

Guidelines for Office-Based Surgery

Background

The movement of health care services away from traditional inpatient facilities to outpatient settings has escalated the volume of surgery (including invasive procedures) being performed in the private offices of health care practitioners. While the vast majority of these services are provided in a safe and effective manner, the complexity of services and procedures being performed in private practitioners' offices is increasing at unprecedented levels. National reports of liposuction-related morbidity and data from Florida's mandatory reporting of office surgery complications, as well as other reports, suggest that office procedures may be less safe than those performed in hospitals or ambulatory surgery centers.

While surgery performed in Kentucky medical facilities (hospitals and diagnostic and treatment centers, including ambulatory surgery centers) is subject to regulatory standards under the state Cabinet for Health Services Office of Inspector General (including invasive procedures) performed in the private office of a physician, dentist or podiatrist is not subject to the same or similar regulatory standards, regardless of the scope or complexity of the surgical procedure.

A practitioner's authority to perform procedures in an office is established by that practitioner's license to practice his or her profession. The care delivered in such offices is expected to meet prevailing standards of care for the licensed profession. At this time, no such prevailing standards of care for office-based surgery exist.

Summary of Guidelines

The office surgery guidelines document is 21 pages long. The major contents are summarized in Table 1 and a brief summary of each section follows.

Definitions

The first section is definitions. This section defines the common terms used throughout the document.

Facility Requirements

Much of this document deals with the facility requirements for offices in which surgery will be performed. Offices are classified as Level I, II, or III based upon the complexity of anesthesia and surgical procedures performed.

Level I Offices

Level I office surgery includes minor procedures performed under topical or local anesthesia not involving drug-induced alteration of consciousness other than minimal preoperative anti-anxiety medications.

These offices must maintain basic emergency equipment as listed in Appendix 1 and have an established emergency transfer plan. It is recommended that the surgeon obtain Advanced Cardiac Life Support certification.

Level II Offices

Level II office surgery includes any procedure which requires administration of minimal or moderate sedation/analgesia making post-operative monitoring necessary. The surgical procedures are limited to those in which there is only a small risk of surgical and anesthetic complications and hospitalization as a result of these complications is unlikely.

In addition to Level 1 requirements, these offices must maintain full emergency equipment and medications as summarized in Appendix 2. There must be established emergency transfer plans, peer review, and performance improvement programs. Accreditation by one of the agencies listed in Table 2 is required. The surgeon and one assistant must be currently certified in Basic Life Support and the surgeon or at least one assistant must be certified in Advanced Cardiac Life Support or have a qualified anesthetic provider.

Level III Offices

Level III office surgery is a procedure which requires or reasonably should require the use of deep sedation/analgesia, general anesthesia, or major conduction blockade. The known complications of the surgical procedure may be serious or life-threatening.

In addition to Level I and Level II requirements, these offices must maintain full emergency equipment and medications as summarized in Appendix 2. There must be established emergency transfer plans, peer review, and performance improvement programs. Accreditation by one of the agencies listed in Table 2 is *mandatory*. The surgeon and at least one assistant must be currently certified in advanced cardiac life support and recovery should be monitored by an ACLS trained practitioner.

Emergency Transfer and Reporting

In the event of an anesthetic, medical or surgical complication or emergency all office personnel should be familiar with a documented plan for the timely and safe transfer of patients to a nearby hospital. This plan should include

arrangements for emergency medical services, and appropriate escort of the patient to the hospital.

Anesthetic or surgical mishaps requiring resuscitation, emergency transfer, or death must be reported to the medical board within three business days using a specified form.

Credentialing

The guidelines address the qualifications that each practitioner should possess. The practitioner should have an appropriate level of training and experience for the specific surgical procedure performed. Criteria considered should include: 1) procedure-specific education, training, experience and successful evaluation 2) American Board of Medical Specialists or equivalent board certification or eligibility 3) participation in peer and quality review 4) continuing medical education (5) malpractice coverage (6) active hospital and/or ambulatory surgical center privileges and (7) adherence to professional society standards.

Unlicensed personnel may not be assigned duties or responsibilities that require professional licensure. Duties assigned to unlicensed personnel should be in accordance with their training education and experience and under the direct supervision of a practitioner.

Anesthesia

Anesthesia should be administered only by a licensed, qualified and competent practitioner. Registered nurses who administer analgesic or sedative drugs as part of a medical procedure must have training and experience appropriate to the level of anesthesia administered and function in accordance with their scope of practice. Registered nurses must have documented competence to administer conscious sedation and to assist in any support or resuscitation measures as required. The individual administering conscious sedation and/or monitoring the patient cannot assist the surgeon in performing the surgical procedure.

