



**Office-based surgery  
regulation:**  
*Improving patient safety and quality care*

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**T**he number of surgical procedures performed in physician offices has escalated dramatically over the last 10 years. This increase is partly due to: the efforts of managed care to seek less expensive alternatives to surgical procedures performed in hospitals; new and improved surgical techniques; and technologic advances in equipment, which make operations in nontraditional settings much safer for patients. In addition, physician offices typically are not subject to the same state and federal licensing rules as hospitals and other health care facilities, making it relatively easy to open an office-based surgical practice.

While physicians have embraced the advances that have made office-based surgery safer and more convenient for the patient, the media, state-elected officials, and state regulatory agencies have not been as enthusiastic about these developments. In the September 17, 2000, edition of the *Chicago Sun-Times*, the medical editor of WBBM-Channel 2 in Chicago, IL, opined about the recent moratorium on office-based surgery in Florida discussed later in this article. He began the piece by stating, "You're likely to get your next operation right in your doctor's office; and you may be putting your life on the line as a result."<sup>1</sup> In its series, "Managed Care & Doctors: The Broken Promise," New York's *Newsday* published a report on the increase in numbers of office-based surgical procedures, predominantly cosmetic in nature, and resulting adverse events, including a few deaths.<sup>2</sup>

Due to these reports and the very few reported deaths in **California** and **Florida**, a small number of states have begun regulating office-based surgery. In the coming years, it is anticipated that many more states will do so, especially if any patient deaths are attributable to the procedures and the media follow up with extensive coverage.

Because most office-based surgery is fairly unregulated, it is difficult to gather statistical information—at least information that is not considered proprietary by third-party payors—on what procedures are performed in the office and how the number of these procedures increases annually. According to an article in the April 2000 issue of *The Journal of Ambulatory Care Management*, surgical procedures commonly performed in an office include liposuction, laser cosmetic surgery, breast augmentation and reduction, endoscopy, pregnancy termi-

nation, invasive radiology procedures involving sedation, colonoscopy, and microlaparoscopy.<sup>3</sup>

The American Society of Plastic Surgeons (ASPS), through its National Clearinghouse of Plastic Surgery Statistics, has compiled data from 1992 on plastic and reconstructive surgical procedures. Many of these procedures have moved into the office setting, and significant increases were experienced from 1992 to 1999 in the top three cosmetic procedures performed in the office: liposuction (389%), breast augmentation (413%), and eyelid surgery (139%).<sup>4</sup>

### **Current state regulation**

Six states—**New Jersey** in 1998, **California**, **Pennsylvania**, **Rhode Island**, and **Texas** in 1999, and **Florida** in 2000—have addressed the issue of office-based surgery and have implemented regulatory requirements. Of them, California, Pennsylvania, Rhode Island, and Texas passed enabling legislation requiring the Medical Board, Department of Health, or Board of Medical Examiners to develop and implement appropriate regulatory mechanisms, including reporting requirements, accreditation and certification standards, anesthesia standards, facility and equipment requirements, safety and emergency procedures, and staffing requirements. Florida and New Jersey took the "rules and regulations" approach and, through the Board of Medicine/Board of Medical Examiners, issued a set of comprehensive regulations.

The range of regulation varies widely among these states. At one end of the spectrum, California and Texas took a more limited approach to regulating office surgery by focusing more on the number and qualifications of personnel, agreements for transferring patients to hospitals, and general requirements for the administration of anesthesia, although Texas was more specific than California in this regard. California law applies to any setting outside of a hospital and requires that each office have a written transfer agreement with a hospital, a physician/surgeon with hospital privileges, or a detailed emergency procedure approved by an accrediting agency. Liability insurance coverage is required for those procedures performed outside the hospital, and the Medical Board of California is required to develop appropriate accreditation standards (not completed at press time).

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Adverse events must be reported to the Medical Board.

The Texas statute applies to an outpatient setting not part of a hospital or ambulatory surgical center where general, regional, or monitored anesthesia is administered. Excluded are outpatient settings accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF), or Accreditation Association for Ambulatory Health Care (AAAHC). The statute requires that the American Society of Anesthesiologists' (ASA) standards and guidelines for office-based anesthesia be followed and mandates that anesthesia be provided by a physician or anesthesiologist or delegated to a certified registered nurse anesthetist (CRNA) under their supervision. A transfer agreement with the local emergency medical services (EMS) system is required, and adverse incidents must be reported to the Board of Medical Examiners.

