

OMICDIGEST

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Ophthalmic Risk Management Digest

Anesthesia and Sedation Risks and Precautions

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Advances in science, technology, and training, combined with reimbursement pressures by third party payors, have had the effect of moving the vast majority of ophthalmic procedures from hospitals to freestanding ambulatory surgery centers (ASCs) and office-based facilities. While this change has generally benefited ophthalmologists and their patients, there are concerns about compromised patient safety and increased physician liability when sedation and anesthesia are administered outside the hospital setting. The first section of this article outlines several risk avoidance practices that can help ophthalmologists, especially those operating in office-based settings, maximize patient safety and minimize sedation and anesthesia-related liability risks.

In some cases, sedation or anesthesia may be administered by an anesthesiologist or other qualified anesthesia provider, such as a certified registered nurse anesthetist (CRNA). Federal and state guidelines often require that in hospital and ASC settings, the treating surgeon supervise the CRNA. The second section of this article addresses the surgeon's supervisory role and how it affects liability risk.

While hospitals and ASCs are typically closely regulated by accrediting agencies, the office-based surgical setting is currently only regulated in a handful of states. If surgeons do not follow reasonable and published guidelines for office-based surgery and sedation, there is an increased risk that procedures may be performed in settings lacking the appropriately educated and trained clinical staff and/or sufficient equipment and emergency protocols to handle adverse reactions to sedation or anesthesia or other emergencies that may arise. Administering sedation and anesthesia without adequate experience or equipment can have devastating consequences.

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Eye on OMIC

Due to the increasing vulnerability of physicians to fraud and abuse and HIPAA privacy claims, OMIC is enhancing its policy for 2005 to include coverage for fines and penalties and EMTALA claims . . . Responding to requests for resources to help ophthalmologists and administrators better understand and manage the insurance needs of the ophthalmic practice, OMIC and the AAOE have collaborated on an insurance resource guide for their members.

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Policy Issues

Allegations related to physician advertising are surfacing with increasing regularity in medical malpractice claims and expose the physician to punitive damages and other uninsured risks. OMIC has developed a "Review of Advertising" form to help insureds identify aspects of their ads that could potentially lead to a claim.

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Closed Claim Study

Defense of a case involving a globe perforation and resulting vision loss in a high myopic, deaf patient was hampered by the anesthesiologist's claim that had the ophthalmologist fully informed him about the patient's eye abnormalities, he would not have performed a peribulbar block.

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Risk Management Hotline

Ophthalmologists are performing an increasing number of diagnostic and therapeutic procedures on children in office settings. What are the particular risks and safety concerns of office-based pediatric sedation?

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Calendar of Events

OMIC continues its popular risk management program in 2005 with online courses, audioconferences, and seminars.

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Precautions for In-Office Procedures

The decision to perform a procedure in an office-based setting should only be made after careful evaluation. The surgeon is responsible for conducting or reviewing an appropriate physical exam and formulating and prescribing a written patient-specific plan for sedation or anesthesia care that addresses fasting requirements and treatment locale. Because it is impossible to accurately predict how each patient will respond to sedation or anesthesia of any type, and given the fact that the physician and office staff may be called upon to rescue the patient if an adverse reaction occurs, all staff should be thoroughly trained in emergency treatment protocols. The surgeon and other clinical support staff should be certified in Basic Life Support (BLS); Advanced Cardiac Life Support (ACLS) or Pediatric Advanced Life Support (PALS) certification is ideal.

To address patient safety concerns, the physician must have an adequate number of competent, professional staff members available to monitor the patient during the sedation. The person responsible for monitoring the patient during the procedure cannot be the same one performing it. This person should be familiar with the medications used; know how to recognize airway obstruction and correct it; know how to monitor the required parameters, recognize abnormalities in them, and intervene; and be able to manage ventilation with a self-inflating bag valve mask. Additionally, all staff members who will be involved in patient care duties must meet all licensure and certification requirements; have sufficient experience to perform their duties; and be supervised by the operating surgeon or other licensed physician throughout the peri, intra, and postoperative/anesthesia periods.

Upon completion of the surgical procedure, the ophthalmologist who administered or medically directed the sedation should evaluate the patient prior to transferring the care to a qualified licensed nurse. The nurse assuming care of the patient should be qualified to identify surgical and sedation or anesthetic complications that might occur during the postoperative period. The patient should be sent home only after discharge criteria are met and in the company of a competent adult. (For more information on office-based sedation, see **Hotline** article.)

