Safety, Regulation, Compliance, and Billing of In-Office Ambulatory Surgeries

Office surgery accreditation can be attained by adhering to the state and agency standards.

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Largely unregulated two decades ago, office surgery now is the subject of stringent regulation in many, if not all, states. In the past 20 years, the subspecialty of office-based anesthesia has increased, with more than 25% of all surgical procedures now being performed in offices.[1]

In part, Medicare and other payers have influenced this trend by providing augmented fees for procedures performed in the office setting. Unlike surgeries performed in a hospital or an ambulatory surgical center, the third-party payer is not required to pay a "facility fee" for surgeries in the office setting.

History

Less than 20 years ago, surgery performed in the office setting was almost completely unregulated in almost all 50 states. However, the safety of office-based procedures has been brought into question in recent years. Perhaps the most notorious case was the cardiac arrest of Joan Rivers at Yorkville Endoscopy, an office-based surgery center in New York City, on August 28, 2014. She died eight days later, on September 4, after suffering complications. The 81-year-old woman had undergone a gastrointestinal endoscopy procedure and laryngoscopy. A sequence of events resulted in the celebrity suffering cardiopulmonary arrest. Her family initiated a medical malpractice suit that was settled for an undisclosed but "substantial" amount. Rivers' family released a statement that it was their intent to help improve patient safety in office-based procedures and prevent future tragedies.[2]

Largely unregulated two decades ago, office surgery now is the subject of stringent regulation in many, if not all, states.

Examples of office-based surgery (OBS) procedures include, but are not limited to: vascular access–related procedures when accompanied by moderate or deep sedation; major lower extremity nerve blocks; and neuraxial or general anesthesia. Procedures such as botulinum toxin injections and minor integumentary procedures are performed with minimal or no sedation and, therefore, can be performed in offices without OBS accreditation. Magnetic resonance imaging (MRI) procedures usually are not subject to this law. However, MRIs and other imaging studies that involve administration of intravenous contrast must be performed in an accredited OBS office if the patient involved receives moderate or deep sedation, major upper or lower extremity nerve blocks, or neuraxial or general anesthesia.

Regulation

Recently, most states have adopted some approach to regulation of procedures and anesthesia performed in surgery offices. The Federation of State Medical Boards keeps an updated list of state requirements for OBS practices.[3] A few states have no regulations; some states have elaborate state-specific regulations; and some states, such as New York, defer accreditation to one of three major organizations.

The Joint Commission, founded in 1951, is the oldest of the three and is best known for hospital accreditation. The Accreditation Association for Ambulatory Health Care was founded in

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1979. The American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF) was founded in 1980. (See sidebar for contact information for these agencies.)

All three agencies have clearly outlined criteria for what constitutes acceptable standards in office structure, personnel, medication, and sterilization standards, which are readily available in their manuals. These standards are in alignment with the American Society of Anesthesiology's (ASA) Office-Based Anesthesia Guidelines.[4]

As an example, in New York, the OBS laws are Public Health Laws (PHL) §§ 230-d and 2998-e and State Education Law § 6530(48). To view copies of those laws, updates, and frequently asked questions, go to www.health.ny.gov/ professionals/ office-based surgery/.

The FAQs have been developed to assist practitioners in understanding PHL § 230-d, the Office-based Surgery Law. This law defines office-based surgery, requires private physician practices in which OBS is performed to maintain accreditation from an accrediting agency designated by the Commissioner of Health, and mandates reporting of select adverse events that occur subsequent to OBS. Effective February 17, 2014, podiatrists privileged to perform ankle surgery by the State Education Department must comply with the OBS law if they perform such surgeries in a private practice office utilizing more than minimal sedation or local anesthesia. Practices seeking to perform OBS must comply with the OBS law as well as all other applicable statutes and regulations.

Setting Up an In-Office Ambulatory Surgery

Following are the criteria of the acceptable standards from these agencies to achieve certification:

- Personnel: All surgeons who perform procedures in office surgery suites must be appropriately credentialed. The credentialing procedure will include examining hospital privileging and board certification. Any action against the medical licenses of physicians must be reported to the respective agency. Practitioners must be present who have BLS/ACLS (i.e., basic life support/advanced cardiac life support) cards.
- Structure and Equipment: All equipment must be regularly inspected by a biomedical engineer and tagged appropriately. Standard ASA monitoring must be done.
- Medication: All facilities that stock malignant hyperthermia–triggering agents must have an adequate supply of dantrolene to begin resuscitation, if necessary. A full arsenal of code drugs and equipment must be stocked.
- Sterilization: There must be adequate record-keeping of all sterilized instrumentation and regular testing of the sterilization equipment.