As required by statutes and administrative regulations, supervision of the sedation/analgesia component of the medical procedure should be provided by a *physician who is physically present*, who is qualified to supervise the administration of the anesthetic and who has accepted responsibility for supervision. The physician providing supervision should assure that an appropriate pre-anesthetic examination is performed, prescribe the anesthesia, assure that qualified practitioners participate, be available for diagnosis, treatment, and management of anesthesia-related complications or emergencies, and assure the provision of indicated post-anesthesia care.

Liposuction

Tumescent liposuction total lidocaine dosage should not exceed 15 mg/kg in a Level I facility. Total supranatant fat removal should not exceed 4000 cc in any office facility.

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Chapter A

Statement of Intent and Goals

The purpose of these guidelines is to promote patient safety in the non-hospital setting during procedures that require the administration of conscious sedation, local, or general anesthesia, or minor or major conduction blockade. Moreover, these guidelines have been developed to provide practitioners performing office-based surgery, (including cryosurgery and laser surgery), that requires anesthesia (including tumescent anesthesia), analgesia or sedation the benefit of uniform professional standards regarding qualification of practitioners and staff, equipment, facilities and policies and procedures for patient assessment and monitoring. *Minor procedures in which unsupplemented local anesthesia is used in quantities equal to or less than the manufacturer's recommended dose, adjusted for weight, are excluded from these guidelines. Nonetheless, it is expected that any practice performing office-based surgery regardless of anesthesia will have the necessary equipment, protocol, and personnel to handle emergencies resulting from the procedure and/or anesthesia.*

Chapter B

Definitions

For the purpose of these guidelines, the following terms are defined:

1. *“Advanced cardiac life support trained”* means that a licensee has successfully completed and requalified periodically an advanced cardiac life support course offered by a recognized accrediting organization appropriate to the licensee's field of practice. For example, for those licensees treating adult patients, training in advanced cardiac life support (ACLS) is appropriate; for those treating children, training in pediatric advanced life support (PALS) or advanced pediatric life support (APLS) is appropriate.

2. *“Anesthesiologist”* means a physician who has successfully completed a residency program in anesthesiology approved by the Accreditation Council of Graduate Medical Education (ACGME) or the American Osteopathic Association (AOA), or who is currently a diplomate of either the American Board of Anesthesiology or the American Osteopathic Board of Anesthesiology, or who was made a Fellow of the American College of Anesthesiology before 1982.
3. *“Anesthetizing location”* means any location in an office where anesthetic agents are administered to a patient.
4. *“Board”* means the Kentucky Board of Medical Licensure.
5. *“Certified registered nurse anesthetist” (CRNA)* means a registered nurse who successfully completed an advanced, organized formal educational program in nurse anesthesia accredited by the national certifying organization of such specialty which is recognized by the Kentucky Board of Nursing; and is certified by a board approved national certifying organization, and who demonstrates advanced knowledge and skill in the delivery of anesthesia services. The Certified Registered Nurse Anesthetist must practice in accordance with approved written guidelines developed under the supervision of a licensed physician or dentist or approved by the medical staff within the facility where the practice privileges have been granted.
6. *“Complications”* means an untoward event occurring at any time within 48 hours of surgery, special procedure or the administration of anesthesia in an office setting including, but not limited to, any of the following: paralysis, nerve injury, malignant hyperthermia, seizures, myocardial infarction, renal failure, significant cardiac events, respiratory arrest, aspiration of gastric contents, cerebral vascular accident, transfusion reaction, pneumothorax, allergic reaction to anesthesia, unintended hospitalization for more than 24 hours, or death.
7. *“Credentialed”* means that a practitioner or physician has been granted and continues to maintain the privilege by a facility licensed in the jurisdiction in which it is located to provide specified services, such as surgery or the administration or supervision of the administration of one or more types of anesthetic agents or procedures, or can show adequate documentation of training experience in specified services such as surgery that is performed more often in an office or outpatient setting.
8. *“Deep sedation/analgesia”* means the administration of a drug or drugs which produces depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.
9. *“General anesthesia”* means a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients

often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.

