Since the 1980s, health care has seen a dramatic increase in the movement of surgical cases out of the hospital operating suite and into dedicated ambulatory surgical centers (ASCs) or physician offices. This change was enabled by advances in surgical technology, in particular laparoscopy and lasers, that reduced surgical procedure complexity and risk and decreased the length of surgery and by improvements in anesthesia and pain management that decreased patient recovery time, and it was economically motivated by the lower cost of nonhospital surgery and changes in third-party reimbursement that provided financial incentives for ambulatory surgery. In 2005, the New York Times reported that more than 20 percent of all surgical procedures were done in nonhospital settings. By 2007, about half of 43 million procedures were performed outside hospitals, about 10 million each in doctors' offices and free-standing outpatient centers. Highly publicized reports of surgical patient deaths after surgical procedures went awry in a nonhospital setting have resulted in increased patient safety concerns, legislation, regulation, accreditation, and medical and specialty society oversight.

This chapter will deal specifically with office-based surgery (OBS), which is surgery occurring in a physician office practice setting as opposed to a free-standing ASC. (See § 14.03[B], for an additional discussion of ambulatory surgical care.) An overview of the state regulations targeting office-based surgery is provided in Exhibit 13–1. As this exhibit illustrates, uniform, national regulations and standards do not exist at this point, although most states do regulate the performance of office-based surgery in some way.

[A] Accreditation

Several states have enacted legislation that mandates accreditation of office-based surgical practices, with New York being the most recent. The New York law mandated accreditation of OBS to be obtained and maintained by July 14, 2009; New York defines OBS as follows:

Any surgical or other invasive procedure, requiring general anesthesia, moderate sedation, or deep sedation, and any liposuction procedure, where such surgical or other invasive procedure or liposuction is performed by a licensee in a location other than a hospital, as such term is defined in article twenty-eight of this chapter, excluding minor procedures and procedures requiring minimal sedation.

Additionally, many practices choose to go through an accreditation process regardless of whether or not it is mandatory in their state to demonstrate their commitment to providing optimal, safe medical and surgical care to their patients.

Currently, there are three bodies that perform accreditation of practices performing office-based surgery (each of which is specifically cited as meeting the mandatory accreditation requirement of the New York regulation):

1. The Joint Commission (formerly JCAHO) <http://www.jointcommission.org/AccreditationPrograms/Office-BasedSurgery/>.

According to the Joint Commission's Comprehensive Accreditation Manual for Office-Based Surgery, practices must meet all of the following criteria to be eligible for accreditation under the OBS program:

- The practice is composed of four or fewer surgeons (physician, dentist, or podiatrist) performing operative or invasive procedures. OBS practices, including multisite practices, are limited to four or fewer licensed independent practitioners.
- The practice must be surgeon owned or operated (e.g., a professional services corporation, private physician office, or small group practice).
Invasive procedures are provided to patients. (Practices providing only procedures such as excisions of skin lesions, moles, warts, and abscess drainage limited to the skin and subcutaneous tissue are not typically surveyed under OBS standards.)

Local anesthesia, minimal sedation, conscious sedation, or general anesthesia is administered. (However, laser eye surgery using topical anesthesia does qualify.)

**EXHIBIT 13–1. OFFICE-BASED SURGERY REGULATION OVERVIEW BY STATE**

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*Note:* Office-based practices that render four or more patients incapable of self-preservation at the same time are required to meet the provisions of the Life-Safety Code®.

In addition, the Joint Commission has 16 National Patient Safety Goals specifically related to OBS for 2009.?

2. **The American Association for the Accreditation of Ambulatory Surgical Facilities** (AAAASF) [<www.aaaasf.org> accredits single-specialty and multispecialty surgery facilities and ASCs, owned and/or directed by American Board of Medical Specialties Surgeons. This has been expanded to include facilities owned or directed by American Osteopathic Association Bureau of Osteopathic Specialists Surgeons. The AAAASF does onsite evaluation every three years; in the intervening years, the facility performs and submits a self-evaluation to demonstrate continued compliance with AAAASF standards. The Basic Mandates of the AAAASF** are:

   • Surgical procedures should be of a duration and degree to permit safe recovery and discharge from the facility.
   • Patients receiving anesthetic agents other than topical or local anesthesia should be supervised in the immediate post-discharge period by a responsible adult for at least 12 to 24 hours, depending on the operation and anesthesia used.
   • Changes in facility ownership must be reported to the AAAASF Office within thirty (30) days.
   • Any death occurring in an accredited facility, or any death occurring within thirty (30) days of a surgical procedure performed in an accredited facility, must be reported to the AAAASF office within five (5) business days after the facility is notified or otherwise becomes aware of that death. In addition to this notification, the death must also be reported as an unanticipated operative sequela in the biannual Peer Review report. In the event of a death occurring within thirty (30) days of an operation done in an AAAASF accredited facility, an unannounced inspection will be done by a senior inspector.
   • All individuals using the facility must meet one of the following criteria:
     - A Doctor of Medicine certified or eligible for certification by one of the member boards of the American Board of Medical Specialties (ABMS medical or surgical specialty).
     - A Doctor of Osteopathy certified or eligible for certification by the American Osteopathic Association Bureau of Osteopathic Specialists (AOABS).
     - A podiatrist certified or eligible for certification by the American Board of Podiatric Surgery (ABPS).
     - An oral and maxillofacial surgeon certified or eligible for certification by the American Board of Oral and Maxillofacial Surgery (ABOMS).
   • Every physician, podiatrist, and oral and maxillofacial surgeon operating in an AAAASF accredited facility, must hold, or must demonstrate that they have held, unrestricted hospital privileges in their specialty at an accredited and/or licensed acute care hospital within thirty (30) minutes of the accredited facility for all operations that they perform within the facility. Only surgical procedures included in those hospital privileges may be performed within the AAAASF accredited facility. A physician must be present when anesthesia other than strictly local is being administered in Class B, Class C-M, and C accredited facilities.
3. **The Accreditation Association for Ambulatory Health Care (AAAHC) < www.aaahc.org >.** An organization is eligible for an accreditation survey by the AAAHC if it:

   - Has been providing health care services for at least six months before the onsite survey (excluding organizations seeking accreditation through the Accreditation Association Early Option Survey Program);
   - Is either a formally organized and legally constituted entity that primarily provides health care services, or a subunit that primarily provides such services within a formally organized and legally constituted entity that may be, but need not be, health related;
   - Is in compliance with applicable federal, state, and local laws and regulations, or for organizations operating in Canada, applicable federal, provincial, and local laws and regulations;
   - Is licensed by the state in which it is located, if the state requires licensure for that organization, unless the organization is applying for a survey that will be used to obtain licensure in a state that recognizes the Accreditation Association's accreditation program for this purpose;
   - Provides health care services under the direction of one of the following health care professionals:
     - doctor of medicine or osteopathy (MD/DO)
     - doctor of dental surgery or dental medicine (DDS/DMD)
     - doctor of podiatric medicine (DPM)
     - doctor of optometry (OD)
     - doctor of chiropractic (DC)
     - advanced practice registered nurse (APRN), in states where such providers can practice independent of physician supervision

   **Note:** These individuals or groups of professionals must accept responsibility for the health care provided by the organization and are licensed in accordance with applicable state laws.

   - Shares the facilities, equipment, business management, and records involved in patient care among the members of the organization;
   - Operates in compliance with the U.S. Equal Employment Opportunity Commission Rules and Regulations;
   - Provides the signed Application for Survey and other documents in advance of the survey;
   - Pays the appropriate fees;
   - Acts in good faith in providing complete and accurate information to the Accreditation Association during the accreditation or reaccreditation process.

Office-based surgical practices may also be subject to accreditation under the Clinical Laboratory Improvement Amendments (CLIA) < http://www.cms.hhs.gov/clia/> if they have an onsite laboratory. See § 13.03[B] for an in-depth discussion of CLIA. (See also Exhibit 14–35, Bases for Evaluation of Ambulatory or In-Office Surgical Facilities.)

[B] **OBS Practice Guidelines**

Several entities have provided guidelines relative to the performance of surgery in the physician office setting. Obviously, the standards promulgated by the accrediting bodies listed in the previous section either establish practice guidelines themselves or hold facilities to the cited standards of other professional organizations or licensing entities. In addition, several states have released guidelines for OBS as part of their laws and regulations for these facilities (e.g., Kentucky, North Carolina, Oklahoma, and South Carolina). The summary of the Kentucky State Board of Medicine's Guidelines for Office-Based Surgery, as adopted in December 2003, is found in Exhibit 13–2. OBS facilities in New York state must meet standards of care as set by the New York State Surgical and Invasive Procedure Protocol (NYSSIPP), which has been
applicable to “Hospitals, Diagnostic and Treatment Centers, and Individual Practitioners” since March 2007
(see Exhibit 13–3, on pages 13-28 to 13-32).

EXHIBIT 13–2. KENTUCKY 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), surgery 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 (Table 1)
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 I 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 II. 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 II. 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.

**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 noninvasive 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. Procanavamide

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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 interchange ability 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 percent 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.

**Table 2**

**Major Accrediting Agencies**

*American Association for Accreditation of Ambulatory Surgical Facilities, Inc. (AAAASF)*
EXHIBIT 13–3. NEW YORK STATE SURGICAL AND INVASIVE PROCEDURE PROTOCOL (NYSSIPP)

A. SCHEDULING

Scheduling must include:

1. Entire procedure, exact site, level, digit, and side/laterality (including spelling out "Left," "Right" and "Bilateral"—no abbreviations other than C-Cervical, T-Thoracic, L-Lumbar, S-Sacral when identifying spinal levels—e.g. L4-5).
2. Specific information on implant/implant system and/or equipment.
3. Specific information on removal of device.
4. Information on harvest and donor sites.
5. The Operating Room (OR), or the person responsible for accepting requests to schedule procedures, must verify the information provided by the surgeon/physician. The information should be verified in a manner agreed to by both the institution and physicians (read-back, fax, e-mail, etc).

B. CONSENT DOCUMENT

Consent documentation must include:

1. First and last name, date of birth of patient and medical record number of the patient.
2. Name and description of surgery or procedure in terms that are understandable to the patient (correct site/side, level and digit with the side spelled out as "Left," "Right" or "Bilateral").
3. No acronyms or abbreviations (except spinal levels noted in section A above).
4. Specific implant/implant system to be placed or device to be removed.
5. Patient/family/guardian/health care agent signature and date.
6. Witness signature and date.
7. Physician signature and date.
8. If the consent is altered or illegible it must be re-done and re-signed by all parties.

C. PRE-OPERATIVE/PRE-PROCEDURAL VERIFICATION PROCESS
Verification of the correct person, procedure site and side must occur (as applicable):

1. At the time the surgery or invasive procedure is scheduled.
2. At the time of admission or entry into the facility.
3. With the patient involved, awake and aware, if possible.
4. Anytime the responsibility for care of the patient is transferred to another caregiver or location in the pre-operative or pre-procedural process.
5. Before the patient leaves the pre-operative area or enters the procedure/surgical room.
6. In ALL clinical settings where invasive procedures are performed, including but not limited to endoscopy suites, catheterization laboratories, interventional radiology suites, intensive care units, labor and delivery areas, emergency departments, etc. There are recognized benefits to applying this to all bedside procedures.

A pre-operative or pre-procedural verification checklist must be utilized to ensure availability and actual review of the following, prior to the start of the procedure:

1. Relevant documentation: History & Physical, signed consent and any other documents required by the organization as part of the pre-operative evaluation process. The consent must be signed by the patient/legal representative, and surgeon.
2. Relevant images, properly labeled and displayed including photographs.
   - In “High Risk” procedures (as determined by the surgeon), the images should be reviewed by the surgeon and radiologist together pre-operatively.
   - Someone other than the primary surgeon confirms the name, date of the study and “Left-Right” orientation.
   - The surgeon is responsible for assessing what films/images are appropriate for viewing before and during the surgery.
   - When intra-operative imaging studies are performed, appropriate consultation should be available for interpretation of intra-operative studies.
3. Relevant diagnostic reports or studies (ultrasound, endoscopy, etc.).
4. Relevant pathology reports.
5. Necessary patient-specific implants and special equipment.
6. Confirm identity using two (2) identifiers, confirm procedure and site marking if appropriate.