At the other extreme are Florida, New Jersey, Pennsylvania, and Rhode Island, which have gone to great lengths to spell out in considerable detail requirements for anesthesia and personnel, along with type or level of surgery, facility requirements, including crash carts and equipment mandates, accreditation and certification standards, and procedures to respond to emergencies.

The New Jersey Board of Medical Examiners issued rules that incorporated anesthesia standards of care for sedation and analgesia by nonanesthesiologists as published by the ASA. While not covering minor surgical procedures, these rules are strict about appropriate provision of anesthesia and personnel administering anesthesia, equipment and supplies, safety systems and monitoring devices, and recovery area requirements. Interestingly, the New Jersey rules apply to offices with only one operating room and that are not subject to the jurisdiction and licensure requirements of the New Jersey Department of Health and Senior Services.

The Pennsylvania statute applies to ambulatory surgical facilities including that portion of a physician's office devoted to surgical procedures. There are three classes of facilities: A, B, and C, which are based on the procedure, patient status, and anesthesia administered. Class A facilities include a private or group practice where only local

or topical anesthesia is used, and while facility licensure is not required, they do have to be accredited by the JCAHO, AAAHC, or AAAASF. Class B facilities include single or multispecialty facilities where sedation anesthesia or dissociative drugs are administered and are limited to patients in ASA Physical Status (PS) 1 or 2 unless the patient's PS status would not be adversely affected by the procedure. Class B facilities must be licensed and accredited. Class C facilities include single or multispecialty facilities administering general anesthesia, and are limited to PS 1, 2, or 3 status patients. They must be licensed and accredited.

Other Pennsylvania requirements include transfer agreements with hospitals and a limit of four hours or less on the duration of surgical procedures. Anesthesia can be administered by an anesthesiologist or a CRNA, dental anesthetist, or other practitioner under the supervision of a physician, dentist, or anesthesiologist.

Rhode Island goes so far as to limit to two hours the length of surgical procedures, and any procedure exceeding that limit must be documented and reviewed. Offices must follow the ASA physical status classification, and physicians performing the procedures must have clinical privileges to perform the same procedure in the hospital. Anesthesia of most types must be administered by an anesthesiologist or a CRNA under the supervision of a qualified physician. Adverse events must be reported to the state's Department of Health. In addition, the office must be licensed by January 1, 2001, and accredited by the JCAHO, AAAASF, or AAAHC within 24 months of licensure.

In the case of Florida, these regulations were primarily based on level of anesthesia used, but also named specific procedures in the first two levels (minor procedures in Level I, such as excision of skin lesions, repair of lacerations, drainage of abscesses, limited endoscopies, and so on). After a number of hearings, these rules went into effect in February 2000. The Florida scheme includes Level I, Level II, Level IIA, and Level III office surgery, and the higher the level, the more stringent the anesthesia and personnel requirements. The state also incorporates the ASA physical status classification, and, for Level II and III office surgery, requires administration of anesthesia by an anesthesiologist, CRNA, or physician assistant. Offices using intravenous sedation or general anesthesia

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must be accredited by JCAHO, AAAASF, or AAAHC, and adverse incidents must be reported to the Medical Board of Florida.

Not only were the Florida rules extensive in scope, they were also contentious, resulting in the filing of a number of lawsuits against the Florida Board of Medicine. In addition, the Board became increasingly concerned with the number of adverse outcomes (nine injuries, including five total deaths) reported to it during the period of March through July 2000. As a result, the Board issued an emergency rule on August 10, 2000, placing a 90-day moratorium on the performance of Level III surgery (procedures using general anesthesia) in physician offices.<sup>5</sup>

When the moratorium expired, the Board issued emergency rules effective immediately that: (1) prohibited the combination of abdominoplasty with liposuction and liposuction in combination with other surgical procedures; (2) required risk management systems in offices where Level II and III surgical procedures are performed; (3) mandated submission of surgical logs for Level II and III surgical procedures; (4) prohibited Level III procedures in office settings for ASA physical status III patients; (5) required all ASA physical status II patients over the age of 40 years to have complete medical work-up for Level III procedures in office settings; and (6) mandated compliance with ASA anesthetic monitoring guidelines.<sup>6</sup>

### **State activity in 2000**

Only a few states considered legislation pertaining to office-based surgery during 2000. In a couple of cases, these bills focused on data collection with no attempt to actually regulate office surgery.

