qualified anesthesia provider ad-
masters minimal, moderate, or deep sedation, or general anesthesia.

(18) "Parenteral" means a technique of administration in which the drug bypasses the
gastrointestinal (GI) tract, that is, through an intramuscular, intravenous, intranasal, submuco-
sal, subcutaneous, or intraosseous administration.

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

(20) "Qualified dentist" means a dentist with the appropriate training and permit to provide
sedation and anesthesia in compliance with state rules and regulations.

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

[(21) "Pediatric Advanced Life Support" or "PALS" means a certification that an individual
has successfully completed a pediatric advanced life support course that meets or exceeds the
standards established by the American Heart Association and incorporated by reference in 201
KAR 8:532.

(22) "Sedation" means the reduction of stress or excitement by the administration of a drug
that has a soothing, calming, or tranquilizing effect.]

Section 2. Statement of Policy. (1) The administration of local anesthesia, sedation, and
general anesthesia is an integral part of dental practice. The board is committed to the safe
and effective use of these modalities by appropriately educated and trained dentists.

(2) The use of local anesthetics is the foundation of pain control in dentistry; dentists must
be aware of the maximum, safe dosage limits for each patient. Large doses of local anesthet-
ics carry the risk of central nervous system depression, especially in combination with sedative
agents.

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

(4) Because sedation and general anesthesia are a continuum, it is not always possible to
predict how an individual patient will respond. Practitioners 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 assistance arrives, or the patient returns to the intended level
of sedation without airway or cardiovascular complications.

(5) New indications, agents, and techniques will lead to changes in anesthesia and sedation
practices. The board shall evaluate such changes for safety, efficacy, and to what extent such
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 specific sedation permit or by a Kentucky-licensed dental
hygienist permitted to deliver nitrous oxide analgesia under the direct supervision of a den-
tist certified to administer block and infiltration anesthesia and nitrous oxide analgesia.

(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) Insure 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[A dental assistant may only deliver nitrous oxide at a rate specified by direct orders of a dentist].

Section 4.[Section 3-] Minimal Sedation[Without a Permit]. (1) No license or permit is required for Minimal Sedation as described in this administrative regulation.
(2) Patients 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, when used in combination with a sedative agent, may 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 properties of 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 qualified dentist or independently practicing 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 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 and medication use. In addition, patients with significant medical considerations (ASA III, IV) may require 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, pulse rate, and respiration 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. At least one (1) additional person trained in Basic Life Support for Healthcare Providers shall be present throughout the administration of minimal sedation, in addition to the operating dentist.

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 which is appropriately examined and calibrated and a functioning device which prohibits the delivery of less than thirty (30) percent oxygen, or an appropriately calibrated and functioning in-line oxygen analyzer with audible alarm.
   d. An appropriate scavenging system shall be used if gases other than oxygen or air are delivered to a patient.

3. Monitoring and Documentation.
   a. Monitoring: A qualified dentist, or an appropriately trained individual chosen by the operating dentist, shall remain in the operating area during active dental treatment to monitor the patient continuously until the patient meets the criteria for discharge to the recovery area. The qualified dentist or other individual monitoring the treatment shall be familiar with monitoring techniques and equipment. The following shall be monitored:
      b. Consciousness. The patient’s level of sedation and responsiveness to verbal commands shall be continually assessed.
      c. Oxygenation. Oxygen saturation by pulse oximetry may be clinically useful and shall be considered.
      d. Ventilation. The patient’s chest excursions shall be monitored, and their respirations verified.
      e. Circulation. Blood pressure and heart rate shall be evaluated pre-operatively. Intraoperative monitoring of blood pressure may be clinically useful and shall be considered.
   f. Documentation. An appropriate sedative record shall be maintained for each patient to whom sedation is administered which 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 available immediately if a separate recovery area is utilized.
   b. A qualified dentist, or an appropriately trained individual chosen by the operating dentist shall monitor the patient during recovery until the patient is ready for discharge by the operating dentist.
   c. A qualified dentist shall determine and document whether the patient’s level of consciousness, oxygenation, ventilation, and circulation are satisfactory 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) The board shall issue a license or permit to a dentist prior to the administration of moderate sedation to a patient.

(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 may 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) Education requirements for adult moderate sedation.

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

1. A comprehensive training program in moderate sedation which satisfies the requirements described in the Moderate Sedation section of the ADA Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students at the time training was commenced; or

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


(b) Any person currently holding a permit to provide adult moderate sedation prior to the effective date of this administrative regulation who fails to meet the requirements of this subsection shall be afforded two (2) years by the board to comply with the requirements of this subsection. Any valid moderate sedation permits issued prior to this administrative regulation shall remain active until their expiration or renewal date, at which time the requirements of this subsection shall have been met prior to renewal.