10. "*Health care personnel*" means any office staff member who is licensed or certified by a recognized professional or health care organization such as but not limited to a professional registered nurse, licensed practical nurse, physician assistant or certified medical assistant.
11. "*Hospital*" means a hospital licensed by the state in which it is situated.
12. "*Local anesthesia*" means the administration of an agent which produces a transient and reversible loss of sensation in a circumscribed portion of the body.
13. "*Major surgery*" means surgery which requires moderate sedation, deep sedation, general anesthesia, or major conduction blockade for patient comfort.
14. "*Major conduction blockade*" means the injection of local anesthesia to stop or prevent a painful sensation in a region of the body. Major conduction blocks include, but are not limited to, axillary, interscalene, and supraclavicular block of the brachial plexus; spinal (subarachnoid), epidural and caudal blocks.
15. "*Minimal sedation*" (*anxiolysis*) means the administration of a drug or drugs which produces a state of consciousness that allows the patient to tolerate unpleasant medical procedures while responding normally to verbal commands. Cardiovascular or respiratory function should remain unaffected and defensive airway reflexes should remain intact.
16. "*Minor surgery*" means surgery which can be safely and comfortably performed on a patient who has received local or topical anesthesia, without more than minimal pre-operative medication or minimal intraoperative sedation and where the likelihood of complications requiring hospitalization is remote.
17. "*Minor conduction block*" means the injection of local anesthesia to stop or prevent a painful sensation in a circumscribed area of the body (that is, infiltration or local nerve block), or the block of a nerve by direct pressure and refrigeration. Minor conduction blocks include, but are not limited to, intercostal, retrobulbar, paravertebral, peribulbar, pudendal, sciatic nerve and ankle blocks.
18. "*Moderate sedation/analgesia*" means the administration of a drug or drugs which produces depression of consciousness during which patients respond purposely to verbal commands, either alone or accompanied by a light tactile stimulation. Reflex withdrawal from painful stimulation is NOT considered a purposeful response. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.
19. "*Monitoring*" means continuous visual observation of a patient and regular observation of the patient as deemed appropriate by the level of sedation or recovery using instruments to measure, display and record physiologic

- values such as heart rate, blood pressure, respiration and oxygen saturation.
20. “*Office*” means a location at which medical or surgical services are rendered and which is not subject to a jurisdiction and licensing requirements of the South Carolina Department of Health.
 21. “*Office-Based Surgery*” means the performance of any surgical or other invasive procedure requiring anesthesia, analgesia, or sedation, including cryosurgery and laser surgery, which results in patient stay of less than 24 consecutive hours and is performed by a practitioner in a location other than a hospital or a diagnostic treatment center, including free-standing ambulatory surgery centers.
 22. “*Operating room*” means that location in the office dedicated to the performance of surgery or special procedures.
 23. “*Physical status classification*” means a description of a patient used in determining if an office surgery or procedure is appropriate. The American Society of Anesthesiologists enumerates classification: I – Normal, healthy patient; II – A patient with mild systemic disease; III – A patient with severe systemic disease limiting activity but not incapacitating; IV – A patient with incapacitating systemic disease that is a constant threat to life; and V – Moribund patients not expected to live 24 hours with or without operation.
 24. “*Physician*” means an individual holding an M.D. or D.O. degree licensed pursuant to the Kentucky Medical and Osteopathic Practices Act.
 25. “*Practitioner*” means a physician.
 26. “*Recovery area*” means a room or limited access area of an office dedicated to providing medical services to patients recovering from surgery or anesthesia.
 27. “*Special procedure*” means patient care which requires entering the body with instruments in a potentially painful manner, or which requires the patient to be immobile, for a diagnostic or therapeutic procedure requiring anesthesia services; for example, diagnostic or therapeutic endoscopy, invasive radiologic procedures, pediatric magnetic resonance imaging; manipulation under anesthesia or endoscopic examination with the use of general anesthetic.
 28. “*Surgery*” means any operative or manual procedures, including the use of lasers as used under the direction of a physician in certain cases, performed for the purpose of preserving health, diagnosing or treating disease, repairing injury, correcting deformity or defects, prolonging life or relieving suffering, or any elective procedure for aesthetic or cosmetic purposes. This includes, but is not limited to: incision or curettage of tissue or an organ; suture or other repair of tissue or an organ; extraction of tissue from the uterus; insertion of natural or artificial implants; closed or open fracture reduction; or an endoscopic examination with use of local or general anesthetic.

29. “*Topical Anesthesia*” means an anesthetic agent applied directly or by spray to the skin or mucous membranes, intended to produce a transient and reversible loss of sensation to a circumscribed area.

Chapter C

Office Administration

The following summarizes some of the important written document and policies and procedures that office-based practices are encouraged to develop and implement. The policies and procedures should undergo periodic review and updating.

1. Policies and Procedures

Written policies and procedures can assist office-based practices in providing safe and quality surgical care, assure consistent personnel performance, and promote an awareness and understanding of the inherent rights of patients. The following are important aspects of an office-based practice that should benefit from simple policy and procedure statements.