**Connecticut**—The General Assembly considered H.B. 5652, which would have required any unlicensed facility operated by a licensed health care practitioner or practitioner group at which moderate sedation/analgesia, deep sedation/analgesia, or general anesthesia is administered to meet the accreditation standards of the Medicare program, AAAHC, AAAASF, or JCAHO. The Public Health Committee voted in support of H.B. 5652, but the house did not act on it before adjourning for the year.

On August 22, 2000, Connecticut's Office of Health Care Access issued a notice of intent to adopt regulations applying to office surgical pro-

cedures. Under these proposed regulations, minor surgical procedures would be exempt, as would procedures limited to the skin and subcutaneous tissues or other procedures performed under topical or local anesthesia not involving drug-induced alteration of consciousness other than minimal preoperative tranquilization. Current hospital privileges would be required of physicians performing procedures in their offices, and the duration of these procedures must be two hours or less.

**Michigan**—The legislature passed and the governor signed H.B. 4599. Under terms of this new law, a private physician's office where 50 percent or more of the patients annually served at the facility undergo an abortion must be licensed as a freestanding outpatient surgical facility. This facility would be exempt from meeting the certificate of need requirements in order to be granted a license.

**New York**—The senate considered, but did not pass, a bill that would have required a health care practitioner who performs office-based surgery to report at least quarterly any adverse incident (all complications, emergencies, transfers of patients to hospitals as a result of such emergencies, mortalities, and so on) to the Commissioner of Health. Office-based surgery was defined as any operation or other invasive procedure requiring anesthesia, analgesia, or sedation—including cryosurgery, laser surgery, and high-volume liposuction—which is scheduled to result in a patient stay of less than 24 consecutive hours and is performed in a location other than a hospital.

This legislation came about as a result of a report issued in 1999 titled "Problems of Office Surgery." The report, produced by the New York Senate Committee on Investigations, Taxation, and Government Operations, focused on adverse incidents and the physicians who perform surgical procedures outside the scope of their training and experience. Thus, the report presented a bleak picture of the state of office-based surgery in New York, although it did acknowledge that "not every office surgeon is a charlatan."<sup>7</sup>

**Virginia**—The legislature approved but the governor vetoed legislation that would have required any physician performing surgical procedures in his or her office to report outpatient surgical data to the Board of Health for inclusion in the Virginia Patient Level Data System. These data would have

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included principal and secondary diagnosis, external cause of injury, comorbid conditions existing but not treated, procedures and procedure dates, revenue center codes, units and charges, and total charges.


### **Federal activity**

The federal government has not been particularly active in the area of physician office surgery, as the states are responsible for licensing physicians. However, a proposal was developed in August 2000 by the Department of Health and Human Services, Office of Inspector General, to conduct a study on the quality of surgical care through the Medicare program provided in various ambulatory settings: hospital outpatient departments, ambulatory surgical centers, and physician offices.

### **Outlook for 2001**

It is difficult to predict with certainty which states will take up the issue of regulating office-based surgery in 2001. As this issue becomes more familiar to state legislators, there may be greater legislative activity, particularly if a patient experiences a serious injury or death. Further, it is likely that current hot spots, such as Florida and New York, will continue to promulgate legislation and regulations. In addition, areas of the country with traditionally more active legislatures, such as New England and the Pacific Northwest, may see some activity centered on this issue.

### **ACS guidelines**

The ACS Board of Governors' Committee on Ambulatory Surgical Care has developed *Guidelines for Optimal Ambulatory Surgical Care and Office-based Surgery*. The third edition of these guidelines was published in May 2000 and is intended to ensure and maintain superior quality of care for the surgical patient who undergoes an outpatient surgical procedure in an office-based or ambulatory surgical facility. Surgeons seeking to order a copy of these guidelines should visit the ACS Web site at <http://www.facs.org/commerce/guidelines.html>. The first copy is provided at no charge. 

issue of office-based surgery and compares a few states' regulation with ACS guidelines. This publication is available on the ACS Web site at [http://www.facs.org/about\\_college/acsdept/hpa\\_dept/hpa\\_pubs/pubs.html](http://www.facs.org/about_college/acsdept/hpa_dept/hpa_pubs/pubs.html).

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**Author's note:** The ACS *Health Policy Brief*, "Office Surgery Regulation: Improving Patient Safety and Quality Care," provides a more detailed discussion of the