(6) Educational requirements for pediatric moderate sedation. (a) 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 which provides comprehensive and appropriate 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 Advanced Cardiac Life Support and, if administering sedation to pediatric patients, Pediatric Advanced Life Support.

(b) 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 dentist to provide moderate sedation.

(7) Clinical Guidelines. Patient History and Evaluation. Patients considered for moderate
sedation 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, and ASA status. In addition, patients with significant medical considerations (ASA III, IV) may require a consultation with their treating physician prior to being administered moderate sedation.

(8) Pre-Operative Evaluation and Preparation. (a) 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 moderate sedation.

3. The patient shall be physically examined prior to the administration of minimal sedation. Baseline vital signs including body weight, height, blood pressure, pulse rate, and respiration 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, 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. At least one (1) additional person certified in Advanced Cardiac Life Support shall be present throughout the administration of moderate sedation to an adult patient, in addition to the operating dentist. At least one (1) additional person certified in Pediatric Advanced Life Support shall be present throughout the administration of moderate sedation to a pediatric patient, in addition to the operating dentist.

(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 which is appropriately examined and calibrated and a functioning device which prohibits the delivery of less than thirty (30) percent oxygen, or an appropriately calibrated and functioning in-line oxygen analyzer with audible alarm.

4. An appropriate 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 available until the patient meets discharge criteria.

(10) Monitoring and Documentation.

(a) Monitoring. The operating dentist shall remain in the operating room to monitor the patient continuously until the patient has recovered to a minimally sedated level. When active treatment concludes and the patient recovers to a minimally sedated level, the dentist may choose an appropriately trained individual to remain with and continue to monitor the patient until the patient is discharged from the facility. The operating dentist shall not leave the facility
until the patient is discharged from the facility.

(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 operating dentist 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 operating dentist shall continually evaluate blood pressure and heart rate unless invalidated by the nature of the patient and noted in the time-oriented anesthesia record.
5. The patient’s pulse oximetry, heart rate, end tidal CO2, respiratory rate, blood pressure, and level of consciousness shall be monitored continually and recorded at least every five (5) minutes.
6. The operating dentist shall consider the continuous ECG monitoring of a patient with significant cardiovascular disease.
(c) Documentation. An appropriate sedative record shall be maintained for each patient to whom sedation is administered which 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 available immediately if a separate recovery area is utilized.
(b) The operating dentist or appropriately trained individual shall continually monitor the patient’s blood pressure, heart rate, oxygenation, and level of consciousness during recovery.
(c) A qualified dentist shall determine and document whether the patient’s level of consciousness, oxygenation, ventilation, and circulation are satisfactory 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.
(e) If a pharmacological reversal agent is administered before the patient’s discharge criteria have been met, the patient shall be monitored for a longer period than usual before discharge, since re-sedation may occur once the effects of the reversal agent have waned.

(12) Emergency Management.
(a) 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.
(b) 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 moderate sedation and patient rescue.

(1) The board shall issue a license or permit to a dentist prior to the administration of moderate sedation to a patient.
(2) 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 and appropriate training necessary to administer and manage
deep sedation or general anesthesia; and

2. Current certifications in Basic Life Support for Healthcare Providers and Advanced Cardiac Life Support and, if administering sedation to pediatric patients, Pediatric Advanced Life Support.

(b) 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 dentist to provide moderate sedation, with at least one (1) additional person certified in Advanced Cardiac Life Support or an equivalent.

(3) Clinical Guidelines. Patient History and Evaluation. Patients 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) may require a consultation with their treating physician prior to being administered moderate sedation. Patients with elevated BMI may be at increased risk for airway associated morbidity, particularly if in association with other factors such as obstructive sleep apnea.

(4) Pre-Operative Evaluation and Preparation.

(a) 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 moderate sedation.

3. The patient shall be physically examined prior to the administration of minimal sedation. Baseline vital signs including body weight, height, blood pressure, blood oxygen saturation, pulse rate, and respiration 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. The patient, or the patient’s parent, legal guardian, or caregiver, shall be given pre-operative 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.

5. An intravenous line shall be established and secured throughout the procedure, except for patients with special needs as provided in subsection (8) of this section.

(5) 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. At least one (1) additional person certified in Advanced Cardiac Life Support shall be present throughout the administration of moderate sedation to an adult patient, in addition to the operating dentist. At least one (1) additional person certified in Pediatric Advanced Life Support shall be present throughout the administration of moderate sedation to a pediatric patient, in addition to the operating dentist.