- a. Emergency Care and Transfer Plan:** A plan should be developed for the provision of emergency medical care as well as the safe and timely transfer of patients to a nearby hospital should hospitalization be necessary.
 1. Age appropriate emergency supplies, equipment and medication should be provided in accordance with the scope of surgical and anesthesia services provided at the practitioner’s office.
 2. In an office where anesthesia services are provided to infants and children, the required emergency equipment should be appropriately sized for a pediatric population, and personnel should be appropriately trained to handle pediatric emergencies (APLS or PALS certified).
 3. A practitioner who is qualified in resuscitation techniques and emergency care should be present and available until all patients having more than local anesthesia or minor conductive block anesthesia have been discharged from the office (Advanced adult or pediatric life support certified).
 4. In the event of untoward anesthetic, medical or surgical complications or emergencies, personnel should be familiar with the procedures and plan to be followed, and able to take the necessary actions. All office personnel should be familiar with a documented plan for the timely

and safe transfer of patients to a nearby hospital. This plan should include arrangements for emergency medical services, if necessary, or when appropriate escort of the patient to the hospital by an appropriate practitioner. If advanced cardiac life support is instituted, the plan should include immediate contact with emergency medical services.

- b. Medical Record Maintenance and Security:** The practice should have a procedure for initiating and maintaining a health record for every patient evaluated or treated. The record should include a procedure code or suitable narrative description of the procedure and should have sufficient information to identify the patient, support the diagnosis, justify the treatment and document the outcome and required follow-up care. For procedures requiring patient consent, there should be a documented informed written consent. If analgesia/sedation, minor or major conduction blockade or general anesthesia are provided, the record should include documentation of the type of anesthesia used, drugs (type and dose) and fluids administered, the record of monitoring of vital signs, level of consciousness during the procedure, patient weight, estimated blood loss, duration of the procedure, and any complications related to the procedure or anesthesia. Procedures should also be established to assure patient confidentiality and security of all patient data and information.
- c. Infection Control Policy:** The practice should comply with state and federal regulations regarding infection control. For all surgical procedures, the level of sterilization should meet current OSHA requirements. There should be a procedure and schedule for cleaning, disinfecting and sterilizing equipment and patient care items. Personnel should be trained in infection control practices, implementation of universal precautions, and disposal of hazardous waste products. Protective clothing and equipment should be readily available.
- d. Performance Improvement:** A performance improvement program should be implemented to provide a mechanism to periodically review (minimum of every six months) the current practice activities and quality of care provided to patients, including peer review by members not affiliated with the same practice. Level I facilities are exempt from Performance Improvement Programs. Performance improvement (PI) can be established by:

 1. Establishment of a PI program by the practice; or
 2. Cooperative agreement with a hospital-based performance or quality improvement program; or

3. Cooperative agreement with another practice to jointly conduct PI activities; or
 4. A cooperative agreement with a peer review organization, a managed care organization, specialty society, or other.
- e. **Reporting of Adverse Incidents:** Anesthetic or surgical mishaps requiring resuscitation, emergency transfer, or death should be reported to the Board within three business days using the form contained in Appendix VI.
- f. **Federal and State Laws and Regulations:** Federal and state laws and regulations that affect the practice should be identified and procedures developed to comply with those requirements. The following are some of the key requirements upon which office-based practices should focus:
1. Non-Discrimination (see Civil Rights statutes and the Americans with Disabilities Act)
 2. Personal Safety (see Occupational Safety and Health Administration information)
 3. Controlled Substance Safeguards
 4. Laboratory Operations and Performance (CLIA)
 5. Personnel Licensure Scope of Practice and Limitations
- g. **Patients' Bill of Rights:** Office personnel should recognize the basic rights of patients and understand the importance of maintaining patients' rights. A patients' rights documents should be readily available upon request.

Chapter D

Credentialing

1. **Surgical Facility:** Practices performing office-based surgery or procedures that require the administration of moderate or deep sedation, or general anesthesia (Level II and III facilities as defined below) should be accredited by an accreditation agency, including the American Association of Ambulatory Surgical Facilities (AAAASF), Accreditation Association for Ambulatory Health Care (AAAHC) or the Joint Commission of Accreditation of HealthCare Organizations (JCAHO), or any other agency approved by the Board within the first year of operation. The accrediting agency must submit a yearly summary report for each facility to the Board. Any licensee performing Level II or Level III office surgery should register with the Board. Such registration should include each address at which Level II or Level III office surgery is performed and identification of the accreditation agency that accredits each location (when applicable). Rule of Thumb: The capacity of the patient at all times to retain his/her life-protective reflexes and to respond to verbal command (i.e., the depth of sedation or anesthesia) – rather than the specific

procedure performed – lies at the core of differentiating Level II from Level III surgery.

a. Level I Office Surgery:

1. Scope: Level I office surgery includes:
 - a. Minor procedures performed under topical or local anesthesia (including digital block) not involving drug-induced alteration of consciousness other than minimal preoperative anti-anxiety medications.
 - b. Tumescent liposuction: total lidocaine dosage should not exceed 15 mg/kg in a Level I facility.
 - c. Preoperative medications are not required or used other than minimal preoperative perioperative oral or intramuscular anti-anxiety producing drugs; anesthesia is local, topical, or none. No drug-induced alteration of consciousness other than minimal anxiolysis of the patient is permitted in Level I Office Surgery.
 - d. Chances of Complications requiring hospitalization are remote.

