Advances in technology and anesthesia allow invasive procedures once done only in hospitals or ambulatory surgical centers to be performed in physician offices. The trend toward office-based surgery is evident in numerous specialties: otolaryngology, ophthalmology, gynecology, dermatology, general surgery, gastroenterology, oral surgery, podiatry, and plastic surgery, among others. It is estimated that out of 80 million outpatient procedures performed in 2009, more than 12 million (15%) were performed in a doctor’s office (Midey).

However, research regarding patient safety in an ambulatory setting is still limited. A review conducted by the American Medical Association concluded that, though office-based surgery has been a focus of some such studies in recent years, little is known about how to improve patient safety in an ambulatory setting, partly because of the unique nature of each practice setting (Latner).

All operative or invasive procedures, particularly those that use sedation or anesthetic agents, carry inherent risk. This article examines regulations, standards, and guidelines promulgated by states, state boards, accrediting agencies, and professional associations and presents examples of court cases that demonstrate the importance of creating strategies to mitigate risk in office-based surgical services.

### Anesthesia

Anesthesia should be “administered only by a licensed, qualified, and competent practitioner,” according to the American College of Surgeons (ACS Guidelines). ACS continues to recommend that any registered nurse who administers anesthesia must be trained and have sufficient experience appropriate to the procedures being performed. Such competence should be documented.

Also, the staff member administering the anesthesia may not assist the procedure in any other way, recommends ACS. Both ACS and the Federation of State Medical Boards (FSMB) specify that administration should be overseen by a qualified physician who is both in the room and aware of this responsibility.

The administering staff member should work within the scope of his or her practice, and when this staff member is a nonphysician, he or she should be under the supervision of an anesthesiologist or the operating physician “unless state law permits otherwise” (FSMB). This physician is responsible for ensuring that an appropriate preexamination takes place—including developing a plan of care, educating the patient about it, and discussing all potential risks and safety precautions to be taken—prescribing the anesthetic, ensuring the qualifications of the administering staff member, and being immediately available in the event of any complication (ACS Guidelines). FSMB agrees: this individual should be physically present and available before, during, and after the procedure, until the patient is discharged from anesthesia care (FSMB).
Informed consent

“Informed consent for the nature and objectives of the anesthesia planned and surgery to be performed should be in writing and obtained from patients before the procedure is performed. Informed consent should only be obtained after a discussion of the risks, benefits, and alternatives and should be documented in the medical record” (FSMB).

A discussion that includes the nature of the procedure offered, along with its risks (including any risks specific to the office setting compared with a hospital setting), benefits, and alternatives—as well as their risks and benefits—should take place well before the procedure is scheduled to occur, when both the patient and healthcare practitioner can focus on the discussion and address the patient’s concerns. This discussion should be documented thoroughly, and the practitioner should verify, using a method such as teach back, that the patient understands the information presented during the informed consent discussion and that all questions raised by the patient are answered.

Regulation and accreditation

Office-based surgery may be regulated by state statutes or regulations or through state medical boards, though not in every state. According to the Accreditation Association for Ambulatory Health Care, Inc. (AAAHC), Connecticut, Indiana, Nevada, New Jersey, New York, Ohio, Oregon, Pennsylvania, Rhode Island, South Carolina, and Washington require accreditation.

Other states’ requirements differ; for example, Kansas practices must meet accreditation requirements, California and Florida accept either state certification or accreditation, and Louisiana, North Carolina, and Texas allow accredited facilities to be exempt from surgery and anesthesia regulations or guidelines. Colorado, Kentucky, Massachusetts, and Oklahoma have voluntary guidelines. Alabama, Illinois, Mississippi, New Jersey, Tennessee, and Virginia have implemented surgery or anesthesia regulations (AAAHC).

Facility leadership should be aware of state requirements, and these should be reviewed regularly to ensure that the facility is in compliance. AAAHC provides up-to-date information on regulatory requirements at http://www.aaahc.org/en/news/aaahc-resources/laws-regulations.

FSMB offers model guidelines for state boards and recommends that state boards follow these in addition to national accrediting organization standards and individual state standards. The FSMB model includes guidance on the administration of an office-based surgical practice, including the leadership and organizational structure of the facility and patients’ rights. FSMB also offers recommendations on personnel licensure, credentialing, and patient evaluation (FSMB).

Another factor in accreditation is the individuality of patient care. This includes
the preprocedure anesthesia evaluation and anesthesia plan, as well as participation of qualified practitioners before, during, and after the procedure (FSMB).

Credentialing is addressed in some guidelines promulgated by professional associations. For example, ACS recommends that each practitioner have “an appropriate level of training and experience for the specific procedure performed.” The group suggests the following (ACS Guidelines):

- Review staff members’ specific education regarding each procedure to be performed, as well as his or her training, experience, evaluations, and continuing medical education.
- Verify or review each staff member’s board certification or eligibility.
- Consider staff members’ participation in peer review and quality improvement initiatives.
- Review staff members’ malpractice coverage, as well as their active hospital or surgical center privileges.
- Evaluate staff members’ adherence to professional society standards.