(b) A minimum of three (3) individuals shall be present while a patient is being treated with deep sedation or general anesthesia. When a pediatric patient is being treated with deep sedation or general anesthesia, a separate qualified anesthesia provider, in addition to the operating dentist, 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 which is appropriately examined and calibrated and a functioning device which prohibits the delivery of less than thirty (30) percent oxygen, or an appropriately calibrated and functioning in-line oxygen analyzer with audible alarm.
4. An appropriate 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 available.
6. Resuscitation medications, an appropriate defibrillator, and equipment and drugs necessary to provide advanced airway management and advanced cardiac life support shall be immediately available.

(6) Monitoring and Documentation.
(a) Monitoring. A qualified dentist administering deep sedation or general anesthesia shall remain in the operating room to monitor the patient continuously until the patient meets the criteria for recovery. The qualified dentist shall not leave the facility until the patient is discharged from the facility.
(b) The following shall be monitored:
1. Oxygenation. Oxygen saturation by pulse oximetry shall be continually evaluated.
2. 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.
3. Circulation. The qualified dentist shall continually evaluate heart rate and rhythm by ECG throughout the procedure, as well as the patient’s pulse rate by pulse oximetry.
4. 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 whenever triggering agents associated with malignant hyperthermia are administered.
5. The patient’s respiration rate and blood pressure shall be continually monitored and evaluated.
6. The patient’s pulse oximetry, heart rate, end tidal CO2, respiratory rate, blood pressure, and level of consciousness shall be monitored continually and recorded at least every five (5) minutes.
(b) Documentation. An appropriate sedative record shall be maintained for each patient to whom sedation is administered which shall include the names of all drugs administered including local anesthetics, the time administered, the route of administration, dosages, and monitored physiological parameters.

(7) Recovery and Discharge.
(a) Oxygen and suction equipment shall be available immediately if a separate recovery area is utilized.
(b) The qualified dentist shall continually monitor the patient’s blood pressure, heart rate, oxygenation, and level of consciousness until the patient reaches a minimal level of sedation.
(c) The qualified dentist shall determine and document whether the patient’s level of consciousness, oxygenation, ventilation, and circulation are satisfactory 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.

(8) 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.

(9) Emergency Management. 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 patient rescue and deep sedation or general anesthesia.

(1) A permit shall not be required for a dentist to administer minimal enteral sedation for patients age thirteen (13) and older.

(2) A dentist who intends to administer minimal sedation shall indicate the intent to administer minimal sedation in the patient’s record.

(3) Medication used to produce minimal sedation shall not exceed the manufacturer’s recommended dose (MRD) for unmonitored use by the individual. Additional dosing shall be within the MRD limits.

(4) A dentist who administers minimal sedation shall maintain a margin of safety and a level of consciousness that does not approach moderate sedation and other deeper states of sedation and general anesthesia.

(5) Nitrous oxide may be combined with an oral medication. If nitrous oxide is combined with an oral medication, the level of sedation shall be maintained at the level of minimal sedation.

Section 4. Permit and Location Certificate Required. (1) A dentist shall not administer an anesthetic technique in order to attain a level beyond minimal sedation for the practice of dentistry unless:

(a) The dentist holds an appropriate Minimal Pediatric Sedation, Moderate Enteral Sedation, Moderate Parenteral Sedation, Moderate Pediatric Sedation, or Deep Sedation or General Anesthesia permit issued by the board; or

(b) The dentist holds a conscious sedation or general anesthesia permit that shall be converted to a Minimal Pediatric Sedation, Moderate Enteral Sedation, Moderate Parenteral Sedation, Moderate Pediatric Sedation, or Deep Sedation or General Anesthesia permit at the next license renewal.

(2) A dentist shall not administer an anesthetic technique under a Minimal Pediatric Sedation, Moderate Enteral Sedation, Moderate Parenteral Sedation, Moderate Pediatric Sedation, Deep Sedation or General Anesthesia, conscious sedation, or general anesthesia permit issued by the board at a facility unless:

(a) The facility has a current Anesthesia and Sedation Facility Certificate issued by the board; or

(b) The facility passed an inspection by the board for the purpose of issuing a conscious sedation or general anesthesia permit.

(3) A treating dentist who does not hold an anesthesia and sedation permit shall not allow a
physician anesthesiologist, another dentist who holds an anesthesia and sedation permit, or a certified registered nurse anesthetist to administer an anesthetic technique in order to attain a level beyond minimal sedation for the practice of dentistry at a facility owned or operated by the treating dentist unless:

(a) The facility has a current Anesthesia and Sedation Facility Certificate issued by the board; or

(b) The facility passed an inspection by the board for the purpose of issuing a conscious sedation or general anesthesia permit.