Maintaining Certification

Re-certification is scheduled periodically, and a quality improvement program and a peer review program may be required. Certain events can trigger immediate re-inspection. Individual states have reporting requirements in addition to agency-specific requirements. As one example, New York requires reporting of certain adverse outcomes, as follows:

"Unplanned emergency department visits within seventy-two hours of office surgery. Unscheduled assignment to observation services within a hospital within seventy-two hours of the office-based surgery. Unplanned transfer to a hospital or emergency department from an OBS practice. Unscheduled admission to the hospital for longer than 24 hours within seventy-two hours of office-based surgery. Patient death within thirty days. Suspected transmission of blood-borne pathogens from staff to patients or between patients. Any other serious or life-threatening event."[5]

The AAAASF requires that deaths be reported promptly:

"Any death occurring in an accredited facility, or any death occurring within thirty (30) days of a 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 procedure sequela in the semi-annual Peer Review report. In the event of a death occurring within thirty (30) days of a procedure done in an AAAASF accredited facility, an unannounced inspection may be done by a senior inspector."[6]

Effective February 17, 2014, podiatrists privileged to perform ankle surgery by the State Education Department must comply with the OBS law if they perform such surgeries in a private practice office utilizing more than minimal sedation or local anesthesia.

Compliance

Public Health Law (PHL) §§ 230-d defines "office surgery" as 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.

For the purposes of OBS, the New York State Department of Health has adopted the following definition of invasive procedures: Invasive procedures are procedures performed for diagnostic or treatment purposes which involve puncture, penetration, or incision of the skin, insertion of

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an instrument through the skin or a natural orifice, or insertion of foreign material other than medication into the body. Invasive procedures include, but are not limited to, the injection of contrast materials such as used for an MRI or computed tomography scans when these imaging procedures are accompanied by moderate or deep sedation, major upper or lower extremity nerve blocks, neuraxial or general anesthesia.

The OBS law initially defined "licensee" as an "individual licensed or otherwise authorized under articles one hundred thirty-one or one hundred thirty-one-B of the education law." Individuals licensed under these laws include physicians, physician assistants, and specialist assistants. In 2012, the definition of "licensees" in the OBS law was expanded to include podiatrists licensed under article one hundred forty-one of education law and privileged by the State Education Department to perform ankle surgery. The OBS law defines "minor procedures" as "(i) procedures that can be performed safely with a minimum of discomfort where the likelihood of complications requiring hospitalization is minimal; (ii) procedures performed with local or topical anesthesia; or (iii) liposuction with removal of less than 500 ml of fat under unsupplemented local anesthesia."

Any invasive or surgical procedure performed by a physician or a podiatrist performing ankle surgery requiring more than minimal sedation and/or local or topical anesthesia to complete or attain sufficient patient comfort does not meet the criteria for the minor procedure exemption as defined in the OBS statute and should therefore be performed in an Article 28–licensed facility or an accredited OBS practice.

In addition, neither neuraxial anesthesia nor major upper or lower extremity nerve blocks are equivalent to the "local or topical anesthesia" exemption identified in the definition of minor procedure and should therefore be performed in an Article 28–licensed facility or an accredited OBS practice.

The intended level of sedation of the patient is what determines the need for accreditation and provision of care consistent with ASA standards. Neither specific medications nor specific routes of administration are mentioned in the statute or the ASA definitions.

PHL § 230-d identifies the first five levels of sedation (listed below) consistent with the definitions established by the ASA. When moderate sedation, deep sedation, major upper or lower nerve blocks, neuraxial, or general anesthesia is provided in con-

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junction with performance of an invasive or surgical medical procedure or ankle surgery performed by a privileged podiatrist, the office should be OBS accredited. Procedures performed with minimal sedation do not require accreditation.

The levels of sedation used in OBS that require accreditation are as follows:

- Moderate sedation/analgesia: a drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function usually is maintained without assistance.
- Deep sedation/analgesia: This a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function usually is maintained without assistance.
- Major upper and lower extremity nerve blocks: These are types of regional anesthesia in which pain sensation is modified or blocked to a large area of the extremity by the administration of medication around the nerves supplying that region of the extremity.
- Neuraxial anesthesia: This a form of regional anesthesia in which pain sensation is modified or blocked by administration of medication into the epidural space or spinal canal.
- General anesthesia: This is a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.

Accreditation status does not require a third-party insurer to pay a facility fee.

Billing

PHL § 230-d does not address or require reimbursement of an OBS facility fee. Accreditation status does not require a third-party insurer to pay a facility fee. An OBS practice is not a healthcare facility under PHL Article 28 or as defined by PHL § 18. Neither Medicaid nor Medicare pays a facility fee to private physicians' offices for office surgery. The Department of Health does not establish fee schedules or billing guidelines for OBS.

Summary

To add another dimension to your practice's services and revenue stream, consider implementing in-office surgeries consistent with your specialty. Although strictly regulated in most states to ensure high quality patient care, office surgery accreditation can be attained by adhering to the state and agency standards with respect to personnel, equipment, medications, and sterilization protocols. **PM**

Accrediting Agencies

You can contact the accrediting agencies at:

American Association for Accreditation of Ambulatory Surgery Facilities
5101 Washington Street, Suite 2F
Gurnee, IL 60031
www.aaaasf.org

Accreditation Association for Ambulatory Health Care
5250 Old Orchard Road, Suite 200
Skokie, IL 60077
www.aaahc.org

The Joint Commission
One Renaissance Boulevard
Oakbrook Terrace, IL 60181
www.jointcommission.org/

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