D. MARKING THE OPERATIVE/PROCEDURAL SITE

1. The physician/dentist/podiatrist doing the procedure must do the site marking using his/her own initials. Site marking must be legible and unambiguous (see exceptions). Note: If the surgeon's initials are “N.O.,” utilize three initials.
2. All sites involving laterality (e.g. brain) and/or paired organs, multiple structures (fingers, toes, hernias, lesions) or multiple levels (spine). Make the mark at or near the incision site(s) so that it/they will be visible when the patient is draped. (See following exceptions).
3. For hand and foot surgery, the surgeon must mark the surface(s) of the digit to be operated on, anterior, posterior or both.
4. The appropriate site must be verified before any cast is split. For relevant orthopedic cases, the skin/site should be marked immediately after cast/splint is removed.
5. For surgery of the spine, pre-operative skin marking is required to indicate laterality, when appropriate. A second time out must be performed when the intra-operative imaging is done to confirm the level.
6. When the site or level is not visually identifiable, the surgeon must obtain an intra-operative image, using markers that will not move, to confirm the exact level/site.
7. Do NOT mark any non-operative site(s).
8. The mark must be visible in the operative field after the patient is prepped and draped.
9. The mark must be made using an FDA approved marker that is sufficiently permanent to remain visible after completion of the skin prep. Adhesive site markers should not be used as the sole means of marking the site.
10. In the event of multiple surgical procedures by different surgeons, all relevant surgical sites must be marked prior to the first surgery. The surgeon marking the site(s) must be present for and participate in the "time out" performed for each procedure he/she marks.

11. Marking must take place with the patient/family involved, awake and aware, if possible.

12. If a smaller mark is necessary, such as near the eye in Pediatric Ophthalmology cases, a dot near the eye constitutes the site marking. A special purpose wristband is also an option.

13. A special purpose wristband must be used for patients:
   - who refuse marking,
   - a neonate (as marking may cause a permanent tattoo),
   - problematic surgical site(s) to mark (e.g., perineum or anus) or when marking can be done only after shaving a patient's head prior to a neurosurgical/cranial procedure.
   - The first and last name of the patient, a second identifier, the anatomical site and name of the procedure must be written on the special purpose wristband.

14. Final verification of the site mark must take place during the "time out."

E. EXCEPTIONS TO SITE MARKING

1. Single organ cases, which do not involve laterality (e.g., hysterectomy, appendectomy).

2. Spinal block for pain management or epidural does not require an intra-operative marker if fluoroscopy is used. However, it does require skin marking.

3. Interventional cases for which the catheter/instrument insertion site is not predetermined (e.g., cardiac catheterization).

4. Dental cases, where the operative tooth number or name(s) can be indicated on documentation or the operative tooth (teeth) including laterality can be marked on the dental radiographs or dental diagram.

5. Endoscopic or other procedures done through a midline orifice.

6. Situations in which the primary pathology itself is plainly visible (single laceration).

7. When the operative pathology has been identified by real time imaging in the immediate pre-operative period such as for frameless stereotactic neurosurgical procedures or microcalcifications in a breast biopsy.

8. Life threatening emergency when any delay in initiating the surgery would compromise the safety or outcome of the patient (e.g., ruptured aortic aneurysm).

9. When movement of a patient to create a marking would compromise the safety or outcome of the procedure (e.g., movement of a patient with an unstable spine fracture.)

   NOTE: A practitioner is NOT exempt from the site-marking requirement when he or she is in continuous attendance with the patient (from the time of the decision to do the procedure through the conduct of the procedure). The requirement for "time out" applies as well. This is based on reports of wrong-sided procedures being done despite the continued presence of the person performing the procedure from time of decision to completion of the procedure.

F. "TIME OUT" IMMEDIATELY BEFORE STARTING THE PROCEDURE

Purpose: To conduct a final verification of the correct patient, site/side, procedure and, as applicable, implants.

The "time out" must be conducted in the location where the procedure will be done, after the patient is prepped and draped and just before starting the procedure. This applies to all invasive procedures performed in all settings. All work should cease during the "time out" to allow all members of the team to focus on the "time out." For instances when the procedure is being performed without assistance, it is strongly advised to enlist an observer or assistant to participate in the "time out." It must involve the entire operative/procedural team, use "active communication," and be documented. The "time out" is a standardized procedure, and documentation indicates the procedure was followed in its entirety without deviation.

"Time out" includes the following:

1. Identification of the patient using 2 patient identifiers, such as, name (first and last) and a second identifier as determined by the organization.
2. Identification of the correct site and side(s).
3. Procedure to be performed and proper patient position.
4. Availability of correct implants and any special equipment or special requirements.
5. Verification of the wristband and chart takes place as the patient is brought into the room and before the "time out." The "time out" requires that all participants agree on the information and does not require checking the wristband at that time.
6. Radiological review, when germane to the case (see below).

The above information should be confirmed with the medical record and should be documented along with the identification of those who participated in the "time out."

Additional Confirmatory "Time out" should be undertaken if a new surgeon arrives and is assuming primary responsibility for the case, or if the patient/operative site is re-draped. The name of the patient and the procedure should be verified during this second "time out."

Radiological Review: The surgeon performing the operation is responsible for determining that the images to be displayed are relevant to the surgery. A second team member confirms that the image belongs to the patient (first and last names and second identifier) and that the image is displayed in the correct orientation, using markers on the image. The team confirms the site and side of the lesion as part of the "time out."

- For spinal cases in which an intra-operative image is used to determine the spinal level, a second "time out" must be performed to review the image and correlate with intra-spinal markers.

Procedures Performed Outside the OR: The person(s) performing the procedure must conduct and document the "time out" confirming all of the above information with another person when possible.

For Surgical Procedures: Instruments/equipment are not offered until after the "time out" is performed. STOP the procedure if there is any discrepancy in information identified by any member of the surgical team. Resolve the discrepancy or disagreement before proceeding.

Required Policy and Procedure

All organizations must have a policy and procedure that incorporates the contents of NYSSIPP, and ensures that the requirements for patient identification, site marking, pre-operative/pre-procedural verification, and "time out" are consistently followed whenever invasive procedures are performed, including, but not limited to procedures performed in the operating room, radiology, obstetrics/labor and delivery, emergency departments, cardiac catheterization lab, clinical units, and out-patient areas. The institutional policy and procedure must specify the actions to be taken when a discrepancy occurs at any step in the process.


In addition, national specialty organizations are also a source of practice guidelines and standards with regard to office-based surgery. Surgeons operating in an office-based setting will be expected to meet the standards or guidelines of their national specialty organizations as well; for example, for plastic surgeons, the American Society of Plastic Surgery (ASPS) Practice Advisory, Procedures in the Office-based Surgery Setting;\(^\text{11}\) the American Society for Dermatologic Surgery (ASDS) Position Statement on office-based surgery;\(^\text{12}\) and the American College of Surgeons (ACS) Guidelines for Optimal Office-Based Surgery\(^\text{13}\) and Patient Safety Principles (\textit{Exhibit 13–4}).

Physician practices doing office-based surgery have to determine the specific state laws and licensing regulations applicable to them based on the type(s) of surgery and specific procedures being performed and develop facility policies and procedures accordingly to assure compliance and patient safety. The same holds true of applicable specialty organizations and their standards, guidelines, or practice advisories on surgery in the physician office setting.

Other good sources of guidelines on the performance of OBS are state medical societies (e.g., the Massachusetts Medical Society issued \textit{Office-Based Surgery Guidelines}\(^\text{14}\) in 2004) and quality improvement groups like the Michigan Quality Improvement Consortium, which released its \textit{Guideline on Office-Based Surgery}\(^\text{15}\) in March 2009.

\(^\text{11}\) \textit{Exhibit 13–4}.
[C] Patient Safety

As discussed earlier in the chapter, the issue of patient safety has been closely tied to the performance of surgical procedures in the physician office setting—probably since the first internist proposed doing a colonoscopy in a his or her office, or the first ophthalmologist decided to do cataract surgery in an office OR, or a general surgeon first offered in-office laparoscopic repair of inguinal hernias, or again when a urologist said, "I'm going to do in-office vasectomies," and then again when the plastic surgeons jumped on the band wagon, offering their patients office-based surgery and a level of privacy far beyond what could be expected if the procedure were done in a hospital setting, something especially appealing to the cosmetic surgery patient. But then the problem cases began appearing in the news, and the patients and their families told their stories on the Today Show, Oprah, and Dr. Phil.

The physician office setting does have some advantages to offer both surgeon and patient. For the surgeon, there are few or no scheduling hassles booking an OR or lining up an anesthesia or surgical support team; no unknowns as to the experience and skills of the personnel involved; and usually higher surgeon reimbursement, just to name a few. For the patient, having surgery in a physician office has advantages as well, including wider schedule options; less risk of infection; increased privacy; and usually a reduced price over the cost of the same procedure in a hospital or ambulatory surgical center, something that has high importance when the patient is paying out-of-pocket, for example, for an elective, cosmetic procedure.

However, there are associated disadvantages and risks when the surgery takes place in an office setting. A major benefit of a surgeon's performing a procedure in a traditional hospital setting is the quick and easy access to all the hospital's available resources—human, equipment, pharmacy, medical supplies, etc.—should something go contrary to plan during the procedure. There are just more people readily available not only to provide help in an emergency but also to possibly recognize the impending trouble sooner. Even the best equipped office surgical suite with the best surgeon and support personnel can't match that benefit when faced with an unexpected intra- or postoperative complication. A physician practice performing OBS must be able to not only identify possible risks inherent in surgery in a nonhospital setting but also have personnel, systems, and equipment in place to manage those risks, before the first surgical patient sets foot in that office.

EXHIBIT 13–4. ACS PATIENT SAFETY PRINCIPLES FOR OFFICE-BASED SURGERY UTILIZING MODERATE SEDATION/ANALGESIA, DEEP SEDATION, OR GENERAL ANESTHESIA

Click to Launch

Exhibit 13–4.1 presents a list of general risk management strategies for OBS practices.

EXHIBIT 13–4.1. RISK MANAGEMENT STRATEGIES FOR OFFICE-BASED SURGERY PRACTICES

A number of practical enterprise risk management strategies can help address office-based surgery practices. These strategies are applicable to both hospital-owned and independent office-practice programs and include more than those that offer cosmetic procedures. Hence, the strategies are useful for dental surgery offices and those who engage in restorative and interventional treatment programs. These strategies include the following:


Conduct a complete review of clinical practices in the office-based surgery practice that takes into consideration patient screening, preparation, anesthesia, recovery, and documentation practices. Develop a plan to modify those practices in need of improvement.

2. Use a Comprehensive GAP Assessment Tool.

Take into consideration applicable state law and regulation requirements as well as accreditation requirements when designing the GAP assessment tool. Incorporate into the tool relevant federal requirements that address accessibility (Americans with Disabilities Act), HIPAA, and provisions that address
the need for assistance with language interpretation. Recognize that state and federal requirements set *minimum* standards. Building in practice criteria can help facilitate good risk management and patient safety for the delivery of office-based surgical procedures.


Follow guidance from respected, national professional groups in the selection of patients who want to undergo elective surgical procedures in the office-based setting. In taking such an approach consider important guidance from anesthesia providers such as the American Association for Nurse Anesthetists (www.aana.org). Implement a process for careful screening and good “drill down” questions to identify those patients for whom it may be prudent to consider procedures in an ambulatory surgery center or an acute care facility.