Section 5. Classifications of Anesthesia and Sedation Permits. The following permits shall be issued by the board to a qualified licensed dentist:

1. Minimal Pediatric Sedation permit that authorizes a dentist to use minimal enteral sedation for patients age five (5) to twelve (12). Medication or medications used to produce minimal sedation shall not exceed the manufacturer's recommended dose (MRD) for unmonitored use by the individual. Incremental dosing shall be prohibited. All dosing shall be administered in the dental office. A dentist who administers minimal sedation shall maintain a margin of safety and a level of consciousness that does not approach moderate sedation and other deeper states of sedation and general anesthesia. Nitrous oxide may be combined with an oral medication. If nitrous oxide is combined with an oral medication, the level of sedation shall be maintained at the level of minimal sedation;

2. Moderate Enteral Sedation permit that authorizes a dentist to use moderate enteral sedation for patients age thirteen (13) and older;

3. Moderate Parenteral Sedation permit that authorizes a dentist to use moderate parenteral sedation for patients age thirteen (13) and older;

4. Moderate Pediatric Sedation permit that authorizes a dentist to use moderate sedation by any route of administration for patients age twelve (12) and under; and

5. Deep Sedation or General Anesthesia permit that authorizes a dentist to use:

(a) General anesthesia; or

(b) Deep sedation.

Section 6. Qualifications for Obtaining a Minimal Pediatric Sedation Permit. To qualify for a Minimal Pediatric Sedation permit, an applicant shall:

1. Submit an Application for Sedation or Anesthesia Permit;
2. Pay the fee required by 201 KAR 8:520;
3. Hold current certification in either ACLS or PALS or successfully complete a six (6) hour board-approved course that provides instruction on medical emergencies and airway management; and
4. Provide proof of successful completion of: (a) a Commission on Dental Accreditation (CODA) accredited postdoctoral training program that affords comprehensive and appropriate training necessary to administer and manage minimal sedation; or

(b) Provide proof of successful completion of a board-approved course that shall consist of a minimum of twenty-four (24) hours of didactic instruction on pediatric minimal sedation by the enteral route or the combination enteral and nitrous oxide route.

Section 7. Qualifications for Obtaining a Moderate Enteral Sedation Permit. To qualify for a Moderate Enteral Sedation permit, an applicant shall:

1. Submit an Application for Sedation or Anesthesia Permit;
2. Pay the fee required by 201 KAR 8:520;
3. Hold current certification in either ACLS or PALS or successfully complete a six (6) hour
board-approved course that provides instruction on medical emergencies and airway management; and

(4) Provide proof of successful completion of: (a) A Commission on Dental Accreditation (CODA) accredited postdoctoral training program that affords comprehensive and appropriate training necessary to administer and manage moderate sedation; or

(b) Provide proof of successful completion of a board-approved course that shall consist of a minimum of twenty-four (24) hours of didactic instruction plus management of at least ten (10) adult case experiences by the enteral route or the combination enteral and nitrous oxide route. These ten (10) cases shall include at least three (3) live (on sight) clinical dental experiences managed by participants in groups that shall not exceed five (5) individuals. These three (3) live (on sight) experiences may be obtained by observing a permit level dentist in his or her office, and the remaining cases may include simulations and video presentations and shall include at least one (1) experience in returning a patient from deep to moderate sedation.

Section 8. Qualifications for Obtaining a Moderate Parenteral Sedation Permit. To qualify for a Moderate Parenteral Sedation permit, an applicant shall:

(1) Submit an Application for Sedation or Anesthesia Permit;
(2) Pay the fee required by 201 KAR 8:520;
(3) Hold current certification in either ACLS or PALS or successfully complete a six (6) hour board-approved course that provides instruction on medical emergencies and airway management; and

(4) Provide proof of successful completion of: (a) A CODA-accredited postdoctoral training program that affords comprehensive and appropriate training necessary to administer and manage moderate parenteral sedation; or

(b) Provide proof of successful completion of a board-approved course that shall consist of a minimum of sixty (60) hours of didactic instruction plus management of at least twenty (20) patients per course participant in moderate parenteral sedation techniques.

Section 9. Qualifications for Obtaining a Moderate Pediatric Sedation Permit. To qualify for a Moderate Pediatric Sedation permit, an applicant shall:

(1) Submit an Application for Sedation or Anesthesia Permit;
(2) Pay the fee required by administrative regulation;
(3) Hold current certification in either ACLS or PALS or successfully complete a six (6) hour board-approved course that provides instruction on medical emergencies and airway management; and

(4) Provide proof of successful completion of a CODA-accredited postdoctoral training program that affords comprehensive and appropriate training necessary to administer and manage moderate sedation for patients age twelve (12) and under.