b. Level II Office Surgery:

2. Scope: Level II office surgery includes the following:
 - a. Any procedure which requires the administration of minimal or moderate intravenous, intramuscular, or rectal sedation/analgesia, thus making post-operative monitoring necessary.
 - b. Level II office surgery shall be limited to procedures where there is only a moderate risk of surgical and/or anesthetic complications and the likelihood of hospitalization as a result of these complications is unlikely. Level II office surgery includes local or peripheral nerve block, minor conduction blockade, and Bier block.

c. Level III Office Surgery:

3. Scope: Level III office surgery includes the following:
 - a. Level III office surgery is any procedure which requires, or reasonably should require, the use of deep sedation/analgesia, general anesthesia, or major conduction blockade, and/or in which the known complications of the proposed surgical procedure may be serious or life-threatening.
 - b. Tumescent liposuction: supranatant fat removal should not exceed 4000cc.

2. Practitioner:

- a. The specific office based surgical procedures and anesthesia services that each practitioner is qualified and competent to perform should be commensurate with practitioner's level of training and should be commensurate with practitioner's level of training and experience. Criteria to be considered to demonstrate competence include:
 1. State licensure
 2. Procedure-specific education, training, experience and successful evaluation appropriate for the patient population being treated (i.e., pediatrics)
 3. For physician practitioners, board certification, board eligibility or completion of a training program in a field of specialization recognized by the ACGME for expertise and proficiency in that field. Board certification is understood as American Board of Medical Specialists (ABMS) or equivalent board certification as determined by the Board for non-physician practitioners, certification that is appropriate and applicable for the practitioner.
 4. Professional misconduct and malpractice history.
 5. Participation in peer and quality review
 6. Participation in continuing education consistent with the statutory requirements and requirements of the practitioner's professional organization
 7. Malpractice insurance coverage adequate for the specialty
 8. Procedure-specific competence (and competence in the use of new procedures/technology), which should encompass education, training, experience and evaluation, and which may include the following:
 - a. Adherence to professional society standards
 - b. Hospital and/or ambulatory surgical privileges for the scope of services performed in the office based setting
 - c. Credentials approved by a nationally recognized accrediting/credentialing organization;
 - d. Didactic course complimented by hands-on, observed experience; training is to be followed by a specified number of cases supervised by a practitioner already competent in the respective procedure, in accordance

with professional society standards and guidelines may be acceptable if approved by the Kentucky Board of Medical Licensure.

- b. Unlicensed personnel may not be assigned duties or responsibilities that require professional licensure. Duties assigned to unlicensed personnel should be in accordance with their training, education and experience and under the direct supervision of a practitioner.

Chapter E

Standards for Office Procedures

1. Level I Office Procedures:

- a. Training required: The surgeon is encouraged to pursue continuing medical education in proper drug dosages, management of toxicity or hypersensitivity to local anesthetic and other drugs. It is recommended that the surgeon obtain Advanced Cardiac Life Support certification.
- b. Equipment and supplies: Oxygen, positive pressure ventilation device, epinephrine, atropine, antihistamine, and corticosteroids should be available if any anesthesia is used.
- c. Assistance of Other Personnel: No other assistance is required, unless dictated by the surgical procedure.
- d. Accreditation: No accreditation is necessary for Level I office surgery.

2. Level II Office Procedures:

- a. **Training Required:** The surgeon must have staff privileges to perform the same procedure in that hospital as that being performed in the outpatient setting or must be able to document satisfactory completion of training such as board certification or board eligibility by a board approved by the American Board of Medical Specialties, formal training, or experience. The surgeon and one assistant must be currently certified in Basic Life Support and the surgeon or at least one assistant must be currently certified in Advanced Cardiac Life Support or have a qualified anesthetic provider practicing within the scope of the provider's license to manage the anesthetic.
- b. **Equipment and Supplies Required:** Emergency resuscitative equipment and a reliable source of oxygen as outlined in the appendix must be current and readily available. Monitoring equipment should include a continuous suction device, pulse oximeter, and noninvasive blood pressure cuff. Electrocardiographic monitoring should be available for patients with a history of cardiac disease. Age appropriate sized monitors and resuscitative equipment should be available for pediatric patients.