Make certain that office policies, procedures and protocols follow prudent methods for staff hiring, training and demonstrated competencies for the office-based surgery practice. Build into contracts with staffing agencies or agreements with anesthesia providers appropriate requirements for demonstrated competencies in the office-based surgery practice.

5. Stress the Importance of Team Management Training.

Recognize that intra-operative and post-operative care management is important in terms of patient safety and risk management. Reinforce this point with team on team training and requiring demonstrated proficiencies for all involved in the clinic care of office-based surgery patients. Address identified opportunities for improvement.


Implement effective comprehensive communication practices with patients. Offer clear instructions on how to prepare for the procedure, what to do if the patient becomes ill prior to elective surgery, and what to bring and not to bring on the day of surgery. Follow established state requirements on informed consent to surgery. Build into the consent process information about the choice to have the procedure done in a healthcare facility rather than an office-based setting. Make certain that the consent process is documented in accordance with state requirements, and, when relevant, applicable accreditation standards.

7. Emphasize the Importance of Complication Management.

Anticipate the potential for complications to occur at any stage of a patient’s office-based surgery experience. Provide clear and concise guidance for managing complications. Include in this approach immediate access to cardiac resuscitation, rescue medication from anesthesia-induced malignant hyperthermia, rescue kits for allergic reactions and other essential approaches to avoid permanent untoward outcomes in the office-based surgery practice.

8. Have a Dedicated Transfer Agreement.

Work with legal counsel on implementing a transfer agreement for prompt transfer of patients with complications to an acute care facility.


Make certain there is in place a comprehensive infection control program for the environment of care in which surgical procedures are performed in the office based setting. Include in this plan specifications for sterilization, cleaning and disinfecting equipment. Encourage use of a quality control audit for infection control. Address identified opportunities for improvement.

10. Implement Effective Post-Operative Recovery Plans.

Follow national standards, guidelines and “good practices” in the design and implementation of post-operative, office-based surgery recovery plans. Examine carefully staffing, equipment requirements as well as the propriety of patients “boarding” overnight in the office-based practice. Built into the plan “safe practices” for ambulation following conscious sedation and anesthesia.

11. Close the Loop on Discharge Instructions.
Implement a patient-oriented discharge process for patients who have undergone office-based surgical procedures. Consider a number of practical issues such as:

- Medication
- Diet
- Level of activity
- Return to work
- Possible complications
- What to do if a complication occurs
- Scheduling follow-up visits
- Who to call regarding questions
- Teach-back on information provided
- Health literacy level of written information

Documentation of the discharge process is important, including who completed it, the time, date, and staff member's name and signature. Identifying who was the responsible person with the patient at the time of discharge is important as it helps to reinforce the process in most office-based surgery practices that the patient has an identified individual accompanying him or her.


Develop a process for secure storage of patient belongings in the office-based surgery setting. Take into consideration wallets, watches, handbags, cell phones, hearing aids, eyeglasses and dentures. Consider lockers and documentation of the "safe storage" process.


Provide orientation and in-service education to office staff personnel on their respective roles and responsibilities. Include in this process reception personnel and administrative support staff. Give them guidance on how to handle patient or family calls or requests, especially with respect to questions about postponing the procedure or post-operative complaints and complications.

14. Close the Loop with Follow-Up Calls.

Develop a set of questions for designated personnel to use when calling post-procedure patients. Use the calls to identify possible complications or side effects that mitigate to encouraging a visit to the practice or encouragement to seek emergency medical attention. Build in an "escalate call" process for complications, side effects complaints or expressions of dissatisfaction. Document the date and time of the call, and the name of the person with whom the staff member communicated.


The most common Patient Safety/Risk Management issues associated with OBS are discussed below.

[1] Appropriate Patient: Patient Screening and Assessment

Not every patient is a candidate for surgery in an outpatient setting, nor should every surgical procedure be performed outside a hospital OR. Every OBS facility should have written procedures and guidelines with regard to patient assessment and selection as a candidate for OBS. A complete preoperative history (health, family, social, and physician exam) is imperative. Most offices utilize the American Society of Anesthesiology (ASA) Physician Status Classification System\(^\text{16}\) to determine a patient's potential for complications, and an accurate assessment and status assignment are extremely important. Generally, P1 and P2 patients are considered appropriate for office-based surgery. Some OBS facilities will allow a P3 patient to have surgery as an outpatient, depending on such things as the specific surgery, the type of anesthesia involved, and the absence of co-morbidities and associated risks; others make level P2 and under the office policy in this regard. Obviously, if an office's written protocols indicate that surgery will only be performed on P1 and P2 patients, there should be no deviation from that policy. There is no good reason to take that risk.
The facility's routine assessment protocol should include preoperative testing, such as ECG, preoperative blood work, and chest x-ray, with the results of these tests used in the final determination of whether the patient is an appropriate candidate for OBS.

Assessment should also include determination of anticipated length of the procedure to be performed—will there be sufficient time for the procedure itself, adequate patient recovery time, and discharge time within the normal office hours—and consideration of anticipated blood loss during the procedure. (The ASPS guidelines recommend that any procedure with a potential blood loss over 500 mL should not be performed as OBS.\textsuperscript{17}) These are important factors in the surgeon's ultimate decision of whether the procedure will be done in hospital or as OBS.

\textbf{Exhibit 13–5} is a sample preoperative patient safety checklist for OBS developed by the American Academy of Orthopaedic Surgeons as part of its "TAKE CARE! Patient Safety Is No Accident" campaign. \textbf{Exhibit 13–5.1} is a sample health history form that may be sent to the primary care physician or the referring physician for completion before the day of surgery. \textbf{Exhibit 13–5.2}, Nursing Preoperative Screening, can be used for nursing preadmission before the day of surgery—either for telephone or in-person screening per facility policy and procedure.

\section*{[2] Appropriate Physician/Staff: Credentialing}

A physician practice performing OBS should have written credentialing guidelines and procedures in place for all clinical staff positions, with detailed descriptions and requirements available for each position. Surgeons working in the office practice should be required to provide evidence of training in procedures they will be performing, proof of board certification or board eligibility, and privileges to perform comparable surgical procedures at a local hospital or ambulatory surgical center. Physician staff members should be expected to keep up to date on developments within their particular field or area of expertise by meeting CME requirements of their specialty organization, medical society, or state. Credentials should be kept on file for each provider and verified on a regular basis.

The provider delivering anesthesia in the office should be appropriately trained, licensed, and especially if a nonphysician, working within his or her defined scope of practice and appropriately supervised in compliance with state licensure or medical board regulations. Most practices performing OBS require the anesthesiology staff (or at least one member of the staff per shift) to maintain current training or certification in advanced resuscitative techniques, such as ATLS, ACLS, or PALS; documentation of up-to-date certification should be kept on file in the practice.

\textbf{EXHIBIT 13–5. OFFICE-BASED SURGERY, PATIENT SAFETY CHECKLIST, PREOPERATIVE}

Click to Launch


\textbf{EXHIBIT 13–5.1. HEALTH HISTORY FORM}

Click to Launch


\textbf{EXHIBIT 13–5.2. NURSING PREOPERATIVE SCREENING}

Click to Launch


\section*{[3] Adequate Equipment/Facilities}
Obviously, a physician practice cannot decide one day to start doing office-based surgery and do the first surgical procedure the next. After the decision, significant planning is involved to make sure the physical facilities and equipment are adequate to safely perform the planned surgical procedures. While equipping and outfitting an office surgical suite is beyond the realm and expertise of risk management, a physician OBS practice that is accredited by one of the recognized accrediting bodies (AAAASF, AAAHC, Joint Commission) and licensed in accordance with state requirements should be appropriately equipped to perform surgery in a safe environment for patients and staff.

Special consideration should be given to pediatric patients, morbidly obese patients, and the elderly. OBS may not be right for these categories of patients because of their particular needs and limitations. For example, does the office have the specialized airway and supplies that a pediatric patient will require routinely available? Are the practice's existing surgical equipment and supplies—even the OR table itself—adequate to safely and comfortably accommodate a patient who weighs over 300 pounds? Are there pediatric or oversized wheelchairs available? Facilities accepting pediatric or obese patients have to ensure that monitoring equipment, medical supplies, and emergency resuscitative equipment are appropriately sized to fit these patients and in stock when needed.


The importance of providing a patient scheduled for OBS with adequate information about the procedure he or she will undergo and the facility in which it will be performed cannot be understated. As with any surgical procedure, the surgeon needs to comply with informed consent requirements of his or her state of practice. Most states require, at a minimum, a description of the procedure, the reason why the surgeon is recommending the procedure, the potential risks of the procedure, the alternative treatment(s) available, and the consequences of no treatment. The informed consent discussion should be given by the surgeon (or his or her designated representative if permitted by state law) to the patient, allowing the patient adequate opportunity and time for questions and concerns. (See also Chapter 6, Consent to Treatment.)

The physician should also document the discussion that took place with the patient, including what was discussed, any questions asked by the patient, and answers given by the physician. A separate informed consent discussion should take place between the patient and the anesthesiologist to go over the same information as it applies to the delivery of the specific anesthesia selected for that patient. In some practices, one consent form may be used that covers both surgery and anesthesia. Keep in mind, however, that informed consent is not a form; it is the process of informing the patient. It is the discussion between the patient and physician that provides the patient with adequate information to make an informed decision about whether or not to consent to the recommended surgery.

Aside from the informed consent discussion, patient education should include information about the procedure being performed and, when the procedure is being performed in an office-based surgical facility, about OBS in general. This should be uniformly and routinely done—that is, all patients undergoing the same procedure receive the same patient education material about that procedure—and documented in the patient’s record (e.g., patient given standard materials on laparoscopic herniorrhaphy, 4/5/09). A good practice is to maintain a set of all patient education materials in a file so that, should the need arise, for instance, to defend against a patient's allegations that “I didn't know I'd have a scar like that,” the practice can quickly present the patient educational material given to that patient.

A risk management concern with OBS is that patients may tend to minimize the seriousness of the procedure and its possible risks and complications because of its performance in a nonhospital setting: “If this were something serious, I'd have to go to the hospital to have it done. It's just one of those 'in-and-out' things.” This type of misunderstanding and misinformed patient expectations can lead to very unhappy patients and patient families when something does go wrong in the office surgical suite. Patient education using printed material or audiovisual information can be extremely helpful in this regard. For instance, the ASA has a patient information brochure specifically on anesthesia for ambulatory surgery in its Anesthesia and You series. Many physician practices performing OBS develop information brochures on the practice that can be very helpful in this regard as well. Exhibit 13–6 is a patient information sheet, Tips for Outpatient Surgery, developed and distributed by the Pennsylvania Department of Health to educate patients about...
what to expect, what questions to ask, and what information to provide, all to make the outpatient surgical experience safer and help achieve a good outcome.

EXHIBIT 13–6. TIPS FOR OUTPATIENT SURGERY

The number and types of medical procedures and surgeries performed in outpatient facilities—facilities that are outside of a traditional hospital setting—are on the rise. Advances in medical technology allow physicians to provide high-quality care in an outpatient setting and, in some situations, consumers prefer the convenience of outpatient facilities. Many procedures once performed in a hospital, requiring several days of hospitalization, are now performed in an outpatient setting. And an individual undergoing an outpatient procedure can often be released within several hours.

Although more procedures can now be performed in an outpatient setting, it is still important to thoroughly discuss health issues with your physician prior to any procedure or surgery.