Section 10. Qualifications for Obtaining a Deep Sedation or General Anesthesia Permit. To qualify for a Deep Sedation or General Anesthesia permit, an applicant shall:

(1) Submit an Application for Sedation or Anesthesia Permit;
(2) Pay the fee required by administrative regulation;
(3) Hold current certification in either ACLS or PALS; and (4) Provide proof of successful completion of:

(a) A board-approved Accreditation Council for Graduate Medical Education (ACGME) accredited postdoctoral training program in anesthesiology which affords comprehensive and appropriate training necessary to administer deep sedation and general anesthesia;

(b) A board-approved nurse anesthesia program accredited by the Council on Accreditation
of Nurse Anesthesia Educational Programs that affords comprehensive and appropriate training necessary to administer deep sedation and general anesthesia;

c) Successful completion of a minimum of two (2) years advanced clinical training in anesthesiology from a Joint Commission on Accreditation of Healthcare Organization (JCAHO) accredited institution that meets the objectives set forth in part two (2) of the American Dental Association’s Guidelines for Teaching the Comprehensive Control of Anxiety and Pain in Dentistry; or

d) Provide proof of successful completion of a CODA-accredited postdoctoral training program that affords comprehensive and appropriate training necessary to administer and manage deep sedation and general anesthesia.

Section 7. Multiple Application Levels Permitted. Dentists with the required education and training to provide more than one (1) level of sedation may mark their levels of qualification on the Application for Sedation or Anesthesia Permit based on the requirements of Sections 6 through 10 of this administrative regulation.

Section 8. Location Requirement. A dentist holding a Minimal Pediatric Sedation, Moderate Enteral Sedation, Moderate Parenteral Sedation, Moderate Pediatric Sedation, Deep Sedation or General Anesthesia, conscious sedation, or general anesthesia permit under 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 Anesthesia and Sedation Permit Location Notification Form within ten (10) business days of the change.

Section 9. Anesthesia and Sedation Facility Certificates. (1) The owner or operator of a facility shall obtain a facility certificate from the board for any location at which:

(a) a dentist holding a sedation or Minimal Pediatric Sedation, Moderate Enteral Sedation, Moderate Parenteral Sedation, Moderate Pediatric Sedation, Deep Sedation or General Anesthesia, conscious sedation, or general anesthesia permit provides moderate sedation, deep sedation or general anesthesia. A facility certificate is not required for minimal sedation or nitrous oxide sedation alone.

(b) A facility certificate shall be required if a dentist allows an independently practicing qualified anesthesia provider to administer sedation or general anesthesia in a dental office. The treating dentist may allow a physician anesthesiologist, another dentist who holds an anesthesia and sedation permit, or a certified registered nurse anesthetist to administer an anesthetic technique in order to attain a level beyond minimal sedation for the practice of dentistry.

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

(a) Submit an Application for a facility certificate

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

(c) Attest that the facility meets the requirements of this administrative regulation. Successfully pass a facility inspection as outlined in Section 14 of this administration. (3) A dentist currently in an advanced training course for sedation may request the Board of Dentistry complete a Sedation Facility Inspection prior to completion of the course.

(3) 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 under this administrative regula-
The owner or operator of a facility shall maintain for seven (7) years for inspection by the board the name and license number of each dentist or independently practicing qualified anesthesia provider, physician anesthesiologist, or certified registered nurse anesthetist who has administered anesthesia or moderate sedation at that location.

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

The owner or operator of a facility shall ensure that the facility:

(a) Remains properly equipped in accordance with Section 14 of this administrative regulation; and
(b) Remains properly staffed in accordance with Section 15 of this administrative regulation.

In addition to the requirements contained in subsection (6) of this section, the owner or operator of a facility shall ensure that the facility has appropriate nonexpired emergency and sedation medications.

Section 10. Renewal of Facility Certificate. (1) Active facility certificates issued prior to the effective date of this administrative regulation shall expire on December 31 of the second year following their date of issuance.

(2) New facility certificates shall remain active for a period of two (2) years.

(3) To renew a facility certificate, the owner or operator shall:
   (a) Submit a completed and signed Application for Renewal of Facility Certificate;
   (b) Pay the fee required by 201 KAR 8:520; and
   (c) Attest that the facility meets the requirements of this administrative regulation.

