Washington Ambulatory Surgery Center Association
Our Patients Come First

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Medical Quality Assurance Commission to Adopt New Office-Based Surgery Rules

Background

While the ambulatory surgical facility licensure requirements were effective July 1, 2009, significant confusion regarding the Washington State Department of Health's interpretation of their applicability to practitioner offices continued until the department issued clarifying guidance on October 20, 2009.[1]

Codified at Chapter 70.230 RCW, the ambulatory surgical facility licensure law excludes from its scope "outpatient specialty or multispecialty surgical services routinely and customarily performed in the office of a practitioner in an individual or group practice that do not require general anesthesia".[2] This provision in the licensure law is often referred to as the "practitioner office exception." On October 20, 2009, the department issued guidance in the form of "Frequently Asked Questions" which broadens the practitioner office exception.[3] In the guidance, the department reiterated that all ambulatory surgical facilities in the State of Washington are required to obtain a license. However, the department communicated a change in its interpretation of the definition of the term "ambulatory surgical facility." The department now interprets the term to include only "[a] facility that performs outpatient surgeries and uses general anesthesia." Accordingly, the department indicated that:

> Any facility or office that does not use general anesthesia does not need, and cannot get, [an ambulatory surgical facility] license. ...

While surgery centers that do not use general anesthesia are not within the scope of the ambulatory surgical facility licensure law (as that law is interpreted by the department), these centers likely will be within the scope of the revised office-based surgery rules anticipated next year. Below is a discussion of the most recent iteration of the "Office-Based Surgery Rules."

New Office-Based Surgery Rules

The Medical Quality Assurance Commission intends to introduce new rules regulating physicians who perform surgical procedures in office-based settings ("Office-Based Surgery Rules"). The Commission determined the revised Office-Based Surgery Rules were needed in order to directly regulate office-based surgery, including administration of sedation and anesthesia, and to reduce the risk of substandard care by osteopathic

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[1] Chapter 70.230 RCW.
[2] RCW 70.230.040(3). The exclusion is reiterated in the regulations implementing the licensure law. See WAC 246-330-010(6) ("excluded from the definition of the term "ambulatory surgical facility" is "a practitioner's office where surgical procedures are conducted without general anesthesia").
[3] See www.doh.wa.gov/hsqa/FSL/AmbulSurgFac/.

practitioners who perform surgery in their offices. Through the rules, the Commission seeks to establish enforceable standards and to authorize the Commission to address complaints of unprofessional conduct and allegations of violations of these rules pursuant to the Medical Practice Act and the Uniform Disciplinary Act.[4]

"Office-Based Surgery"

Under the Office-Based Surgery Rules, the term "office-based surgery" is defined to include any surgery or invasive medical procedure requiring analgesia or sedation that is performed in a location other than a hospital, a hospital-associated surgical center, or an ambulatory surgical facility licensed under chapter 70.230 RCW.

Applicability of Regulations

The Office-Based Surgery Rules apply to physicians practicing independently or in a group setting who perform office-based surgery employing one or more of the following levels of sedation or anesthesia:

- Moderate sedation or analgesia;
- Deep sedation or analgesia; or
- Major conduction anesthesia.

In contrast, the rules do not apply to physicians who:

- Perform surgery and medical procedures that require only minimal sedation or infiltration of local anesthetic around peripheral nerves; or
- Perform oral and maxillofacial surgery, if the physician i) is licensed both as a physician under chapter 18.71 RCW and as a dentist under chapter 18.32 RCW, ii) complies with dental quality assurance commission regulations, iii) holds a valid anesthesia permit, and iv) practices within the scope of his or her specialty.

In addition, consistent with the definition of "office-based surgery" the new rules specifically exempt surgery in an ambulatory surgical facility licensed under chapter 70.230 RCW and surgery utilizing general anesthesia.

The Office-Based Surgery Rules set forth the following requirements.

Certification or Accreditation

Within 180 calendar days of the effective date of the Office-Based Surgery Rules, a physician who performs office-based surgery must ensure that the surgery is performed in a facility that is certified or accredited from one of the following:

- The Joint Commission;
- The Accreditation Association for Ambulatory Health Care;
- The American Association for Accreditation of Ambulatory Surgery Facilities; or
- The Centers for Medicare and Medicaid Services.

Competency

A physician performing office-based surgery must be competent and qualified to perform the operative procedure and to provide sedation and analgesia. Qualifications for administration of sedation and analgesia may include:

- Completion of a continuing medical education course in conscious sedation;
- Relevant training in a residency training program;
- Having privileges for conscious sedation granted by a hospital medical staff.

At least one physician certified in advanced resuscitative techniques appropriate for the patient age group must be present or immediately available with age-size-appropriate resuscitative equipment throughout the procedure and until the patient has met the criteria for discharge from the facility.

[4] Chapter 18.71, RCW; Chapter 18.130, RCW.

Sedation Assessment and Management

Physicians intending to produce a given level of sedation should be able to "rescue" patients who enter a deeper level of sedation than intended.[5] If a patient unintentionally enters into a deeper level of sedation than planned, the patient must be returned to the lighter level of sedation as quickly as possible, while the patient is closely monitored to ensure the airway is patent, the patient is breathing, and that oxygenation, heart rate and blood pressure are within acceptable values.

Separation of Surgical and Monitoring Functions

The physician performing the surgical procedure must not provide the anesthesia or monitoring. The physician (or health care practitioner) performing the anesthesia or monitoring, must not perform or assist in the surgical procedure.

Emergency Care and Transfer Protocols

A physician performing office-based surgery must ensure that in the event of a complication or emergency, all office personnel are familiar with a written and documented plan to timely and safely transfer patients to an appropriate hospital. The plan must include arrangements for emergency medical services and appropriate escort of the patient to the hospital.

Medical Records

The physician must maintain an accurate, complete and comprehensive medical record for each patient. The medical record must include: a) identity of the patient; b) history and physical, diagnosis and plan; c) appropriate lab, x-ray or other diagnostic reports; d) appropriate preanesthesia evaluation; e) narrative description of procedure; f) pathology reports; and g) documentation of the outcome and the follow-up plan. When moderate or deep sedation, or major conduction anesthesia is used, the patient medical record must include a separate anesthetic record that documents the type of sedation or anesthesia used, drugs (name and dose) and fluids administered during the procedure, patient weight, level of consciousness, estimated blood loss, duration of procedure, and any complication or unusual events related to the procedure or sedation/anesthesia. The medical record must document, at regular intervals, information obtained from intraoperative and postoperative monitoring and also document which, if any, tissues and other specimens have been submitted for histopathologic diagnosis. Finally, the medical record must document provision for continuity of post-operative care.

The department has indicated that it anticipates the Office-Based Surgery Rules will become effective in early next year. WASCA has asked for comments from its membership regarding the rules so that it can address these concerns in its discussions with the department.

This article has been prepared by Emily R. Studebaker of Garvey Schubert Barer, P.S.

[5] The regulations acknowledge that, depending on the patient's response to drugs, the drugs administered, and the dose and timing of drug administration, it is possible that a deeper level of sedation will be produced than initially intended.