The Department of Health offers the following tips to patients considering outpatient surgery:

• Provide your physician with your complete medical and surgical history; include all previous surgeries and anesthesia services, including dental procedures;
• Provide your physician with a list of all medications you are taking, including over-the-counter medications, vitamins and supplements;
• Tell your physician if you use tobacco, alcohol or other substances; this information is important because such substances can affect recovery from anesthesia and surgery;
• Inform your physician if you have had any allergic reactions, particularly if related to anesthesia; also include information about family members who may have had allergic reactions or other complications related to surgery or anesthesia;
• Make sure you understand who will perform the surgical procedure and who will be providing the anesthesia services; it is not unreasonable to ask providers about their experience in providing these services or the experience of the staff at the facility; this is particularly important when services are being provided to children;
• Ambulatory surgical facilities (ASF) performing certain procedures must have a license issued by the Department of Health; it is not unreasonable to ask if the particular procedure you are having done must be performed in a licensed ASF and whether the facility has such a license;
• Make sure you understand the manner in which your physician, other health care providers and the facility are prepared to handle emergencies or complications that may occur; it is wise to ask if individuals at the facility are certified in Cardio Pulmonary Resuscitation (CPR), Advanced Cardiac Life Supports (ACLS) and, in the case of children, Pediatric Advanced Life Support (PALS); also, it is reasonable to ask about what plans are in place in the event that emergency transportation to a local hospital is required;
• Make sure you understand who will provide your post-operative care and what you can expect during your recovery at the facility; ask how long you should expect to stay and have a plan for how you will get home;
• Make sure you understand who will be responsible for your care once you are discharged from the facility; make sure you understand all of the instructions that are provided prior to your discharge from the facility; if possible, have a family member or a friend accompany you to help you better understand the instructions that are provided;
• Make sure you know who you should contact if you have questions or experience any problems once discharged.


[5] In the Operating Room

From a risk management perspective, the care the patient receives in the operating room of a physician office practice should be consistent with care in any operative setting and in compliance with established standards and procedures for anesthesiology and surgery and patient safety in an OBS. This includes site marking and verification techniques, a "time out" before beginning to confirm correct patient, correct side/site,
correct procedure, correct position, and correct equipment (including emergency equipment), medications, and supplies ready and waiting.

See also § 8.04[D] of Chapter 8, Patient Safety, and Exhibits 8–15 through 8–23 for more on right site, right patient, right procedure protocols.


The patient should be monitored in recovery by staff, with the surgeon remaining onsite until the patient is discharged. It is also important to require that at least one staff member who has been trained in advance resuscitation is present in the office until all surgical patients are discharged. Discharge criteria should be established and in writing and should include, minimally, vital signs, patient responsiveness and orientation, pain evaluation, and patient voluntary movement.

The OBS facility should have standard printed discharge instructions for each procedure performed there. The instructions should provide information on what the patient can expect postoperatively and the next day with regard to wound appearance, pain, and so on; instructions about what potential complications to be alert for that would warrant an immediate call to the physician's office (with after-hours contact and numbers provided); any diet restrictions; when to resume normal activities, bathe, drive, or return to work; and when to follow up with the surgeon or with the patient's referring physician. And, of course, these printed instructions should contain adequate space to include patient-specific instructions as well. The patient should also be given any prescriptions for postoperative pain medications with appropriate instructions for pain management.

Exhibit 13–7 is a sample postoperative patient safety checklist for OBS developed by the American Academy of Orthopaedic Surgeons as part of its "TAKE CARE! Patient Safety Is No Accident" campaign.

If the patient had general anesthesia, sedation, or regional block, discharge materials and instructions must be given to another adult family member or friend who has accompanied the patient or is present to provide transportation home.

See also Chapter 14, § 14.03[B][4], Safe Passenger; § 14.03[B][5], Discharge Instruction; and § 14.03[B][6], Follow-up.

EXHIBIT 13–7. OFFICE-BASED SURGERY, PATIENT SAFETY CHECKLIST, POSTOPERATIVE

Click to Launch

[7] Emergency Transfer

A final caveat for practices performing OBS. Policies and procedures must be in place and in writing that address the need for emergency transfer of a surgical patient should the need arise, be it a medical, surgical, or anesthesia emergency. Again, this is an accreditation requirement, so an accredited facility should be prepared for such an event. But it is something that bears repeating: the facility must have the necessary personnel, resuscitative equipment and medications, and other resources needed to respond to a patient emergency promptly and provide initial management and stabilization until emergency transfer is complete. Staff should be adequately trained to handle the emergency, including knowing how and who to contact in emergency medical services for prompt and seamless patient transportation.

An office should have transport arrangements in place with a nearby acute care hospital to accept emergency transfer of patients and any nonemergency patients who will require admission because of not meeting the facility's criteria for discharge to home.

Footnotes

2 B. LaMendola, Study: Surgery performed in doctor's office has higher risk, South Florida Sun Sentinel, (Mar. 30, 2008).


6 Surgeon includes physicians, dentists or podiatrists who meet the definition of a licensed independent practitioner (LIP). An LIP, as defined by the Joint Commission, is an individual permitted by law and by the practice to provide care, treatment and services without direction or supervision, within the scope of the individual's license.


8 See the American Association for the Accreditation of Ambulatory Surgical Facilities Web site: <http://www.aaaasf.org/pub/mandates.htm>.


11 See the American Society of Plastic Surgeons Web site: <http://www.plasticsurgery.org/>.


16 Available at <http://www.asahq.org/clinical/physicalstatus.htm>.


18 American Society of Anesthesiologists through the cooperative efforts of the Society's Committee on Ambulatory Surgical Care and Committee on Communications, "Anesthesia & You ... Anesthesia for Ambulatory Surgery" (Copyright © 2008), available at <http://www.asahq.org/patientEducation/ambulatoryAnes.pdf>.
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| AL    | CHAPTER 540-X-10. OFFICE-BASED SURGERY.  
540-X-10-01. Preamble.  
540-X-10-03. Standards For Each Level Of Anesthesia--Preoperative Assessment.  
540-X-10-04. Standards For Office-Based Procedures--Local Anesthesia.  
540-X-10-05. Standards For Office-Based Procedures--Minimal Sedation.  
540-X-10-06. Standards For Office-Based Procedures--Moderate Sedation/Analgesia.  
540-X-10-09. Recovery Area And Assessment For Discharge With Moderate And Deep Sedation/General Anesthesia--Monitoring Requirement.  
540-X-10-10. Reporting Requirement.  
540-X-10-12. Penalty. | Effective November 2003, the Alabama State Board of Medical Examiners adopted rules on office-based surgery. The rules require physicians who maintain office-based surgical practices to register with the Board. The rules define levels of anesthesia and provide standards for its administration. The rules list requirements for the office setting, including equipment and supplies; medical record maintenance and security; reporting of specific events; emergency and transfer planning; and quality improvement measures. |
| AZ-M  | ARTICLE 7. OFFICE-BASED SURGERY USING SEDATION.  
R4-16-701. Health Care Institution License  
R4-16-702. Administrative Provisions  
R4-16-703. Procedure and Patient Selection  
R4-16-705. Perioperative Period; Patient Discharge  
R4-16-706. Emergency Drugs; Equipment and Space Used for Office-Based Surgery Using Sedation  
R4-16-707. Emergency and Transfer Provisions | Effective January 8, 2008, Arizona Medical Board rules require physicians who use general anesthesia in their office or other outpatient setting to obtain a health care institution license. Administrative provisions require written policies and procedures on patient's rights, informed consent, emergency care, and transfer of patients. Gives guidelines on staff member assistant's qualifications, space and equipment, sedation monitoring standards, and requires physician to be physically present in the room where surgery is performed. |
§ 32-1401(20). (Defines office-based surgery)  
§ 36-402. (Generally exempts physician offices and clinics from registration as health care institutions under certain conditions) | - |
| AR    | - | - |
| CA-M  | Article 11.5. SURGERY IN CERTAIN OUTPATIENT SETTINGS.  
§ 2215. Findings and intent  
§ 2216. Procedures prohibited in outpatient setting  
§ 2216.1. Unprofessional conduct; minimum number of staff persons; licensure | California passed enabling legislation in 1999 to improve patient protection during surgeries and procedures performed in out-of-hospital settings. The basic provisions apply to all outpatient surgery settings whether they are licensed surgical clinics, certified ambulatory surgical |
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<td>§ 2216.2. Failure to provide adequate security by liability insurance</td>
<td>centers, or physicians’ offices and whether or not they are accredited by the state as an outpatient surgery facility. The Act requires reporting of procedures performed in outpatient settings that result in death or transfer to a hospital or emergency center for a period exceeding 24 hours to be reported to the Board. The legislation prescribes minimum staffing requirements and requires physicians to have adequate liability insurance. Outpatient settings are required to post their certificate of accreditation in a visible location. Oversight is through the Medical Board of California.</td>
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<td>Policy Statement 40-12. Office-Based Surgery and Anesthesia.</td>
<td>In November 2001, the Colorado Board of Medical Examiners adopted a policy statement concerning office-based surgery and anesthesia. The policy identifies the</td>
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§ 13.01[A] HEALTH CARE ORGANIZATIONS RISK MANAGEMENT

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<td>DE</td>
<td>§ 19A-400m: Development of surgery protocols by hospitals and outpatient surgical facilities.</td>
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**COMMENT**

- Effective July 2001, the State of Connecticut requires facilities operated by a licensed health care practitioner, using certain designated levels of anesthesia, to be accredited by the American Association for Accreditation of Ambulatory Surgery Facilities, Inc., or the Joint Commission on Accreditation of Healthcare Organizations. Includes any entity other than a hospital providing surgical services or diagnostic procedures for human healthcare utilizing designated surgical areas. Excludes procedures, practices provided if: (1) has no operating room or designated surgical area; (2) bills no facility fees to third party payers; (3) performs only minor surgical procedures; and (4) medical office of the physician or physician's office. Requires each hospital and outpatient surgical facility to develop protocols for accurate identification procedures.
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<td>The D.C. Board of Medicine issued an advisory in April 2000 that the Board would follow guidelines issued by the American Society of Anesthesiologists in assessing whether an acceptable standard of care had been met in cases involving office-based anesthesia. Those guidelines address requirements for a medical director and standards for operating room personnel; facility standards; minimum equipment standards; standards for clinical and preoperative care; and a protocol for emergencies and timely transfer of patients in emergency situations. (ID #40095)</td>
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       | 64B8-9.0091. Requirement for Physician Office Registration; Inspection or Accreditation.  
<pre><code>   | 64B8-9.0092. Approval of Physician Office Accrediting Organizations. | In March 2002, the Board adopted Standards of Care for Office Surgery. The rule defines office surgery and levels of surgery and sets out general requirements for office surgery, including: examination and evaluation of the patient; written informed consent from the patient; and maintaining a log of surgical procedures. The rule adopts the “Standards of the American Society of Anesthesiologists for Basic Anesthetic Monitoring” and specifies requirements and qualifications for anesthesia providers. The rule specifies the training required for surgeons, equipment and supplies required in the office setting, and requirements for transfer agreements and emergency protocols. The requirements for surgeons and anesthesia and the surgical setting vary according to the level of the surgery. |
</code></pre>
<p>| FL-O  | 64B15-14.007. Standard of Care for Office Surgery. | The rule defines office surgery and levels of surgery and sets out general requirements for office surgery, including: examination and evaluation of the patient, written informed consent from the patient, and maintaining a log of surgical procedures. The rule adopts the “Standards of the American Society of Anesthesiologists for Basic Anesthetic Monitoring” and specifies requirements and qualifications for anesthesia providers. The rules specifies the training required for surgeons, equipment and supplies required in |</p>
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<td>the office setting, and requirements for transfer agreements and emergency protocols. The requirements for surgeons and anesthesia and the surgical setting vary according to the level of the surgery.</td>
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<tr>
<td>IL</td>
<td>1285.340 Anesthesia Services in an Office Setting.</td>
<td>In April 2002, the Illinois Department of Professional Regulation adopted rules relating to physician supervision of CRNAs that require the supervising physician or anesthesiologist to be physically present and available on the premises during the delivery of anesthesia services. When anesthesia services are provided in an office setting, the operating physician must have training and experience in the delivery of anesthesia services in order to administer anesthesia or supervise the administration by a CRNA. The rule specifies training and experience requirements. When anesthesia is being administered in an office setting, the operating physician or anesthesiologist, or CRNA, must have documented current Advanced Cardiac Life Support (ACLS) certification. The rule also specifies what procedures are not required to comply with the rule.</td>
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<td>IN</td>
<td>RULE 5. STANDARDS FOR PROCEDURES PERFORMED IN OFFICE-BASED SETTINGS THAT REQUIRE MODERATE SEDATION/ANALGESIA, DEEP SEDATION/ANALGESIA, GENERAL ANESTHESIA, OR REGIONAL ANESTHESIA.</td>
<td>Rules include requirement that practitioner who performs procedures using anesthesia or one directing administration of anesthesia in an office-based setting have admitting privileges at a nearby hospital, a transfer agreement with another practitioner who has admitting privileges at a nearby hospital, or an emergency transfer agreement with a nearby hospital; ensure that a patient's informed consent is obtained in writing before the procedure is performed; show competency by maintaining privileges at an accredited or licensed hospital or ambulatory surgical center; have agreement with local emergency medical service (EMS) for transfer of patients to the hospital in case</td>
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- Rules