Section 11. Facility Inspection Criteria. (1) To qualify for an Anesthesia and Sedation Facility Certificate, the owner or operator of a facility shall attest that the facility has the following:

(a) The following shall be provided by the facility to qualify:
   (1) Oxygen and gas delivery system, backup system fail-safe;
   (2) Gas storage facility;
   (3) Safety indexed gas system;
   (4) Suction and backup system;
   (5) Auxiliary lighting system;
   (6) Suitability of operating room to include:
      (a) Size, which shall be at a minimum ten (10) feet by eight (8) feet or eighty (80) square feet;
      (b) Operating primary light source and secondary portable back-up source, unless back-up generator is available; and
      (c) Accessibility by emergency medical staff;
   (f) Recovery area, including oxygen, suction, and visual and electronic monitoring, which may include the operating room;
   (g) Preoperative medical history and physical evaluation form; and
   (h) Anesthesia and monitoring equipment checked to insure proper working order.

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

(a) Appropriate drugs for each procedure, all of which shall be unexpired, including reversal agents and emergency medications;
(b) Appropriate devices to maintain an airway with positive pressure ventilation;
(c) Anesthesia records, including monitoring and discharge records and a check sheet.
   a. The check sheet shall be signed by the provider and the dentist and placed in each record.
   b. If the dentist is the provider, only the dentist’s signature shall be required;
(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 and blood pressure monitoring;

5. Electrocardiogram (EKG):
   a. May be present for use by Minimal Pediatric Sedation, Moderate Enteral Sedation, Moderate Parenteral Sedation, and Moderate Pediatric Sedation permit holders for patients with significant cardiac history; and
   b. Shall be present for use by Deep Sedation or General Anesthesia permit holders;
6. Defibrillator or automated external defibrillator (AED) for moderate and Deep Sedation or General Anesthesia permits; and
7. For deep sedation or general anesthesia in pediatric patients:
   a. A precordial stethoscope; or
   b. A pretracheal stethoscope.

(2) During a facility inspection, inspectors shall:
(a) Examine the facility’s equipment to determine if it is in proper working order;
(b) Determine if appropriate emergency drugs are present; and
(c) Determine if emergency drugs are nonexpired.

Section 15. Inducing a Level of Sedation for a Patient. (1) Administration of minimal pediatric sedation, moderate enteral sedation, moderate parenteral sedation, moderate pediatric sedation, deep sedation, or general anesthesia to a patient requires at least the following appropriately trained individuals:
(a) The treating dentist;
(b) An individual trained and competent in basic life support (BLS) or its equivalent to assist the treating dentist; and
(c) Another individual trained and competent in BLS or its equivalent in close proximity to assist if needed.
(2) A dentist administering minimal pediatric sedation, moderate enteral sedation, moderate parenteral sedation, moderate pediatric sedation, deep sedation, or general anesthesia to a patient shall not leave the site until the patient:
(a) Is conscious;
(b) Is spontaneously breathing;
(c) Has stable vital signs;
(d) Is ambulatory with assistance; and
(e) Is under the care of a responsible adult.
(3) A treating dentist who allows a physician, another dentist, or certified registered nurse anesthetist to administer minimal pediatric sedation, moderate enteral sedation, moderate parenteral sedation, moderate pediatric sedation, deep sedation, or general anesthesia under Section 22 of this administrative regulation shall ensure that the physician, dentist, or certified registered nurse anesthetist shall not leave the site until the patient:
(a) Is conscious;
(b) Is spontaneously breathing;
(c) Has stable vital signs;
(d) Is ambulatory with assistance; and
(e) Is under the care of a responsible adult.

Section 16. Conscious Sedation Permits and General Anesthesia permits. (1) A dentist who holds a current general anesthesia permit may continue to administer anesthesia and sedation consistent with a Deep Sedation or General Anesthesia permit until the expiration date of the permit.

(2) A dentist who holds a current conscious sedation permit and meets the requirements of Section 9(4) of this administrative regulation may continue to administer anesthesia and sedation consistent with a Moderate Pediatric Sedation permit until the expiration date of the permit.

(3) A dentist who holds a current conscious sedation permit and meets the requirements of Section 8 of this administrative regulation may continue to administer anesthesia and sedation consistent with a Moderate Parenteral Sedation permit until the expiration date of the permit.

(4) During the license renewal process, current general anesthesia permit holders shall convert the permit to a Deep Sedation or General Anesthesia permit.

(5) During the license renewal process, current conscious sedation permit holders shall convert the permit to a minimal pediatric sedation, moderate enteral sedation, moderate parenteral sedation, or moderate pediatric sedation permit.

(6) A dentist who currently practices enteral sedation without a permit may continue without a permit until January 1, 2012 and shall receive a Moderate Enteral Sedation permit by the submission of:
   (a) Twenty-four (24) hours of didactic education plus twenty (20) sedation records documenting their experience; and
   (b) Satisfactory completion of an on-site inspection as outlined in Section 14 of this administrative regulation.

