

Emily R. Studebaker

WASCA General Counsel
Garvey Schubert Barer
1191 Second Avenue, Suite 1800
Seattle, WA 98101
Direct 206.816.1417
Mobile 206.406.2729
estudebaker@gsblaw.com

Medical Quality Assurance Commission Adopts 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 multi-specialty 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" that broadens the practitioner office exception and narrows the applicability of the licensure law.³ In the guidance, the department communicated a change in its interpretation of the definition of the term "ambulatory surgical facility." According to the guidance, the department now interprets the term to include only "[a] facility that performs outpatient surgeries and uses general anesthesia." Accordingly, any physician office or other facility that does not use general anesthesia "does not need, and cannot get, [an ambulatory surgical facility] license. . . ."⁴

While office-based settings where surgical procedures are performed without general anesthesia are not within the scope of the ambulatory surgical facility licensure law, as that law is currently interpreted by the department, a physician performing such procedures may be within the scope of new rules governing office-based surgery recently adopted by the Medical Quality Assurance Commission ("MQAC").

MQAC's Office-Based Surgery Rules

On June 3, 2010, MQAC adopted new rules governing physicians who perform surgical procedures in office-based settings (the "Office-Based Surgery Rules"). MQAC determined the rules were needed in order to directly regulate office-based surgery, including administration of sedation and anesthesia. Through the rules, MQAC sought to establish enforceable standards and to authorize it to address complaints of unprofessional conduct and allegations of violations of the rules pursuant to the Medical Practice Act and the Uniform Disciplinary Act.⁵

¹ See 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/.

⁴ *Id.*

⁵ See chapter 18.71 RCW; chapter 18.130 RCW.

Applicability of Office-Based Surgery Rules

The Office-Based Surgery Rules apply to physicians practicing independently or in a group setting who perform office-based surgery employing moderate sedation or analgesia, deep sedation or analgesia, or major conduction anesthesia.⁶

The term “office-based surgery” includes any surgery or invasive medical procedure requiring analgesia or sedation (including local infiltration for tumescent liposuction) performed in a location other than a licensed hospital or hospital-associated surgical center or a licensed ambulatory surgical facility.⁷

Specifically exempt from the Office-Based Surgery Rules are physicians performing:

- Surgery requiring only minimal sedation or infiltration of local anesthetic around peripheral nerves;
- Surgery utilizing general anesthesia;
- Oral and maxillofacial surgery; or
- Surgery in a licensed hospital or hospital-associated surgical center or a licensed ambulatory surgical facility.⁸

In order to qualify for the oral and maxillofacial surgery exemption, the physician must be licensed both as a physician and as a dentist and must comply with the Washington State Dental Quality Assurance Commission regulations.⁹ In addition, the physician must hold a valid moderate sedation permit, moderate sedation with parenteral agents permit, or general anesthesia and deep sedation permit.¹⁰

Certification or Accreditation

Within 365 days of the effective date of the Office-Based Surgery Rule, a physician who performs

surgery under the rules must ensure that the surgery is performed in a facility that is accredited or certified and in good standing 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.¹¹

Facilities limiting office-based surgery to abortions or abortion-related services may instead be accredited or certified by either the Planned Parenthood Federation of America or the National Abortion Federation.¹²

Competency

Under the Office-Based Surgery Rules, when an anesthesiologist or certified registered nurse anesthetist is not present, a physician performing a surgical procedure and using moderate or deep sedation or major conduction anesthesia must be competent and qualified both to perform the operative procedure and to oversee the administration of intravenous sedation.¹³ In addition, at least one licensed health care practitioner currently certified in advanced resuscitative techniques appropriate for the patient’s age must be present or immediately available with age-size-appropriate resuscitative equipment throughout the operative procedure and until the patient has met the criteria for discharge from the facility.¹⁴

Separation of Surgical and Monitoring Functions

In general, the Office-Based Surgery Rules prohibit a physician from performing a surgical procedure while administering intravenous sedation to the patient or while monitoring the patient.¹⁵ In

⁶ WAC 246-919-601(4).

⁷ WAC 246-919-601(2)(h).

⁸ WAC 246-919-601(3).

⁹ WAC 246-919-601(3)(d). *See also* Chapter 246-817 WAC.

¹⁰ *Id.*

¹¹ WAC 246-919-601(5).

¹² *Id.*

¹³ WAC 246-919-601(6).

¹⁴ WAC 246-919-601(8).

¹⁵ WAC 246-919-601(10)(a).

addition, the rules prohibit any licensed health care practitioner who administers intravenous medications and monitors a patient under deep sedation from performing or assisting in the surgical procedure.¹⁶ However, in response to public comments requesting increased flexibility with respect to surgical and monitoring functions, MQAC added language to the rules permitting a licensed health care practitioner designated by the physician to administer intravenous medications and monitor a patient who is under *minimal or moderate sedation* to assist the physician with *minor, interruptible tasks of short duration* once the patient's level of sedation and vital signs have been stabilized, provided that adequate monitoring of the patient's condition is maintained.¹⁷

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. That plan must include arrangements for emergency medical services and appropriate escort of the patient to the hospital.¹⁸

Medical Records

The Office-Based Surgery Rules require physicians to maintain an accurate, complete and comprehensive medical record for each patient.¹⁹ When moderate or deep sedation or major conduction anesthesia is used, the rules require the patient medical record include a separate anesthesia record that documents, among other things, any complication or unusual events related to the procedure or sedation or anesthesia.²⁰

Conclusion

The department has indicated that it anticipates the Office-Based Surgery Rules will be filed on

September 15, 2010 and effective 31 days thereafter. WASCA will keep its members apprised of any new developments regarding the Office-Based Surgery Rules.

This publication has been prepared by Emily R. Studebaker of Garvey Schubert Barer. It is not a substitute for legal advice or individual analysis of a particular legal matter. Transmission and receipt of this publication does not create an attorney-client relationship.

¹⁶ WAC 246-919-601(10)(b).

¹⁷ *Id.*

¹⁸ WAC 246-919-601(11).

¹⁹ WAC 246-919-601(12)(a).

²⁰ WAC 246-919-601(12)(b).