- c. **Assistance of Other Personnel Required:** Anesthesia should be administered only by a licensed, qualified and competent practitioner. Registered professional nurses (RNs) who administer analgesic or sedative drugs as part of a medical, procedure (*including but not limited to Certified Registered Nurse Anesthetists (CRNAs)*) must have training and experience appropriate to the level of anesthesia administered and function in accordance with their scope of practice. Registered professional nurses (RNs) must have documented competence to administer conscious sedation and to assist in any support or resuscitation measures as required. The individual administering conscious sedation and/or monitoring the patient cannot assist the surgeon in performing the surgical procedure. Supervision of the sedation/analgesia component of the medical procedure should be provided by a *physician who is physically present*, who is qualified by *law, regulation, or hospital appointment to perform* and supervise the administration of the sedation/analgesia or minor conduction blockade and who has accepted responsibility for supervision. The *physician* providing supervision should:
- i. Assure that an appropriate preanesthetic examination and evaluation is performed proximate to the procedure
 - ii. Prescribe the anesthesia;
 - iii. Assure that qualified practitioners participate;
 - iv. Remain physically present during the entire perioperative period and immediately available for diagnosis, treatment, and *management* of anesthesia-related complications or emergencies; and
 - v. Assure the provision of indicated post-anesthesia care.
- A registered nurse who is certified in Basic Cardiac Life Support (BCLS) should monitor the patient postoperatively and have the capability of administering medications as required for analgesia, nausea/vomiting, or other indications. Monitoring in the recovery area should include pulse oximetry and non-invasive blood pressure measurement. The patient should be assessed periodically for level of consciousness, pain relief, or any untoward complication. Each patient should meet discharge criteria as established by the practice, prior to leaving the facility.
- d. **Transfer and Emergency Protocols:** The surgeon must have a transfer protocol in effect with a hospital within reasonable proximity.
- e. **Facility Accreditation:** The surgeon must obtain Level II accreditation of the office setting by one of the approved agencies.

3. Level III Office Procedures

a. Training Required:

1. The surgeon must have documentation of training to perform the particular surgical procedure(s) and in the event he/she is supervising the administration of anesthesia by a Certified Registered Nurse Anesthetist, he/she must have sufficient knowledge of the anesthetic technique specified by him/her for

the procedure to assure compliance with the Kentucky Medical and Osteopathic Practice Act. The CRNA shall practice pursuant to approved written guidelines developed with the supervising licensed physician or dentist or by the medical staff within the facility where practice privileges have been granted. Rule 81-110 requires, among other things, that the surgeon be competent to supervise the specified anesthetic technique. If the surgeon does not possess the requisite knowledge of anesthesia, the anesthesia should be administered by an Anesthesiologist or by a Certified Registered Nurse Anesthetist supervised by an Anesthesiologist.

2. The surgeon and at least one assistant must be currently certified in Basic Cardiac Life Support and the surgeon or at least one assistant must be currently certified in Advanced Cardiac Life Support, and/or if appropriate, Pediatric Advanced Life Support (PALS) (or other profession specific equivalent training).
3. Recovery from general anesthesia or deep sedation should be monitored by an ACLS (PALS or PLS when appropriate) trained practitioner.

b. Equipment and Supplies Required:

1. Emergency resuscitation equipment, suction and a reliable source of oxygen must be readily available (See Appendix). At least 12 ampules of dantrolene sodium must be readily available.
2. Monitoring should include:
 - a. Blood pressure (apparatus and stethoscope)
 - b. Pulse oximetry
 - c. Continuous EKG
 - d. Capnography
 - e. Temperature monitoring for procedures lasting longer than thirty minutes

Facility, in terms of general preparation, equipment and supplies, must be comparable to a free standing ambulatory surgical center, have provisions for proper record keeping, and the ability to recover patients after anesthesia.

c. Assistance of Other Personnel Required:

1. An Anesthesiologist, or other qualified physician, or a Certified Registered Nurse Anesthetist, directed by a physician, must administer the general, deep sedation or major conduction regional anesthesia. If the anesthetic is administered by a Certified Registered Nurse Anesthetist, the anesthetic component of the procedure should be supervised by a *physician, who is physically present*, and who is qualified to supervise the administration of the anesthetic technique specified by him/her and who has accepted responsibility for such supervision. The anesthesia provider cannot function in any other capacity during the procedure. Recovery from general anesthesia, deep sedation, or major conduction blockade should

be monitored by a practitioner with Advanced Cardiac Life Support or Pediatric Advanced Life Support (or other profession specific equivalent training). Recovery from anesthesia should be evaluated by a qualified practitioner for proper anesthesia recovery using criteria that is appropriate for the level of anesthesia.

d. Inspection and Accreditation. The surgeon shall obtain accreditation of the office setting by AAAASF, AAAHC and JCAHO. All expenses related to accreditation or inspection shall be paid by the surgeon.