- 5-5-1 Purpose
- 5-5-2 Application of rule
- 5-5-3 "Accreditation agency" defined
- 5-5-4 "American Society of Anesthesiologists (ASA) Physical Status Classification System" defined
- 5-5-5 "Anesthesia" defined
- 5-5-6 "Deep sedation/analgesia" defined
- 5-5-7 "General anesthesia" defined
- 5-5-8 "Health care provider" defined
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<td>5-5-9 &quot;Immediate presence&quot; defined</td>
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<td>5-5-11 &quot;Minimal sedation/anxiolysis&quot; defined</td>
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<td>5-5-12 &quot;Moderate sedation/analgesia&quot; defined</td>
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<td>5-5-13 &quot;Office-based setting&quot; defined</td>
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<td>5-5-14 &quot;Practitioner&quot; defined</td>
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<td>5-5-15 &quot;Regional anesthesia&quot; defined</td>
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<td>5-5-16 &quot;Rescue&quot; defined</td>
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<td>5-5-17 &quot;Superficial nerve block&quot; defined</td>
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<td>5-5-18 &quot;Topical anesthesia&quot; defined</td>
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<td>5-5-19 Standards for procedures performed in office-based settings</td>
<td>of an emergency, as well as written procedures for peer review.</td>
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<td>5-5-20 Accreditation required</td>
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<td>5-5-21 Approval of accreditation agencies; requirements</td>
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<td>5-5-22 Practitioners requirements</td>
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**IA** - 

**KS** - ARTICLE 25. OFFICE REQUIREMENTS.  
100-25-1 Definitions.  
100-25-2 General requirements.  
100-25-3 Requirements for office-based surgery and special procedures.  
100-25-4 Office-based surgery and special procedures using general anesthesia or a spinal or epidural block.  
100-25-5 Standard of care.  

Effective August 2005, rules provide requirements for general direct patient care in addition to requirements for office-based surgery and special procedures. Defines levels of anesthesia and other relevant terms. Office-based surgery rules address personnel, equipment, administration of anesthesia, and administrative policies and procedures. Standard of care established by regulations of Article 25.

**KY** - Guidelines for Office based Surgery  

The Board adopted guidelines in December 2003, which differentiate between Level I, Level II, and Level III offices based on the types of procedures performed and associated levels of sedation or anesthesia required for such procedures; Level II and III facilities should be accredited by recognized authority. Office administration provisions encourage development and implementation of policies and procedures on emergency care and transfer planning, medical record maintenance and security, infection control, performance improvement, reporting of adverse incidents and compliance with federal and state laws and regulations. Standards for office procedures address training required, equipment and supplies availability, and the assistance of
### § 13.01[A] HEALTH CARE ORGANIZATIONS RISK MANAGEMENT

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The Board endorsed the Massachusetts Medical Society’s Office-Based Surgery Guidelines in December 2004. The guidelines focus on surgical procedures in non-hospital settings that require anesthesia.
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<td>Statement/Guidelines</td>
<td>or sedation. The guidelines propose minimum standards for three classifications of office settings based on the level of anesthesia and the complexity of the surgery. The guidelines reference ASA guidelines for office-based surgery in regard to anesthesia. The guidelines address patient admission and discharge; office administration, including plans for emergency care and transfers to hospitals if needed; handling of medical records; documentation and administration of anesthesia; infection control policies; performance measurement; reporting of adverse incidents; compliance with federal and state regulations; and the patient’s bill of rights. They also address credentialing of practitioners; training of other health care personnel; facility accreditation; and minimum standards for equipment and supplies.</td>
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<td>50 013 001. Chapter 15. Office Based Surgery.</td>
<td>The MS Board adopted rules and regulations pertaining to office-based surgery in June 2002. An office-based surgery procedure is designated as Level I, II, or III with associated requirements related to scope of permitted procedures to be performed; level of anesthesia required; training for health care personnel; and equipment and supplies. The rules apply to the practice of medicine, osteopathic medicine and podiatry and specify general requirements for office surgery that include sterilization procedures; maintenance of medical records; a log of all Level II and Level III surgical procedures; specific requirements for liposuction; a policy and procedures manual; reporting the occurrence of certain surgical events to the Board of Medicine; and a written response plan for emergencies.</td>
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### § 13.01(A) HEALTH CARE ORGANIZATIONS RISK MANAGEMENT

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| NJ    | **SUBCHAPTER 4A. SURGERY, SPECIAL PROCEDURES, AND ANESTHESIA SERVICES PERFORMED IN AN OFFICE SETTING**<br>13:35-4A.1 Purpose<br>13:35-4A.2 Scope<br>13:35-4A.3 Definitions<br>13:35-4A.4 Policies and procedures requirements<br>13:35-4A.5 Duty to report incidents related to surgery, special procedures or anesthesia in an office<br>13:35-4A.6 Standards for performing surgery and special procedures in an office; privileges necessary; pre-procedure counseling; patient records; recovery ...<br>13:35-4A.7 Standards for administering or supervising the administration of anesthesia services in an office; pre-anesthesia counseling; patient ...<br>13:35-4A.8 Performance of general anesthesia; authorized personnel<br>13:35-4A.9 Administration of regional anesthesia; authorized personnel<br>13:35-4A.10 Administration of conscious sedation; authorized personnel<br>13:35-4A.11 Administration of minor conduction blocks; authorized personnel<br>13:35-4A.12 Alternative privileging procedure<br>13:35-4A.13 Requirements for anesthetizing locations; emergency equipment and supplies<br>13:35-4A.14 Requirements for anesthetizing locations; safety systems, monitoring devices<br>13:35-4A.15 Equipment requirements for recovery areas<br>13:35-4A.16 Maintenance requirements<br>13:35-4A.17 Compliance timetables<br>13:35-4A.18 Enforcement | In June 1998, the NJ medical board promulgated rules relating to “Surgery, Special Procedures, and Anesthesia Services Performed in an Office Setting.” The rules establish policies and procedures and staff and equipment requirements for practitioners and physicians who perform surgery (other than minor surgery), special procedures and administer anesthesia services in an office setting. Practitioners who perform such services must establish written policies and procedures on:
- specific surgical or special procedures which may be performed in the office;
- specific anesthesia services which may be performed in the office;
- responsibilities of health care personnel;
- emergency equipment, supplies, maintenance and infection control practices;
- procedures to be followed if a patient requires transport for emergency services;
- procedures to be followed when a procedure must be terminated due to equipment malfunction or other complication;
- procedures for in-office recovery;
- objective criteria for discharging patients;
- requirements for medical records;
- procedures for follow-up on complications and outcomes.
Physicians and anesthesiologists must be credentialed to perform office-based procedures. Physicians are automatically credentialed to perform, in the office, and procedures for which they have privileges in a hospital. |
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<td>Physicians without hospital privileges must obtain “alternative credentialing” through the medical board. The rules set requirements for pre-procedure counseling. Additionally, a mandatory reporting system was created. Physicians are responsible for reporting any deaths, complications, or adverse events that occur during office-based procedures. Violation of the rules is deemed to be professional misconduct. (N.J.A.C. 13:35-4A)</td>
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| NY    | NY Pub. H. Law Sec 230-d. Office-Based Surgery
Licensees “who perform invasive or surgical procedures using more than minimal sedation must practice in an accredited setting. The Commissioner of Health designated The Joint Commission, the American Association for the Accreditation of Ambulatory Surgical Facilities (AAAASF) and the Accreditation Association for Ambulatory Health Care (AAAHC) as the organizations which are authorized to perform the accreditation of practices which meet the definition of Office Based Surgery. A licensee who fails to practice in an accredited setting after July 14, 2009 may be guilty of professional misconduct.”
NY Pub. H. Law Sec 2998-e Reporting of Adverse Events in Office-Based Surgery | In July 2000, the NY Department of Health and the Public Health Council adopted *Clinical Guidelines for Office-Based Surgery*. The guidelines are comprehensive and intended to assist practitioners performing office-based surgery in providing high quality and safe care and to provide uniform professional standards for procedures which require anesthesia or sedation in private offices. Included are recommendations for qualifications of practitioners and staff, equipment, facilities, policies, and procedures for patient assessment and monitoring. |
| NC    | Office-Based Surgery
Position Statement | The NC Medical Board adopted a position in January 2003 that provides guidelines on office-based surgery. Physicians who perform office-based surgical or special procedures must be credentialed to perform the same surgical or special procedures by a hospital or ACS, or substantially comply with criteria set out by the Board. After one year of operation, any physician who performs Level II or Level III procedures in an office should be able to demonstrate substantial compliance with the guidelines or should obtain accreditation by an approved accreditation agency. Special guidelines are adopted for Level II and Level III surgical or special procedures. Certain complications that occur are required to be reported to the Board. |
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<td><strong>ANESTHESIA STANDARDS</strong></td>
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<td>4731-25-01 Definition of terms</td>
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<td>4731-25-02 General provisions</td>
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<td>4731-25-03 Standards for surgery using moderate sedation/analgesia</td>
<td>In August 2003, the Board approved administrative rules governing office-based surgery. The rules require office-based surgical settings using moderate sedation/analgesia or anesthesia services to be accredited by JCAHO, AAAHC, AAAASF, AOA or another accrediting agency approved by the Board. The rules designate who may provide anesthesia services in office settings; requirements for education, training and experience; privileges, and/or board certification. The rules specify what patients are candidates for office-based anesthesia services using the ASA physical status classification system; requirements for equipment and supplies; and requirements for monitoring patients. There are specific guidelines for liposuction.</td>
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<td>4731-25-04 Standards for surgery using anesthesia services</td>
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<td>4731-25-05 Liposuction in the office setting</td>
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<td>4731-25-07 Accreditation of office settings</td>
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<td>OK-M</td>
<td><strong>Guidelines for Office-Based Surgery and Other Invasive Procedures</strong></td>
<td>The Oklahoma State Board of Medicine adopted guidelines in July 2000 for physicians who perform ambulatory surgery and other invasive procedures which require anesthesia or sedation in an office setting. Oklahoma physicians performing office-based surgery are required to address the issues of quality of care, maintenance of the facility and safety, patient and procedure selection, preoperative care, monitoring and equipment, as well as emergencies and transfers.</td>
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<td>OR</td>
<td><strong>DIVISION 17. OFFICE-BASED SURGERY OR PROCEDURES.</strong></td>
<td>Effective in 2006, Medical Board rules specifically acknowledge that Oregon physicians are accountable for the welfare and safety of their patients in providing office-based invasive procedures. Requires facilities in which office-based surgeries or procedures are performed to be accredited by a recognized organization, as well as at least one physician currently certified in advanced resuscitative techniques to be present or immediately available and appropriately equipped until discharge of the patient. Encourages appropriate education and training of those administering sedation or anesthesia, and provides guidelines on selection of procedures and patients, medical</td>
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<td>847-017-0000 Preamble</td>
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<td>847-017-0005 Definitions</td>
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<td>847-017-0010 Patient Safety</td>
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<td>847-017-0015 Selection of Procedures and Patients</td>
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<td>847-017-0020 Patient Medical Records</td>
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<td>847-017-0025 Discharge Evaluation</td>
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<td>847-017-0030 Emergency Care and Transfer Protocols</td>
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<td>847-017-0040 Facility Administration and Equipment</td>
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<td>records, discharge evaluation, and emergency care. In 1999, Pennsylvania adopted regulations requiring ambulatory surgical facilities to be licensed by the state. The licensure requirements do not apply to individual or group practice offices of private physicians unless the offices have a distinct part used solely for outpatient surgical treatment on a regular and organized basis. Facilities requiring licensure are classified as Class A, B, or C. Class A facilities include private or group practice settings where procedures are limited to those requiring local or topical anesthesia and during which reflexes are not obtunded. Class A facilities are not required to be licensed, but must be accredited by a nationally recognized accrediting agency. All Class B and C facilities, as defined, must be licensed and are required to be inspected annually. Oversight is through the Pennsylvania Department of Health. (28PA Code Ch 551, 553, 555, 557, 559, 561, 563, 565, 567, 569, 571, and 573)</td>
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<td>SC</td>
<td>81-96. Office-based Surgery.</td>
<td>The South Carolina Board of Medical Examiners adopted Guidelines for Office-based Surgery in October 2001. The guidelines outline requirements for office-based facilities in which surgery will be performed. Offices are classified as Level I, II, or III based upon the complexity of anesthesia and surgical procedures being performed. The guidelines also include standards for patient selection, evaluation and discharge; procedures for emergency transfers and reporting of adverse incidents; requirements for appropriate credentialing of health care practitioners; and standards for anesthesia administration or supervision.</td>
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<td>Statute/ Rules</td>
<td>0880-2-21. Office Based Surgery.</td>
<td>performed by osteopathic physicians. States that “the Board will always judge the decision to perform surgery in the office setting based upon what was in the patients best interest and through strict application of these rules,” and lists various provisions governing office-based surgery.</td>
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<td>Rules</td>
<td>CHAPTER 192. OFFICE-BASED ANESTHESIA SERVICES s 192.1. Definitions</td>
<td>Effective September 2000, the Texas Board of Medical Examiners promulgated rules to identify the roles and responsibilities of physicians providing or overseeing anesthesia services in outpatient settings and to provide the minimum acceptable standards for the provision of anesthesia services in outpatient settings. The rules also require physicians who administer anesthesia or perform surgical procedures using anesthesia services in an outpatient setting to refer annual with the Board. The rules apply to an outpatient setting that is not part of a hospital or ambulatory surgical center, where general, regional, or monitored anesthesia is administered.</td>
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<td>Rules s 192.2. Provision of Anesthesia Services in Outpatient Settings</td>
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<td>Rules s 192.3. Compliance with Office-Based Anesthesia Rules</td>
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<td>VA PART VIII. OFFICE-BASED ANESTHESIA 18 VAC 85-20-310. Definitions.</td>
<td>The Virginia Board of Medicine regulations define levels of anesthesia and sedation and related terms, and requires physician administering office-based anesthesia to perform a preanesthetic evaluation and examination, develop an anesthesia plan, obtain informed consent, assess and monitor patient, and remain physically present or immediately available to manage complications and emergencies until discharged.</td>
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<td>18 VAC 85-20-330. Qualifications of providers.</td>
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<td>18 VAC 85-20-350. Informed consent.</td>
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<td>18 VAC 85-20-370. Emergency and transfer protocols.</td>
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<td>18 VAC 85-20-380. Discharge policies and procedures.</td>
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<td>AAAASF -- American Association for Accreditation of Ambulatory Surgery Facilities</td>
<td>AAAASF is predominantly an office-practice accrediting organization that mainly accredits plastic surgery facilities. Any facility accredited by the organization must be owned or operated by American Board of Medical Specialties surgeons, who have been board-certified in the procedures they will perform. For all specialties, the physician must have hospital privileges, including transfer privileges, at a nearby facility. The accreditation program addresses facility layout; patient and personnel records; quality assessment and quality improvement plans; and operating room personnel, equipment, operations, management, and sanitation. Once the inspection is complete, the AAAASF’s Operations Committee and BOD issue accreditation, provisional accreditation, or denial of accreditation. The process operates on a three-year cycle. In the intervening years facility directors are required to complete a self-evaluation. Failure to do so voids accreditation.</td>
</tr>
<tr>
<td>AAAHC – Accreditation Association for</td>
<td>The AAAHC accreditation process is similar to that of the AAAASF. Following an initial self-assessment by the facility</td>
</tr>
</tbody>
</table>
Ambulatory Health Care

