KANSAS ADMINISTRATIVE REGULATIONS

AGENCY 100 KANSAS STATE BOARD OF HEALING ARTS

ARTICLE 25. OFFICE REQUIREMENTS

100-25-1. Definitions.

As used in this article, the following terms shall have the meanings specified in this regulation. (a) "General anesthesia" means a drug that, when administered to a patient, results in the patient's controlled state of unconsciousness accompanied by a loss of protective reflexes, including the loss of the independent and continuous ability to maintain the airway and a regular breathing pattern, and the loss of the ability to respond purposefully to verbal commands or tactile stimulation.

- (b) "Local anesthesia" means a drug that, when administered to a localized part of the human body by topical application or by local infiltration in close proximity to a nerve, produces a transient and reversible loss of sensation. This term shall include lidocaine injections not exceeding seven milligrams per kilogram of body weight and also tumescent local anesthesia.
- (c) "Medical care facility" has the meaning specified in $\underline{\text{K.S.A. }65\text{-}425}$ and amendments thereto.
- (d) "Minimal sedation" means an oral sedative or oral analgesic administered in doses appropriate for the unsupervised treatment of insomnia, anxiety, or pain.
- (e) "Minor surgery" means surgery that meets both of the following conditions:
- (1) Any complication from the surgery requiring hospitalization is not reasonably foreseeable.
- (2) The surgery can safely and comfortably be performed either on a patient who has received no anesthesia or on a patient who has received local anesthesia or topical anesthesia.
- (f) "Office" means any place intended for the practice of the healing arts in the state of Kansas. This term shall not include a medical care facility, as defined by <u>K.S.A.</u> 65-425 and amendments thereto, that is licensed by the Kansas department of health and environment.
- (g) "Office-based surgery" means any surgery that requires any anesthesia, parenteral analgesia, or sedation and that is performed by or upon the order of a physician in an office. Office-based surgery shall not include minor surgery.
- (h) "Physician" means a person licensed to practice medicine and surgery or osteopathic medicine and surgery in the state of Kansas.
- (i) "Reportable incident" means any act by a licensee or a person performing professional services under the licensee's supervision, order, or direction that meets either of the following criteria:

- (1) Could be below the applicable standard of care and has a reasonable probability of causing injury to a patient; or
- (2) could be grounds for disciplinary action by the board.
- (j) "Sedation" means a depressed level of consciousness in which the patient retains the independent and continuous ability to perform the following:
- (1) Maintain adequate cardiorespiratory functioning;
- (2) maintain an open airway;
- (3) maintain a regular breathing pattern;
- (4) maintain the protective reflexes; and
- (5) respond purposefully and rationally to tactile stimulation and verbal commands.
- (k) "Special procedure" means any patient care service that involves any potentially painful contact with the human body, with or without instruments, for the purpose of diagnosis or therapy and for which the applicable standard of care necessitates any anesthesia to prevent or reduce pain. This term shall include a diagnostic or therapeutic endoscopy, invasive radiology, manipulation under anesthesia, and an endoscopic examination. This term shall include the conduct of pain management when performed using anesthesia levels exceeding local anesthesia.
- (I) "Surgery" means a manual or operative method that involves the partial or complete excision or resection, destruction, incision, or other structural alteration of human tissue by any means, including the use of lasers, performed upon the human body for the purpose of preserving health, diagnosing or treating disease, repairing injury, correcting deformity or defects, prolonging life, terminating pregnancy, or relieving suffering, or for aesthetic, reconstructive, or cosmetic purposes.
- (m) "Topical anesthesia" means a drug applied to the skin or mucous membranes for the purpose of producing a transient and reversible loss of sensation to a circumscribed area.
- (n) "Tumescent local anesthesia" means local anesthesia administered in large volumes of highly diluted lidocaine not exceeding 55 milligrams per kilogram of body weight, epinephrine not exceeding 1.5 milligrams per liter of solution, and sodium bicarbonate not exceeding 15 milliequivalents per liter of solution in a sterile saline solution by slow infiltration into subcutaneous fat. Tumescent local anesthesia shall not include the concomitant administration of any sedatives, analgesics, or hypnotic drugs, or any combination of these, at any dosage that poses a significant risk of impairing the patient's independent and continuous ability to maintain adequate cardiorespiratory functioning, an open airway, a regular breathing pattern, and protective reflexes and to respond purposefully to tactile stimulation and verbal commands.

100-25-2. General requirements.