Chapter E

Patient Admission and Discharge

1. Patient Selection. The physician should evaluate the condition of the patient and the potential risks associated with the proposed treatment plan. The physician is also responsible for determining that the patient has an adequate support system to provide for necessary follow-up care. Patients with pre-existing medical problems or other conditions, who are at undue risk for complications, should be referred to an appropriate specialist for pre-operative consultation. Patients that are considered high risk or are a physical classification status III or greater, and require a general anesthetic for the surgical procedure, should have the surgery performed in a hospital setting. Patients with a physical status classification of III or greater may be acceptable candidates for moderate sedation/analgesia. ASA Class III patients should be specifically addressed in the operating manual of the surgery center. They may be acceptable candidates if deemed so by a physician qualified to assess the specific disability and its impact on anesthesia and surgical risks. Acceptable candidates for a deep sedation, general anesthesia, or major conduction blockade are patients with a physical status classification of I or II, no airway abnormality, and possess an unremarkable anesthetic history.

2. Informed Consent. The risks, benefits, and potential complications of both the surgery and anesthetic should be discussed with the patient and/or, if applicable, the patient's legal guardian prior to the surgical procedure. Written documentation of informed consent should be included in the medical record.

3. Preoperative Assessment. A medical history and physical examination should be performed, and appropriate laboratory studies obtained within 30 days of the planned surgical procedure, by a practitioner qualified to assess the impact of co-existing disease processes on surgery and anesthesia. A preanesthetic examination and evaluation should be conducted immediately prior to surgery by the physician, who will be administering or supervising the anesthesia. *If a certified registered nurse anesthetist will be administering the anesthesia, she/he should collaborate in such examination or evaluation.* The information and data obtained during the course of these evaluations should be documented in the medical record.

4. Discharge Evaluation. The physician who administered or supervised the anesthesia should evaluate the patient immediately upon completion of the surgery and anesthesia. Care of the patient may then be transferred to the care of qualified nursing personnel in the recovery area. A physician should remain immediately available until the patient meets discharge criteria. Criteria for discharge for all patients who have received anesthesia should include the following:

- 1) Confirmation of stable vital signs
- 2) Stable oxygen saturation levels
- 3) Return to pre-procedure mental status
- 4) Adequate pain control
- 5) Minimal bleeding nausea and vomiting
- 6) Resolving neural blockade, resolution of the neuraxial blockade
- 7) Discharged in the company of a competent adult

5. Patient Instructions. The patient should receive verbal instruction understandable to the patient or guardian, confirmed by written post-operative instructions and emergency contact numbers. The instructions should include:

1. The procedure performed
2. Information about potential complications
3. Telephone numbers to be used by the patient to discuss complications or should questions arise
4. Instructions for medications prescribed and pain management
5. Information regarding the follow-up visit date, time and location
6. Designated treatment facility in the event of emergency

Appendix I

Recommended Emergency and Resuscitation Equipment

A. Level I Facility

- I. Reliable oxygen supply
- II. Airway equipment; appropriate sized oral airways, endotracheal tubes, laryngoscopes, and masks
- III. Positive pressure ventilation device (bag/mask)
- IV. Suction
- V. Drugs:
 - a. Epinephrine
 - b. Atropine
 - c. Antihistamines
 - d. Hydrocortisone
- VI. Monitors:
 - a. If the anesthetic performed possesses any possibility of a complication that may compromise the patient's hemodynamic status or level of conscious, appropriate monitors include non-invasive blood pressure and pulse oximetry.
 - b. If topical anesthesia is applied or minimal anxiolysis administered, no monitoring required.

B. Level II and III Facilities

- I. Reliable oxygen source with back up tank
- II. Airway equipment; appropriate sized oral airways, endotracheal tubes, laryngoscopes, and masks
- III. Positive pressure ventilation device
- IV. Equipment
 - a. Defibrillator
 - b. Double tourniquets if the practice performs Bier blocks
 - c. Non-invasive blood pressure apparatus
 - d. Pulse oximeter
 - e. Capnography
 - f. Electrocardiographic monitor
 - g. Temperature monitoring system for procedures lasting more than 30 minutes
 - h. Oxygen analyzer
- V. Suction Apparatus
- VI. Drugs:
 - a. Epinephrine
 - b. Atropine
 - c. Antihistamines
 - d. Hydrocortisone

- e. Ephedrine
- f. Vasopressors (norepinephrine, isoproterenol, dopamine)
- g. Calcium Chloride or gluconate
- h. Glucose
- i. Naloxone
- j. Romazicon
- k. Antiemetics
- l. Sodium bicarbonate
- m. Lidocaine
- n. Adenosine
- o. Magnesium Sulfate
- p. Digoxin
- q. Furosemide
- r. Potassium Chloride
- s. Heparin sodium
- t. Aspirin
- u. Amiodarone
- v. Verapamil
- w. Procainamide
- x. Nitroglycerin
- y. Esmolol
- z. Labetolol
- aa. A minimum of 12 ampules of dantrolene sodium – if general anesthesia is administered