seeking accreditation, practicing professionals conduct an on-site survey of the facility. The AAAHC issues six-month, one-year, and three-year accreditation, depending on the facility’s ability to meet all clinical and administrative aspects of ambulatory health care standards. Accredited facilities are required to meet standards in the following core areas: rights of patients, governance, administration, quality of care and quality improvement, clinical records, and facilities and environment.

JCAHO – Joint Commission on Accreditation of Healthcare Organizations

JCAHO accredits the widest range of health care facilities, including office-based practices, ambulatory care facilities, and hospitals. Professional surveyors, who have completed JCAHO training programs, tour the organization’s facilities, examine all patient care areas, interview staff members and patients, review documents and selected patient records, and, at the conclusion of the survey, issue a preliminary report and accreditation decision to the facility. In conducting its examination, the JCAHO looks at the facility’s safety, security, treatment of hazardous wastes and materials, emergency preparedness, patient safety, equipment condition, and utility systems. The JCAHO’s accreditation process provides the most exposure of the facility to surveyors and also more flexibility in issuing accreditation.

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EXHIBIT 13–2. KENTUCKY 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), surgery 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 (Table 1)

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 I 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 I requirements, these offices must maintain full emergency equipment and medications as summarized in Appendix II. 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 II. 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.
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 noninvasive 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

a. 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 interchange ability 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 percent 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.

Table 2

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. (AAAHC)*

9933 Lawler Avenue
Skokie, IL 60077-3702

(847)676-9610

The Joint Commission

One Renaissance Boulevard

Oak Brook Terrace, IL 60181

(630)916-5600

EXHIBIT 13–3. NEW YORK STATE SURGICAL AND INVASIVE PROCEDURE PROTOCOL (NYSSIPP)

A. SCHEDULING

Scheduling must include:

1. Entire procedure, exact site, level, digit, and side/laterality (including spelling out “Left,” “Right” and “Bilateral” —no abbreviations other than C-Cervical, T-Thoracic, L-Lumbar, S-Sacral when identifying spinal levels—e.g. L4-5).

2. Specific information on implant/implant system and/or equipment.

3. Specific information on removal of device.

4. Information on harvest and donor sites.

5. The Operating Room (OR), or the person responsible for accepting requests to schedule procedures, must verify the information provided by the surgeon/physician. The information should be verified in a manner agreed to by both the institution and physicians (read-back, fax, e-mail, etc).

B. CONSENT DOCUMENT

Consent documentation must include:

1. First and last name, date of birth of patient and medical record number of the patient.

2. Name and description of surgery or procedure in terms that are understandable to the patient (correct site/side, level and digit with the side spelled out as “Left,” “Right” or “Bilateral”).

3. No acronyms or abbreviations (except spinal levels noted in section A above).

4. Specific implant/implant system to be placed or device to be removed.

5. Patient/family/guardian/health care agent signature and date.

6. Witness signature and date.

7. Physician signature and date.

8. If the consent is altered or illegible it must be re-done and re-signed by all parties.
C. PRE-OPERATIVE/PRE-PROCEDURAL VERIFICATION PROCESS

Verification of the correct person, procedure site and side must occur (as applicable):

1. At the time the surgery or invasive procedure is scheduled.
2. At the time of admission or entry into the facility.
3. With the patient involved, awake and aware, if possible.
4. Anytime the responsibility for care of the patient is transferred to another caregiver or location in the pre-operative or pre-procedural process.
5. Before the patient leaves the pre-operative area or enters the procedure/surgical room.
6. In ALL clinical settings where invasive procedures are performed, including but not limited to endoscopy suites, catheterization laboratories, interventional radiology suites, intensive care units, labor and delivery areas, emergency departments, etc. There are recognized benefits to applying this to all bedside procedures.

A pre-operative or pre-procedural verification checklist must be utilized to ensure availability and actual review of the following, prior to the start of the procedure:

1. Relevant documentation: History & Physical, signed consent and any other documents required by the organization as part of the pre-operative evaluation process. The consent must be signed by the patient/legal representative, and surgeon.
2. Relevant images, properly labeled and displayed including photographs.
   • In “High Risk” procedures (as determined by the surgeon), the images should be reviewed by the surgeon and radiologist together pre-operatively.
   • Someone other than the primary surgeon confirms the name, date of the study and “Left-Right” orientation.
   • The surgeon is responsible for assessing what films/images are appropriate for viewing before and during the surgery.
   • When intra-operative imaging studies are performed, appropriate consultation should be available for interpretation of intra-operative studies.
3. Relevant diagnostic reports or studies (ultrasound, endoscopy, etc.).
4. Relevant pathology reports.

5. Necessary patient-specific implants and special equipment.

6. Confirm identity using two (2) identifiers, confirm procedure and site marking if appropriate.

**D. MARKING THE OPERATIVE/PROCEDURAL SITE**

1. The physician/dentist/podiatrist doing the procedure must do the site marking using his/her own initials. Site marking must be legible and unambiguous (see exceptions). Note: If the surgeon’s initials are “N.O.,” utilize three initials.

2. All sites involving laterality (e.g. brain) and/or paired organs, multiple structures (fingers, toes, hernias, lesions) or multiple levels (spine). Make the mark at or near the incision site(s) so that it/they will be visible when the patient is draped. (See following exceptions).

3. For hand and foot surgery, the surgeon must mark the surface(s) of the digit to be operated on, anterior, posterior or both.

4. The appropriate site must be verified before any cast is split. For relevant orthopedic cases, the skin/site should be marked immediately after cast/splint is removed.

5. For surgery of the spine, pre-operative skin marking is required to indicate laterality, when appropriate. A second time out must be performed when the intra-operative imaging is done to confirm the level.

6. When the site or level is not visually identifiable, the surgeon must obtain an intra-operative image, using markers that will not move, to confirm the exact level/site.

7. Do NOT mark any non-operative site(s).

8. The mark must be visible in the operative field after the patient is prepped and draped.

9. The mark must be made using an FDA approved marker that is sufficiently permanent to remain visible after completion of the skin prep. Adhesive site markers should not be used as the sole means of marking the site.

10. In the event of multiple surgical procedures by different surgeons, all relevant surgical sites must be marked prior to the first surgery. The surgeon marking the site(s) must be present for and participate in the “time out” performed for each procedure he/she marks.
11. Marking must take place with the patient/family involved, awake and aware, if possible.

12. If a smaller mark is necessary, such as near the eye in Pediatric Ophthalmology cases, a dot near the eye constitutes the site marking. A special purpose wristband is also an option.

13. A special purpose wristband must be used for patients:

   - who refuse marking,
   - a neonate (as marking may cause a permanent tattoo),
   - problematic surgical site(s) to mark (e.g. perineum or anus) or when marking can be done only after shaving a patient’s head prior to a neurosurgical/cranial procedure.
   - The first and last name of the patient, a second identifier, the anatomical site and name of the procedure must be written on the special purpose wristband.

14. Final verification of the site mark must take place during the "time out."

E. EXCEPTIONS TO SITE MARKING

1. Single organ cases, which do not involve laterality (e.g., hysterectomy, appendectomy).

2. Spinal block for pain management or epidural does not require an intra-operative marker if fluoroscopy is used. However, it does require skin marking.

3. Interventional cases for which the catheter/instrument insertion site is not predetermined (e.g., cardiac catheterization).