Section 17. Issuance and Expiration of Minimal Pediatric Sedation, Moderate Enteral Sedation, Moderate Parenteral Sedation, Moderate Pediatric Sedation and Deep Sedation or General Anesthesia Permits.

(1) Once an applicant has met the qualifications for obtaining a Minimal Pediatric Sedation, Moderate Enteral Sedation, Moderate Parenteral Sedation, Moderate Pediatric Sedation, or Deep Sedation or General Anesthesia permit the board shall issue a permit in sequential numerical order.

(2) Each permit issued under this administrative regulation shall expire on the same date as the permit holder's license to practice dentistry.

Section 18. Renewal of Minimal Pediatric Sedation, Moderate Enteral Sedation, Moderate Parenteral Sedation, Moderate Pediatric Sedation, and Deep Sedation or General Anesthesia Permits. An individual desiring renewal of an active Minimal Pediatric Sedation, Moderate Enteral Sedation, Moderate Parenteral Sedation, Moderate Pediatric Sedation, and Deep Sedation or General Anesthesia permits shall:

(1) Submit a completed and signed Application for Renewal of Sedation or Anesthesia Permit;
(2) Pay the fee required by 201 KAR 8:520; and
(3) Provide evidence to the board that the applicant meets the continuing education requirements outlined in Section 19 of this administrative regulation.]
Section 12. Continuing Education Requirements for Renewal of a Permit. A qualified dentist applying for renewal of an active permit to administer moderate or deep sedation or general anesthesia shall:

(1) 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

(2) Maintain ACLS or PALS certification.

Section 19. Continuing Education Requirements for Renewal of a Minimal Pediatric Sedation, Moderate Enteral Sedation, Moderate Parenteral Sedation, Moderate Pediatric Sedation, or Deep Sedation or General Anesthesia Permit.

(1) An individual desiring renewal of an active Minimal Pediatric Sedation, Moderate Enteral Sedation, Moderate Parenteral Sedation, or Moderate Pediatric Sedation permit shall:

(a) Complete at least six (6) hours of clinical continuing education related to sedation or anesthesia in a classroom setting that includes hands-on airway management during the two (2) year term of the permit; or

(b) Maintain ACLS or PALS certification.

(2) An individual desiring renewal of an active Deep Sedation or General Anesthesia permit shall:

(a) Complete not less than four (4) hours of on-sight clinical continuing education related to sedation or anesthesia during the two (2) year term of the permit; and

(b) Maintain ACLS or PALS certification.

(3) Continuing education required by this administrative regulation shall:

(a) Not be used to satisfy other continuing education requirements; and

(b) Be in addition to other continuing education requirements of 201 KAR 8:532.

Section 20. Facilities Inspected Prior to February 1, 2011. A facility owner or operator desiring to obtain an Anesthesia and Sedation Facility Certificate for a facility which passed an inspection by the board prior to February 1, 2011 shall provide proof to the board of having passed a facility inspection for the purpose of issuing a conscious sedation or general anesthesia. Section 21. Issuance of an Anesthesia and Sedation Facility Certificate. Once an applicant has met the qualifications for obtaining an Anesthesia and Sedation Facility Certificate the board shall issue a certificate in sequential numerical order.

Section 22. Administration by a Physician Anesthesiologist, Dentist, or Certified Registered Nurse Anesthetist at the Facility of a Treating Dentist.

(1) A treating dentist may allow at his or her dental facility, administration of sedation or anesthesia by a:

(a) Kentucky-licensed physician anesthesiologist or a Kentucky-licensed Certified Registered Nurse Anesthetist; or

(b) Dentist who holds an anesthesia and sedation permit.

(2) Administration by an individual listed in subsection (1)(a) of this section shall:

(a) Comply with this administrative regulation; and

(b) Not require board review.

(3) Nothing in this section shall preclude a dentist from working with a Kentucky-licensed physician anesthesiologist or a Kentucky-licensed Certified Registered Nurse Anesthetist in an ambulatory care center or hospital.

Section 13[23]. 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 its occurrence.
(2) A dentist shall report to the board, in writing, any incident that resulted in hospital in-patient 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 its occurrence.

(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 outlined in this section shall apply to every dentist who administers any type of sedation or anesthesia.

Section 14[24]. Registered Dental Assistant Duties permitted when working with Sedation Permit holders. A registered dental assistant working with a qualified dentist administering sedation or anesthesia under 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 to the operating dentist on a periodic basis and when 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 under this regulation.

Section 15. Administration by an Independently Practicing Qualified Anesthesia Provider.