(a) Except in an emergency, a person licensed to practice a branch of the healing arts shall not perform direct patient care in an office unless all of the following

conditions are met:

- (1) The office at which the direct patient care is performed is sanitary and safe.
- (2) Smoking is prohibited in all patient care areas and all areas where any hazardous material is present.
- (3) Medical services waste is segregated, stored, collected, processed, and disposed of in accordance with K.A.R. 28-29-27.
- (b) On and after July 1, 2006, each person licensed to practice a branch of the healing arts who maintains an office within this state shall adopt and follow a written procedure for sanitation and safety that includes at least the following:
- (1) Standards for maintaining the cleanliness of the office. The standards shall specify the following:
- (A) The methods for and the frequency of cleaning and decontaminating the walls, ceilings, floors, working surfaces, furniture, and fixtures. The written procedure shall identify the types of disinfectants and cleaning materials to be used; and
- (B) the methods to prevent the infestation of insects and rodents and, if necessary, to remove insects and rodents:
- (2) standards for infection control and the disposal of biological waste. The standards shall be at least as stringent as the standards in all applicable laws pertaining to the disposal of medical and hazardous waste and shall specify the following:
- (A) The procedures to limit the spread of infection among patients and personnel through universal precautions, hand hygiene, and the proper handling and disposal of sharp objects;
- (B) the methods to decontaminate infected items with germicidal, virucidal, bactericidal, tuberculocidal, and fungicidal products; and
- (C) the procedures to sterilize reusable medical instruments and devices;
- (3) standards for maintaining drugs, supplies, and medical equipment. The standards shall be at least as stringent as the standards in all applicable laws pertaining to the supply, storage, security, and administration of controlled drugs and shall specify the following:
- (A) The manner of storing drugs and supplies to guard against tampering and theft;
- (B) the procedures for disposal of expired drugs and supplies; and
- (C) the procedures for maintaining, testing, and inspecting medical equipment;
- (4) standards for maintaining the safety of physical facilities. The standards shall require that all of the following conditions are met:
- (A) The office is properly equipped and maintained in good repair as necessary to prevent reasonably foreseeable harm to patients, personnel, and the public;

- (B) the lighting, ventilation, filtration, and temperature control are adequate for the direct patient care to be performed;
- (C) the floors, walls, and ceilings have surfaces that can be cleaned, disinfected, sterilized, or replaced as appropriate for the direct patient care to be performed;
- (D) adequate measures are in place to deter any unauthorized individuals from entering the treatment rooms; and
- (E) all passageways are free of clutter; and
- (5) a plan for reporting each reportable incident pursuant to <u>K.S.A. 65-28,122</u> and <u>K.S.A. 65-4923</u> and amendments thereto.

100-25-3. Requirements for office-based surgery and special procedures.

A physician shall not perform any office-based surgery or special procedure unless the office meets the requirements of <u>K.A.R. 100-25-2</u>. Except in an emergency, a physician shall not perform any office-based surgery or special procedure on and after January 1, 2006 unless all of the following requirements are met: (a) Personnel.

- (1) All health care personnel shall be qualified by training, experience, and licensure as required by law.
- (2) At least one person shall have training in advanced resuscitative techniques and shall be in the patient's immediate presence at all times until the patient is discharged from anesthesia care.
- (b) Office-based surgery and special procedures.
- (1) Each office-based surgery and special procedure shall be within the scope of practice of the physician.
- (2) Each office-based surgery and special procedure shall be of a duration and complexity that can be undertaken safely and that can reasonably be expected to be completed, with the patient discharged, during normal operational hours.
- (3) Before the office-based surgery or special procedure, the physician shall evaluate and record the condition of the patient, any specific morbidities that complicate operative and anesthesia management, the intrinsic risks involved, and the invasiveness of the planned office-based surgery or special procedure or any combination of these.
- (4) The physician or a registered nurse anesthetist administering anesthesia shall be physically present during the intraoperative period and shall be available until the patient has been discharged from anesthesia care.
- (5) Each patient shall be discharged only after meeting clinically appropriate criteria. These criteria shall include, at a minimum, the patient's vital signs, the patient's responsiveness and orientation, the patient's ability to move voluntarily, and the ability to reasonably control the patient's pain, nausea, or vomiting, or any

combination of these.

- (c) Equipment.
- (1) All operating equipment and materials shall be sterile, to the extent necessary to meet the applicable standard of care.
- (2) Each office at which office-based surgery or special procedures are performed shall have a defibrillator, a positive-pressure ventilation device, a reliable source of oxygen, a suction device, resuscitation equipment, appropriate emergency drugs, appropriate anesthesia devices and equipment for proper monitoring, and emergency airway equipment including appropriately sized oral airways, endotracheal tubes, laryngoscopes, and masks.
- (3) Each office shall have sufficient space to accommodate all necessary equipment and personnel and to allow for expeditious access to the patient, anesthesia machine, and all monitoring equipment.
- (4) All equipment shall be maintained and functional to ensure patient safety.
- (5) A backup energy source shall be in place to ensure patient protection if an emergency occurs.
- (d) Administration of anesthesia. In an emergency, appropriate life-support measures shall take precedence over the requirements of this subsection. If the execution of life-support measures requires the temporary suspension of monitoring otherwise required by this subsection, monitoring shall resume as soon as possible and practical. The physician shall identify the emergency in the patient's medical record and state the time when monitoring resumed. All of the following requirements shall apply:
- (1) A preoperative anesthetic risk evaluation shall be performed and documented in the patient's record in each case. In an emergency during which an evaluation cannot be documented preoperatively without endangering the safety of the patient, the anesthetic risk evaluation shall be documented as soon as feasible.
- (2) Each patient receiving intravenous anesthesia shall have the blood pressure and heart rate measured and recorded at least every five minutes.
- (3) Continuous electrocardiography monitoring shall be used for each patient receiving intravenous anesthesia.
- (4) During any anesthesia other than local anesthesia and minimal sedation, patient oxygenation shall be continuously monitored with a pulse oximeter. Whenever an endotracheal tube or laryngeal mask airway is inserted, the correct functioning and positioning in the trachea shall be monitored throughout the duration of placement.
- (5) Additional monitoring for ventilation shall include palpation or observation of the reservoir breathing bag and auscultation of breath sounds.
- (6) Additional monitoring of blood circulation shall include at least one of the following:

- (A) Palpation of the pulse:
- (B) auscultation of heart sounds;
- (C) monitoring of a tracing of intra-arterial pressure;
- (D) pulse plethysmography; or
- (E) ultrasound peripheral pulse monitoring.
- (7) When ventilation is controlled by an automatic mechanical ventilator, the functioning of the ventilator shall be monitored continuously with a device having an audible alarm to warn of disconnection of any component of the breathing system.
- (8) During any anesthesia using an anesthesia machine, the concentration of oxygen in the patient's breathing system shall be measured by an oxygen analyzer with an audible alarm to warn of low oxygen concentration.
- (e) Administrative policies and procedures.
- (1) Each office shall have written protocols in place for the timely and safe transfer of the patients to a prespecified medical care facility within a reasonable proximity if extended or emergency services are needed. The protocols shall include one of the following:
- (A) A plan for patient transfer to the specified medical care facility;
- (B) a transfer agreement with the specified medical care facility; or
- (C) a requirement that all physicians performing any office-based surgery or special procedure at the office have admitting privileges at the specified medical care facility.
- (2) Each physician who performs any office-based surgery or special procedure that results in any of the following quality indicators shall notify the board in writing within 15 calendar days following discovery of the event:
- (A) The death of a patient during any office-based surgery or special procedure, or within 72 hours thereafter;
- (B) the transport of a patient to a hospital emergency department;
- (C) the unscheduled admission of a patient to a hospital within 72 hours of discharge, if the admission is related to the office-based surgery or special procedure;
- (D) the unplanned extension of the office-based surgery or special procedure more than four hours beyond the planned duration of the surgery or procedure being performed;
- (E) the discovery of a foreign object erroneously remaining in a patient from an office-based surgery or special procedure at that office; or

(F) the performance of the wrong surgical procedure, surgery on the wrong site, or surgery on the wrong patient.

100-25-4. Office-based surgery and special procedures using general anesthesia or a spinal or epidural block.

- (a) In addition to meeting the requirements stated in <u>K.A.R. 100-25-2</u> and <u>100-25-3</u>, a physician shall not perform any office-based surgery or special procedure using general anesthesia or a spinal or epidural block unless the office is equipped with the following:
- (1) Medications and equipment available to treat malignant hyperthermia when triggering agents are used. At a minimum, the office shall have a supply of dantrolene sodium adequate to treat each patient until the patient is transferred to an emergency facility;
- (2) tracheotomy and chest tube kits;
- (3) an electrocardiogram that is continuously displayed from the induction and during the maintenance of general anesthesia or the spinal or epidural block;
- (4) a means readily available to measure the patient's temperature; and
- (5) qualified, trained personnel available and dedicated solely to patient monitoring.
- (b) On and after July 1, 2006, each physician who performs any office-based surgery or special procedure using general anesthesia or a spinal or epidural block shall perform the office-based surgery or special procedure only in an office that meets at least one of the following sets of standards, all of which are hereby adopted by reference except as specified:
- (1) Sections 110-010 through 1031-02 in the "standards and checklist for accreditation of ambulatory surgery facilities" by the American association for accreditation of ambulatory surgery facilities, inc., revised in 2005;
- (2) "section two: accreditation" and the glossary, except the definition of "physician," in "accreditation requirements for ambulatory care/surgery facilities" by the healthcare facilities accreditation program of the American osteopathic association, 2001-2002 edition;
- (3) section 1 and section 2 in "accreditation manual for office-based surgery practices" by the joint commission on accreditation of healthcare organizations, second edition, dated 2005;
- (4) "accreditation standards for ambulatory facilities" by the institute for medical quality, 2003 edition. The appendices are not adopted; or
- (5) chapters 1 through 6, 8 through 10, 15, 16, 19, 22, and 24 and appendices A and I in the "accreditation handbook for ambulatory health care" by the accreditation association for ambulatory health care, inc., 2005 edition.
- (c) A physician who maintains an office shall not permit any office-based surgery or

special procedure involving general anesthesia or a spinal or epidural block to be performed in that office unless the office meets at least one of the five sets of standards adopted in subsection (b).

- (d) Accreditation of an office by an organization whose standards are adopted in subsection (b) shall be prima facie evidence that those standards are currently being met.
- (e) This regulation shall not apply to any professional service performed in an emergency.

100-25-5. Standard of care.

Each person licensed to practice a branch of the healing arts who performs direct patient care in an office or who performs any office-based surgery or special procedures in an office shall meet the standard of care established by the regulations in this article.