Practices that meet certain requirements for ownership, staffing, and types of procedures performed may also be eligible for Joint Commission accreditation under its office-based surgery standards. Organizations using this accreditation for Medicare certification must be surveyed under criteria from the Comprehensive Accreditation Manual for Ambulatory Care (Joint Commission).

**Standards and guidelines**

In addition to regulatory and accreditation requirements, many medical specialty and professional associations promulgate guidelines for office-based surgery and anesthesia. The most prominent include ACS, the American Society of Anesthesiologists (ASA), and FSMB.

ACS divides its guidance by the type of facility in which the procedure will be performed (ACS Guidelines):

- **Level I** offices perform minor procedures under topical or local anesthetic only and are required to maintain basic emergency equipment and have an emergency transfer plan.
- **Level II** offices perform procedures requiring up to moderate sedation that requires postoperative monitoring; these facilities must be accredited and have on-site full emergency equipment and medications, peer review, and performance improvement initiatives, in addition to fulfilling the requirements of a Level I facility. The surgeon and at least 1 assistant are required to be certified in basic life support, and the surgeon or at least 1 assistant is required to be certified in advanced cardiac life support.
- **Level III** procedures require deep sedation or general anesthesia. In these facilities, all the requirements of Levels I and II must be met, and patient recovery should be monitored by a practitioner certified in advanced cardiac life support.

Procedures to be performed within the facility should be within the scope of practice of the healthcare practitioners present, and the facility should have sufficient equipment to perform the procedure in question. The procedure’s complexity and duration should be such that the patient will be able to recover and be discharged in a timely fashion appropriate to an office setting (ASA Guidelines).

Emergency planning is another significant portion of the ACS guidelines. In any emergency, such as complication with the surgery or anesthesia, all office personnel should know the facility’s plan to safely and promptly transfer the patient to a hospital and be ready to fulfill their roles (ACS Guidelines). FSMB and ASA recommend a written policy that details the necessary staff, equipment, and procedures to handle any emergency that could arise in relation to the proce-
dures performed and services offered at the facility (FSMB; ASA Guidelines).

ACS also specifies that any event involving anesthesia or related to a surgical complication that requires resuscitation or transfer or results in patient death must be reported to the medical board within 3 days, though reporting requirements vary among professional recommendations (ACS Guidelines). FSMB recommends that any incident following surgery or administration of anesthesia that results in patient death within 30 days, unscheduled transport of patients to a hospital for observation or treatment for a period in excess of 24 hours, or unscheduled hospital admission of patients within 72 hours of discharge after office-based surgery should be required to be reported (FSMB).

ACS, ASA, and the American Medical Association joined to create guidelines for office-based anesthesia and surgery. The 10 principles they agreed to addressed topics such as patient selection, accreditation, informed consent, physician privileges and board certification, and adverse event reporting; the ensuing statement was then agreed upon by many prominent professional associations and accrediting bodies (ACS “Statement”).

Finally, ASA guidelines recommend that facility leadership verify the licensure and certification of staff members and ensure that they practice solely within their scope of experience and training. Leadership is likewise responsible for ensuring the sufficiency of the facility for the procedures to be performed (ASA Guidelines).

In the courts
In states where office-based surgery centers are not regulated, negligence claims often focus on consideration of the healthcare practitioner’s experience, expertise, and certification, as well as facility equipment and available emergency supplies.

For example, the Supreme Court of North Carolina upheld guidance issued by the state medical board that called for physician supervision as a standard of anesthesia care in office-based surgery. The board of nursing challenged the medical board’s position statement on office-based surgery recommending physician oversight of nurse anesthetists, but the court of appeals ruled that “physician supervision of nurse anesthetists providing anesthesia care, when that care includes prescribing medical treatment regimens and making medical diagnoses, is a fundamental patient safety standard required by North Carolina law” (ASA “North Carolina”).

A Las Vegas jury awarded a plaintiff more than $420,000 for a failed breast implant procedure. The defendant reportedly performed the procedure in his office without general anesthesia or intravenous sedation over the course of 7-1/2 hours. The incision on the patient’s right breast reopened and was repaired by the defendant over an additional 8 hours. The incision opened again, at which point the plaintiff was admitted to the hospital for removal of the implants and a regimen of intravenous antibiotics (Bernstein & Poisson, LLC).

In a case presented to the Oregon medical board, a physician administered a fatal overdose of local anesthetic to a patient during an after-hours procedure. The board found that the physician, an internal medicine specialist, failed to perform a patient evaluation before the procedure; performed the surgery alone, with no support staff or crash cart; failed to recognize the symptoms of a drug overdose; and failed to have the necessary drugs available to address such an emergency. The board determined the physician had improperly performed procedures and treatments for friends and had administered treatments with no medical justification (Budnick).

Office leadership should monitor litigation, state regulations, and state board guidance and ensure that the facility remains up to date with these requirements and recommendations.
References