(1) An operating dentist may permit the administration of sedation or anesthesia by a:
   (a) Kentucky-licensed independently practicing qualified anesthesia provider; or
   (b) Kentucky-licensed dentist qualified to administer sedation or anesthesia.

(2) The administration of anesthesia or sedation by an individual listed 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 Kentucky-licensed independently practicing qualified anesthesia provider to provide care in an ambulatory care center or hospital.:

1. A registered dental assistant working with Minimal Pediatric Sedation, Moderate Enteral Sedation, Moderate Parenteral Sedation, Moderate Pediatric Sedation and Deep Sedation or General Anesthesia permit holders may, under direct supervision:
   (a) Apply noninvasive monitors;
   (b) 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;
   (c) Report monitoring parameters to the operating dentist on a periodic basis and when changes in monitored parameters occur;
   (d) Record vital sign measurements in the sedation record; and
   (e) Remove IV lines (Moderate Parenteral Sedation, Moderate Pediatric Sedation and Deep Sedation or General Anesthesia Permit holders only).

2. A registered dental assistant working with Minimal Pediatric Sedation, Moderate Enteral Sedation, Moderate Parenteral Sedation, Moderate Pediatric Sedation and Deep Sedation or General Anesthesia Permit holders, may under direct supervision assist in the management of emergencies.

3. A registered dental assistant working with Moderate Parenteral Sedation, Moderate Pediatric Sedation and Deep Sedation or General Anesthesia Permit holders may, under direct supervision:
   (a) Administer medications into an existing IV line upon the verbal order and direct supervision of a dentist with a Moderate Parenteral Sedation, Moderate Pediatric or Deep Sedation or General Anesthesia permit; and
   (b) Establish an IV line under direct supervision if they have completed a course approved by the Board of Dentistry in intravenous access.]

Section 16[25]. Incorporation by Reference. (1) The following material is incorporated by reference:
(a) "Application for Sedation or Anesthesia Permit", February 2011;
(b) "Application for Sedation or Anesthesia Facility Certificate", February 2011; and
(c) "Sedation or[ef] Anesthesia Permit Location Notification Form", February 2011.
(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
APPROVED BY AGENCY: November 13, 2019
FILED WITH LRC: November 14, 2019 at 11 a.m.
PUBLIC HEARING AND PUBLIC COMMENT PERIOD: A public hearing on this Amendment shall be held on January 24, 2020 at 10:00am, Eastern Time at the Kentucky Board of Dentistry, 312 Whittington Parkway, Suite 101, Louisville, Kentucky 40222. Individuals interested in being heard at this hearing shall notify this agency in writing by five workdays prior to the hearing of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be cancelled. This hearing is open to the public. Any person who wishes to be heard will be given an opportunity to comment on the proposed Amendment. A transcript of the public hearing will not be made unless a written request for a transcript is
made. If you do not wish to be heard at the public hearing, you may submit written comments on the proposed Amendment. Written comments shall be accepted through January 31, 2020. Send written notification of intent to be heard at the public hearing, or written comments on the proposed Amendment to the contact person below.

CONTACT PERSON: Jeff Allen, Executive Director, Kentucky Board of Dentistry, 312 Whittington Parkway, Suite 101, Louisville, Kentucky 40222, phone (502) 429-7280, fax (502) 429-7282, email jeffrey.allen@ky.gov.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact Person: Jeff Allen

(1) Provide a brief summary of:
   (a) What this administrative regulation does: establishes requirements for 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 updates the requirements for permits to perform sedation or anesthesia.
   (b) The necessity of the amendment to this administrative regulation: This amendment is necessary in order to bring the administrative regulation up-to-date with the current legal and regulatory requirements and best practices for permits to perform sedation or anesthesia.
   (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 ensures that the requirements for permits to perform sedation or anesthesia are up-to-date in compliance with applicable law.

(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 three thousand prescribing dentists licensed in Kentucky and any individually qualified anesthesia providers who provide services to patients in cooperating with an operating dentist. Patients who are administered sedation or anesthesia by a Kentucky licensed dentist may also be affected.

(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:
   (a) List the actions that each of the related 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 costs will 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 cost.
   (b) On a continuing basis: No cost.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation? Not applicable.

(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.

(8) State whether or not this administrative regulation established any fees or directly or indirectly increased any fees: No.

(9) TIERING: Is tiering applied? No; this amendment impacts all similarly situated practitioners equally.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

(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.

(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? None.
   (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? None.
   (c) How much will it cost to administer this program for the first year? No cost.
   (d) How much will it cost to administer this program for subsequent years? No cost.

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

Revenues (+/-): None.
Expenditures (+/-): None.
Other explanation: Not applicable.