Appendix II

Required Equipment for the Administration of General Anesthesia or Deep Sedation

- A. Equipment as described in Appendix I, A-F
- B. Equipment required whenever the nature of the procedure requires the presence of an anesthesia circuit:
 - 1. an accepted method of identifying and preventing the interchangeability of anesthetic gases, whenever gases are used
 - 2. a respirometer (volumeter) measuring exhaled tidal volume
 - 3. Oxygen failure-protection devices (“fail-safe” system) which has the capacity to alert the practitioner when a reduction in oxygen pressure and, at lower levels of oxygen pressure, to discontinue other gases when the pressure of the supply of oxygen is reduced.
 - 4. alarm systems for high, low (subatmospheric), and minimum ventilatory pressures (disconnect) in the breathing circuit for each patient under general anesthesia
 - 5. Gas evacuation system
- C. When inhalational anesthetics are administered there should be:
 - 1. a vaporizer exclusion (“interlock”) system when more than one vaporizer is present
 - 2. Pressure compensated anesthesia vaporizers which are placed in the circuit upstream from the oxygen flush valve
 - 3. Flow meters and controllers, which can accurately measure concentration of the oxygen relative to the anesthetic agent and prevent oxygen mixtures of less than 21% from being administered
 - 4. a reliable system to scavenging waste anesthetic gases
 - 5. equipment for the management of the difficult airway and to treat malignant hyperthermia

Appendix III

Sample Patient Bill of Rights

1. The patient has the right to high quality health care delivered in a safe and efficient manner.
2. The patient has a right to dignity and respect.
3. The patient has a right to privacy, confidentiality, and consideration of any legitimate concerns.
4. The patient has a right to know his or her diagnosis, treatment options and prognosis.
5. The risks, benefits, and possible complications of each treatment or procedure need to be addressed.
6. The patient has the right to know the qualifications of individuals who will be participating in their care.
7. The patient has the right to refuse treatment and be advised of the consequences of this decision.
8. The patient has a right to inspect and obtain a copy of his or her medical records.
9. Charges to the patient to obtain the medical record should not be excessive.
10. The patient has a right to inspect and obtain information regarding the billing services.
11. The patient has a right to request information regarding alternative appropriate care.
12. The patient has a right to know the expectations of his or her behavior and the consequences of not complying with these expectations.

Appendix IV

Major Accrediting Agencies

American Association for Accreditation of Ambulatory Surgical Facilities, Inc.
(AAAASF)
1202 Allanson Road
Mundelein, IL 60060
(847)949-6058

Accreditation Association for Ambulatory Health Care, Inc. (AAAHHC)
9933 Lawler Avenue
Skokie, IL 60077-3702
(847)676-9610

Joint Commission on Accreditation of HealthCare Organizations (JCAHO)
One Renaissance Boulevard
Oak Brook Terrace, IL 60181
(630)916-5600

Clinical Laboratory Improvement Amendments of 1988 (CLIA)
Administrator, Health Care Financing Administration
Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201
(202)690-6726

Appendix V

Useful Administrative Information

- A. Occupational Safety and Health Administration (OSHA)
OSHA is a division of the US Department of Labor and is responsible for the enforcement of the health and safety guidelines set forth in the OSHA Act of 1970. Practices are subject to OSHA Hazard Communications Standard of 1987 and the Blood Borne Pathogen Standard 29 CFR 1910 1030. Both standards have very specific requirements and require written policy manuals and formal training regarding the standards. Other applicable OSHA standards include Access to Employee Exposure and Medical Records, and Personal Protective Equipment.
- B. Americans with Disabilities Act
Copies may be obtained by calling the Equal Employment Opportunity Commission at 1-800-669-4000 or www.eeoc.gov
- C. National Fire Protection Association-NFPA Life Safety Code
Copies may be obtained by writing to:
National Fire Protection Association
One Batterymarch Park
P.O. Box 9101
Quincy, MA 02269-9101
(617)770-4543
- D. Codes of Ethical Business and Professional Behavior
American College of Surgeons
55 East Erie Street
Chicago, IL 60611-2797
(312)202-5000
- E. American Society of Anesthesiologists
520 North Northwest Highway
Park Ridge, IL 60068-2573
(847)828-5586
www.asa.hq.org
- F. American Medical Association
515 North State Street
Chicago, IL 60610
1-800-634-6922 or 1-800-621-8335
- G. The American Association of Nurse Anesthetists
222 South Prospect Avenue
Park Ridge, IL 60068-4001
(847)698-7050
www.aana.com

Adopted: December 18, 2003