4. Dental cases, where the operative tooth number or name(s) can be indicated on documentation or the operative tooth (teeth) including laterality can be marked on the dental radiographs or dental diagram.

5. Endoscopic or other procedures done through a midline orifice.

6. Situations in which the primary pathology itself is plainly visible (single laceration).

7. When the operative pathology has been identified by real time imaging in the immediate pre-operative period such as for frameless stereotactic neurosurgical procedures or microcalcifications in a breast biopsy.

8. Life threatening emergency when any delay in initiating the surgery would compromise
the safety or outcome of the patient (e.g. ruptured aortic aneurysm).

9. When movement of a patient to create a marking would compromise the safety or outcome of the procedure (e.g. movement of a patient with an unstable spine fracture.)

NOTE: A practitioner is NOT exempt from the site-marking requirement when he or she is in continuous attendance with the patient (from the time of the decision to do the procedure through the conduct of the procedure). The requirement for “time out” applies as well. This is based on reports of wrong-sided procedures being done despite the continued presence of the person performing the procedure from time of decision to completion of the procedure.

F. “TIME OUT” IMMEDIATELY BEFORE STARTING THE PROCEDURE

Purpose: To conduct a final verification of the correct patient, site/side, procedure and, as applicable, implants.

The “time out” must be conducted in the location where the procedure will be done, after the patient is prepped and draped and just before starting the procedure. This applies to all invasive procedures performed in all settings. All work should cease during the “time out” to allow all members of the team to focus on the “time out.” For instances when the procedure is being performed without assistance, it is strongly advised to enlist an observer or assistant to participate in the “time out.” It must involve the entire operative/procedural team, use “active communication,” and be documented. The “time out” is a standardized procedure, and documentation indicates the procedure was followed in its entirety without deviation.

“Time out” includes the following:

1. Identification of the patient using 2 patient identifiers, such as, name (first and last) and a second identifier as determined by the organization.

2. Identification of the correct site and side(s).

3. Procedure to be performed and proper patient position.

4. Availability of correct implants and any special equipment or special requirements.

5. Verification of the wristband and chart takes place as the patient is brought into the room and before the “time out.” The “time out” requires that all participants agree on the information and does not require checking the wristband at that time.

6. Radiological review, when germane to the case (see below).
The above information should be confirmed with the medical record and should be documented along with the identification of those who participated in the “time out.”

Additional Confirmatory “Time out” should be undertaken if a new surgeon arrives and is assuming primary responsibility for the case, or if the patient/operative site is re-draped. The name of the patient and the procedure should be verified during this second “time out.”

Radiological Review: The surgeon performing the operation is responsible for determining that the images to be displayed are relevant to the surgery. A second team member confirms that the image belongs to the patient (first and last names and second identifier) and that the image is displayed in the correct orientation, using markers on the image. The team confirms the site and side of the lesion as part of the “time out.”

- For spinal cases in which an intra-operative image is used to determine the spinal level, a second “time out” must be performed to review the image and correlate with intra-spinal markers.

Procedures Performed Outside the OR: The person(s) performing the procedure must conduct and document the “time out” confirming all of the above information with another person when possible.

For Surgical Procedures: Instruments/equipment are not offered until after the “time out” is performed.

STOP the procedure if there is any discrepancy in information identified by any member of the surgical team. Resolve the discrepancy or disagreement before proceeding.

Required Policy and Procedure

All organizations must have a policy and procedure that incorporates the contents of NYSSIPP, and ensures that the requirements for patient identification, site marking, pre-operative/pre-procedural verification, and “time out” are consistently followed whenever invasive procedures are performed, including, but not limited to procedures performed in the operating room, radiology, obstetrics/labor and delivery, emergency departments, cardiac catheterization lab, clinical units, and out-patient areas. The institutional policy and procedure must specify the actions to be taken when a discrepancy occurs at any step in the process.

Division of Primary and Acute Care Services (Sept. 2006).
EXHIBIT 13–4. ACS PATIENT SAFETY PRINCIPLES FOR OFFICE-BASED SURGERY UTILIZING MODERATE SEDATION/ANALGESIA, DEEP SEDATION, OR GENERAL ANESTHESIA

Core Principle #1—Guidelines or regulations should be developed by states for office-based surgery according to levels of anesthesia defined by the American Society of Anesthesiologists' (ASA's) "Continuum of Depth of Sedation" statement dated October 13, 1999, excluding local anesthesia or minimal sedation.

Core Principle #2—Physicians should select patients by criteria, including the ASA Patient Selection Physical Status Classification System, and not document.

Core Principle #3—Physicians who perform office-based surgery should have their facilities accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), Accreditation Association for Ambulatory Health Care (AAAHC), American Association for Accreditation of Ambulatory Surgical Facilities (AAAASF), American Osteopathic Association (AOA), or by a state-recognized entity such as the Institute for Medical Quality (IMQ), or be state licensed and/or Medicare certified.

Core Principle #4—Physicians performing office-based surgery must have admitting privileges at a nearby hospital, or a transfer agreement with another physician who has admitting privileges at a nearby hospital, or maintain an emergency transfer agreement with a nearby hospital.

Core Principle #5—States should follow the guidelines outlined by the Federation of State Medical Boards regarding informed consent.

Core Principle #6—States should consider legally privileged adverse incident reporting requirements as recommended by the FSMB® and accompanied by periodic peer review and a program of Continuous Quality Improvement.

Core Principle #7—Physicians performing office-based surgery must obtain and maintain board certification by one of the boards recognized by the American Board of Medical Specialties, American Osteopathic Association, or a board with equivalent standards approved by the state medical board within five years of completing an approved residency training program. The procedure must be one that is generally recognized by that certifying board as falling within the scope of training and practice of the physician providing the care.

Core Principle #8—Physicians performing office-based surgery may show competency by maintaining core privileges at an accredited or licensed hospital or ambulatory surgical center for the procedures they perform in the office setting. Alternatively, the governing body of the office facility is responsible for a peer review process for privileging physicians based on nationally recognized credentialing standards.

Core Principle #9—At least one physician, who is credentialed or currently recognized as having successfully completed a course in advanced resuscitative techniques (ATLS®, ACLS, or PALS), must be present or immediately available with age and size-appropriate resuscitative equipment until the patient has met the criteria for discharge from the facility. In addition, other medical personnel with direct patient contact should at a minimum be trained in Basic Life Support (BLS).

Core Principle #10—Physicians administering or supervising moderate sedation/analgesia, deep sedation/analgesia, or general anesthesia should have appropriate education and training.

The preceding principles were based on a document that was unanimously approved by the following groups during a March 17, 2003, ACS/AMA coordinated consensus meeting on office-based surgery:

- Accreditation Association for Ambulatory Health Care
- American Academy of Cosmetic Surgery
- American Academy of Dermatology
- American Academy of Facial Plastic and Reconstructive Surgery
- American Academy of Ophthalmology
- American Academy of Orthopaedic Surgeons
- American Academy of Otolaryngology—Head and Neck Surgery
- American Academy of Pediatrics
- American Association for Accreditation of Ambulatory Surgery Facilities
- American College of Obstetricians and Gynecologists
- American College of Surgeons
- American Gastroenterological Association
- American Medical Association
- American Osteopathic Association
- American Society for Dermatologic Surgery
- American Society for Reproductive Medicine
- American Society of Anesthesiologists
- American Society of Cataract and Refractive Surgery
- American Society of General Surgeons
- American Society of Plastic Surgeons
- American Urological Association
- Federation of State Medical Boards
- Indiana State Medical Society
- Institute for Medical Quality—California Medical Association
- Joint Commission on Accreditation of Healthcare Organizations
- Kansas Medical Society
- Massachusetts Medical Society
- Medical Association of the State of Alabama
- Medical Society of the State of New York
- Missouri State Medical Association
- National Committee for Quality Assurance
- Pennsylvania Medical Society
- Society of Interventional Radiology

5) Report of the FSMB Special Committee on Outpatient (Office-Based) Surgery.

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EXHIBIT 13–4.1. RISK MANAGEMENT STRATEGIES FOR OFFICE-BASED SURGERY PRACTICES

A number of practical enterprise risk management strategies can help address office-based surgery practices. These strategies are applicable to both hospital-owned and independent office-practice programs and include more than those that offer cosmetic procedures. Hence, the strategies are useful for dental surgery offices and those who engage in restorative and interventional treatment programs. These strategies include the following:

1. **Complete a GAP Analysis of Current Practices.**

   Conduct a complete review of clinical practices in the office-based surgery practice that takes into consideration patient screening, preparation, anesthesia, recovery, and documentation practices. Develop a plan to modify those practices are in need of improvement.

2. **Use a Comprehensive GAP Assessment Tool.**

   Take into consideration applicable state law and regulation requirements as well as accreditation requirements when designing the GAP assessment tool. Incorporate into the tool relevant federal requirements that address accessibility (Americans with Disabilities Act), HIPAA, and provisions that address the need for assistance with language interpretation. Recognize that state and federal requirements set *minimum* standards. Building in practice criteria can help facilitate good risk management and patient safety for the delivery of office-based surgical procedures.

3. **Establish Clear Guidelines for Patient Selection for Office-Based Surgery.**

   Follow guidance from respected, national professional groups in the selection of patients who want to undergo elective surgical procedures in the office-based setting. In taking such an approach consider important guidance from anesthesia providers such as the American Association for Nurse Anesthetists (www.aana.org). Implement a process for careful screening and good “drill down” questions to identify those patients for whom it may be prudent to consider procedures in an ambulatory surgery center or an acute care facility.

4. **Follow Good Practices for Staffing.**

   Make certain that office policies, procedures and protocols follow prudent methods for staff hiring, training and demonstrated competencies for the office-based surgery practice. Build into contracts with staffing agencies or agreements with anesthesia providers appropriate requirements for demonstrated competencies *in the office-based surgery practice*.

5. **Stress the Importance of Team Management Training.**

   Recognize that intra-operative and post-operative care management is important in terms of
patient safety and risk management. Reinforce this point with team on team training and requiring demonstrated proficiencies for all involved in the clinic care of office-based surgery patients. Address identified opportunities for improvement.


Implement effective comprehensive communication practices with patients. Offer clear instructions on how to prepare for the procedure, what to do if the patient becomes ill prior to elective surgery, and what to bring and not to bring on the day of surgery. Follow established state requirements on informed consent to surgery. Build into the consent process information about the choice to have the procedure done in a healthcare facility rather than an office-based setting. Make certain that the consent process is documented in accordance with state requirements, and, when relevant, applicable accreditation standards.

7. Emphasize the Importance of Complication Management.

Anticipate the potential for complications to occur at any stage of a patient's office-based surgery experience. Provide clear and concise guidance for managing complications. Include in this approach immediate access to cardiac resuscitation, rescue medication from anesthesia-induced malignant hyperthermia, rescue kits for allergic reactions and other essential approaches to avoid permanent untoward outcomes in the office-based surgery practice.

8. Have a Dedicated Transfer Agreement.

Work with legal counsel on implementing a transfer agreement for prompt transfer of patients with complications to an acute care facility.


Make certain there is in place a comprehensive infection control program for the environment of care in which surgical procedures are performed in the office based setting. Include in this plan specifications for sterilization, cleaning and disinfecting equipment. Encourage use of a quality control audit for infection control. Address identified opportunities for improvement.

10. Implement Effective Post-Operative Recovery Plans.

Follow national standards, guidelines and “good practices” in the design and implementation of post-operative, office-based surgery recovery plans. Examine carefully staffing, equipment requirements as well as the propriety of patients “boarding” overnight in the office-based practice. Built into the plan “safe practices” for ambulation following conscious sedation and anesthesia.

11. Close the Loop on Discharge Instructions.

Implement a patient-oriented discharge process for patients who have undergone office-
based surgical procedures. Consider a number of practical issues such as:

- Medication
- Diet
- Level of activity
- Return to work
- Possible complications
- What to do if a complication occurs
- Scheduling follow-up visits
- Who to call regarding questions
- Teach-back on information provided
- Health literacy level of written information

Documentation of the discharge process is important, including who completed it, the time, date, and staff member's name and signature. Identifying who was the responsible person with the patient at the time of discharge is important as it helps to reinforce the process in most office-based surgery practices that the patient has an identified individual accompanying him or her home.


Develop a process for secure storage of patient belongings in the office-based surgery setting. Take into consideration wallets, watches, handbags, cell phones, hearing aids, eyeglasses and dentures. Consider lockers and documentation of the "safe storage" process.


Provide orientation and in-service education to office staff personnel on their respective roles and responsibilities. Include in this process reception personnel and administrative support staff. Give them guidance on how to handle patient or family calls or requests, especially with respect to questions about postponing the procedure or post-operative complaints and complications.

14. Close the Loop with Follow-Up Calls.

Develop a set of questions for designated personnel to use when calling post-procedure patients. Use the calls to identify possible complications or side effects that mitigate to encouraging a visit to the practice or encouragement to seek emergency medical attention. Build in an “escalate call” process for complications, side effects complaints or expressions
of dissatisfaction. Document the date and time of the call, and the name of the person with whom the staff member communicated.

EXHIBIT 13-5. OFFICE-BASED SURGERY, PATIENT SAFETY CHECKLIST, PREOPERATIVE

American Academy of Orthopaedic Surgeons

Patient Safety is No Accident.

OFFICE-BASED SURGERY

Patient Safety Checklist

-Pre-Operative-

Clip this checklist to the patient chart and upon completion, insert in file.
Prior to beginning the procedure in the office setting, the orthopaedic surgeon is to complete and sign the patient safety checklist.

Patient’s Name: __________________________ Date: / / __________

Scheduled Procedure: __________________________

I have considered the following as they relate to the safety of my patient undergoing this procedure:

☐ History & Physical Examination Performed
☐ Labs and EKG Attached
☐ Medications:
  ☐ Prescription
  ☐ Over the Counter (OTC)
  ☐ Herbals or Other Supplements (if checked, see detailed listing on AAOS website)
☐ Patient Risk Factors/Co-Morbidities
☐ Prior Anesthetic Complications

I have considered the following as they relate to the safety of my patient undergoing this procedure in my office:

☐ Procedure is appropriate for office-based surgery
☐ Appropriate office personnel are available for this procedure
☐ Anesthesia will be administered by a qualified person
☐ Intra-operative monitoring equipment is present and functioning properly
☐ Resuscitative equipment and supplies are available
☐ Patient has appropriate transportation home

The following processes have been performed:

☐ Primary Care Physician Notified of Procedure
☐ Time-Out Prior to Procedure

☐ Patient Identifier Checked
☐ Surgeon Signed the Site
☐ Appropriate ASA Classification Assigned
☐ Equipment Checked – Present and Functioning Properly

Orthopaedic Surgeon’s Signature: __________________________
## Health History Form

This sample form may be sent to the primary care physician or the referring physician for completion before the day of surgery. This form may be reviewed by anesthesia and nursing staff before the day of surgery, according to facility policy and procedure.

<table>
<thead>
<tr>
<th>Patient Identification No:</th>
<th>Age:</th>
<th>Date of Birth:</th>
<th>Today’s Date:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Home Address:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Gender:</th>
<th>Height:</th>
<th>Weight:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Allergies:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Latex Sensitivity</th>
<th>yes</th>
<th>no</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Advance Directive</th>
<th>yes</th>
<th>no</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Language Spoken (if other than English):</th>
</tr>
</thead>
</table>

### Past Medical History (System)

**Cardiovascular**
- Angina
- Arrhythmia
- Coronary artery disease
- Myocardial infarction (date):
- Hypertension
- Congestive heart failure
- Pacemaker
- AICD (automatic implantable cardioverter defibrillator)
- Other:

**Respiratory**
- Asthma
- COPD (chronic obstructive pulmonary disease)
- Cough
- Shortness of breath
- Obstructive sleep apnea
- CPAP (continuous positive airway pressure)
- Other:

**Endocrine**
- Non-diet-controlled diabetes
- Adrenal disorder
- Active thyroid disease
- Other:

**Hematologic**
- Bleeding
- Bruising
- Clotting
- Anticoagulant use
- Drug and dose
- Other:
## Past Medical History (System)

### Gastrointestinal
- Hiatal hernia
- Gastroesophageal reflux
- Peptic ulcer disease
- Other:

### Neuromuscular/Musculoskeletal
- Seizure disorder
- Central nervous system disease
- TMJ (temporomandibular joint disorder)
- Cervical or thoracic spine pathology
- Other:

### Miscellaneous
- Oncologic process/chemo
- Hepatitis or jaundice
- Renal disease
- Morbid obesity (BMI [body mass index] greater than 30)
- Other:

### Infection/Isolation:
- Site:
- Organism:

### Females
- Possibility of pregnancy
- Date of last menstrual period

### Previous Surgeries or Procedures (describe as applicable)

### Anesthesia History
- Has the patient ever had anesthesia?
- Has the patient ever had a problem with anesthesia?
- Has a family member of the patient ever had a problem with anesthesia?
- Has the patient or a family member had malignant hyperthermia?
- Is there presence of any of the following:
  - Loose or chipped teeth
  - Capped teeth
  - Trouble opening jaw, jaw clicking

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EXHIBIT 13–5.1 CONTINUED

Is there presence of any of the following:
- Dentures
- Hearing aid(s)
- Contact lenses

Prior Health Habits (indicate frequency in comments)
- Alcohol
- Caffeine
- Recreational drugs
- Tobacco

Current Medication History (list all that apply, including herbal supplements and over-the-counter medications)

<table>
<thead>
<tr>
<th>Medication</th>
<th>Dose</th>
<th>Comment</th>
</tr>
</thead>
</table>

Current pharmacy: __________________

Physician completing form: __________________
Signature of physician completing form: __________________ Date: __________

For more information, go to http://www.patientsafetyauthority.org.
This form accompanies the following: Patient screening and assessment in ambulatory surgical facilities.

References:

EXHIBIT 13–5.2 NURSING PREOPERATIVE SCREENING

Nursing Preoperative Screening
This sample form may be used for nursing preadmission before the day of surgery. This form may be used for telephone or in-person screening and modified per facility policy and procedure.

Patient Identification No: ____________________________
Patient Name: ____________________________________
Ages: _______ Date of Birth: ________________ Today’s Date: ________________
Home Address: ____________________________________
Gender: __________________ Height: ___________ Weight: ___________
Allergies: _________________________________________
Latex Sensitivity: [ ] yes [ ] no
Advance Directive: [ ] yes [ ] no
Food List: [ ] yes [ ] no
Language Spoken (if other than English): _______________
Planned Surgical Procedure: ___________________________

Medical History Screening
(check and/or comment on all that apply)

Cardiovascular
[ ] Angina
[ ] Arrhythmia
[ ] Congestive heart failure
[ ] Hypertension
[ ] Myocardial infarction
[ ] Pacemaker
[ ] AICD (automatic implantable cardioverter defibrillator)
[ ] Other: _______________________________________

Respiratory
[ ] Asthma
[ ] COPD (chronic obstructive pulmonary disease)
[ ] Emphysema
[ ] Obstructive sleep apnea
[ ] CPAP (continuous positive airway pressure)
[ ] Recent cold/flu
[ ] Other: _______________________________________

Hematologic
[ ] Anemia
[ ] Bleeding tendency
[ ] Blood transfusions
[ ] Other: _______________________________________

Gastrointestinal
[ ] Problems chewing/swallowing
[ ] Gastroesophageal reflux disease
[ ] Hiatal hernia
[ ] Peptic ulcer disease
[ ] Other: _______________________________________

### Medical History Screening

**Neuromuscular/Musculoskeletal**
- Arthritis
- Back/neck problems
- Seizures
- Amputation/prosthesis
- Other: ____________

**Miscellaneous**
- Diabetes
- Stroke
- Liver disease
- Kidney disease
- Pregnancy
- Last menstrual period
- Communicable disease
- Patient
- Family member

**Prior Health Habits** (Indicate frequency in comments)
- Alcohol
- Caffeine
- Recreational drugs
- Tobacco

**Arriving via**
- Ambulatory
- Wheelchair
- Stretcher
- Other assistive devices: ____________

**Individual who will escort patient home**
- Name: ____________
- Phone number: ____________
- Relationship: ____________

**Sensory Assessment**
- No limitations
- Hearing impairment
- Visual impairment

**Does the patient have any of the following:**
- Dentures
- Hearing aid(s)
- Contact lenses

EXHIBIT 13-5.2. CONTINUED

Previous Surgeries or Procedures (describe as applicable)

Anesthesia History

- Never had anesthesia?
- Patient/family history of problem with anesthesia?
- Patient/family history of malignant hyperthermia?
- Loose teeth?
- Caps?

Yes  No  Don’t know  Comments

Current Medication History (list all that apply, including herbal supplements and over-the-counter medications)

<table>
<thead>
<tr>
<th>Medication</th>
<th>Dose</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tr>
</tbody>
</table>

Current pharmacy: __________

Information obtained from:  □ Patient  □ Spouse  □ Parent  □ Other: __________

Nurse completing form: ____________________________
Nurse's signature: ____________________________ Date: ____________________________

For more information, go to http://www.patientsafetyauthority.org.
This form accompanies the following:
Patient screening and assessment in ambulatory surgical facilities.
Pt Patient Saf Adv

References:


EXHIBIT 13–6.  TIPS FOR OUTPATIENT SURGERY

The number and types of medical procedures and surgeries performed in outpatient facilities—facilities that are outside of a traditional hospital setting—are on the rise. Advances in medical technology allow physicians to provide high-quality care in an outpatient setting and, in some situations, consumers prefer the convenience of outpatient facilities. Many procedures once performed in a hospital, requiring several days of hospitalization, are now performed in an outpatient setting. And an individual undergoing an outpatient procedure can often be released within several hours.

Although more procedures can now be performed in an outpatient setting, it is still important to thoroughly discuss health issues with your physician prior to any procedure or surgery.

The Department of Health offers the following tips to patients considering outpatient surgery:

• Provide your physician with your complete medical and surgical history; include all previous surgeries and anesthesia services, including dental procedures;

• Provide your physician with a list of all medications you are taking, including over-the-counter medications, vitamins and supplements;

• Tell your physician if you use tobacco, alcohol or other substances; this information is important because such substances can affect recovery from anesthesia and surgery;

• Inform your physician if you have had any allergic reactions, particularly if related to anesthesia; also include information about family members who may have had allergic reactions or other complications related to surgery or anesthesia;

• Make sure you understand who will perform the surgical procedure and who will be providing the anesthesia services; it is not unreasonable to ask providers about their experience in providing these services or the experience of the staff at the facility; this is particularly important when services are being provided to children;

• Ambulatory surgical facilities (ASF) performing certain procedures must have a license issued by the Department of Health; it is not unreasonable to ask if the particular procedure you are having done must be performed in a licensed ASF and whether the facility has such a license;

• Make sure you understand the manner in which your physician, other health care providers and the facility are prepared to handle emergencies or complications that may occur; it is wise to ask if individuals at the facility are certified in Cardio Pulmonary
Resuscitation (CPR), Advanced Cardiac Life Supports (ACLS) and, in the case of children, Pediatric Advanced Life Support (PALS); also, it is reasonable to ask about what plans are in place in the event that emergency transportation to a local hospital is required;

• Make sure you understand who will provide your post-operative care and what you can expect during your recovery at the facility; ask how long you should expect to stay and have a plan for how you will get home;

• Make sure you understand who will be responsible for your care once you are discharged from the facility; make sure you understand all of the instructions that are provided prior to your discharge from the facility; if possible, have a family member or a friend accompany you to help you better understand the instructions that are provided;

• Make sure you know who you should contact if you have questions or experience any problems once discharged.