Supervision of CRNAs at Hospitals and ASCs

In ASC and hospital settings, ophthalmologists are often required to supervise nurse anesthetists and sign various anesthesia-related orders, evaluations, and reports. This has raised questions about the ophthalmologist's exposure to claims based on the actions of the CRNA.

Under federal law, it is a condition of participation in the Medicare and Medicaid programs for ASCs that a non-physician anesthetist be under the supervision of the operating physician. The requirement for hospitals varies slightly in that a CRNA must be under the supervision of the operating practitioner or an anesthesiologist who is immediately available if needed.

States may request that their ASCs and hospitals be exempted from this supervision requirement. According to the American Association of Nurse Anesthetists' web site, however, the only states that had opted out of the federal supervision requirement as of November 2004 were Alaska, Idaho, Iowa, Kansas, Minnesota, Montana, Nebraska, New Hampshire, New Mexico, North Dakota, Oregon, and Washington. If your state is not on this list, there is likely a state law that

either mirrors or expands upon the federal provision. See your state government, state medical society, or nurse anesthetists' association web sites for more information.

Proving Supervision Has Occurred

The Centers for Medicare & Medicaid Services (CMS) do not define or specify how to prove supervision. Nevertheless, having the supervising physician sign certain anesthesia orders, evaluations, or records may be the simplest way for the ASC or hospital to confirm that supervision has occurred.

It is OMIC's understanding that the role of the treating physician, in relation to the provision of anesthesia services, is to (1) determine whether a patient requires the surgery or diagnostic procedure, (2) request that anesthesia be administered, and (3) determine that the patient is an appropriate candidate for the procedure and anesthesia. Therefore, it is not uncommon for the treating physician to be asked to sign perioperative orders for anesthesia, sedation, and anxiolytic drugs and to co-sign the pre-anesthesia evaluation conducted by the nurse anesthetist in addition to signing the record of the operation prepared by the circulating nurse as well as the dictated operative report. It is less common, however, for the surgeon to sign the anesthesia record. If asked to do so, the ophthalmic surgeon may wish to clarify with the ASC or hospital the reason for this requirement, since proof of the surgeon's presence and/or supervision during the procedure should be ample from the aforementioned signed orders, co-signed pre-op evaluation, and/or operative records.

Liability for the Actions of CRNAs

Depending on state law, you may be held vicariously liable under the doctrine of "respondeat superior" for the actions of nurse anesthetists

who are your employees. Also termed the “master-servant rule,” this doctrine holds that an employer is liable for the employee’s wrongful (or negligent) acts committed within the scope of employment.

If you supervise nurse anesthetists who are not your employees, however, you are not necessarily liable for their actions. Courts generally focus on the amount of control the treating physician exercises over the anesthesia provider to determine whether the physician should be liable for the anesthetist’s actions (whether the anesthetist is a CRNA or an anesthesiologist). The fact that you sign certain anesthesia orders, evaluations, or records might be used by a plaintiff’s attorney to attempt to prove control, but without further evidence, it would doubtfully be sufficient.

Similarly, the fact that you are required to supervise nurse anesthetists’ provision of services during a procedure does not, by

itself, create an employer-employee relationship, nor does it prevent you from maintaining independent contractor relationships with them (or no formal relationships at all, such as in a hospital setting). The substance of the relationship, not the label, governs the nurse anesthetist’s status as an employee or independent contractor. In order to determine whether a CRNA would be considered an employee, there are several factors to consider:

- Do you have a right to direct and control how the nurse anesthetist does the task for which he or she was hired? An employee is generally subject to the employer’s instructions about when, where, and how to work.
- Does he or she bill separately for his or her own services? Independent contractors are more likely than employees to have non-reimbursed expenses and to bill separately for their own services.

- Is there a written contract describing the relationship of the parties? Do you provide the nurse anesthetist with benefits, such as insurance, a pension plan, vacation pay, or sick pay? Is his or her compensation subject to withholdings for income taxes, unemployment, or workers’ compensation? Whether under contract or not, an employee often will receive benefits and his or her compensation is subject to withholdings.

An ophthalmologist’s supervision of one portion of the nurse anesthetist’s provision of services is not determinative of the nurse anesthetist’s employment status. Rather, it is only one of many factors used to determine the nature of the relationship.

OMIC’s policy covers its insureds for liability arising from the supervision of nurse anesthetists (subject to all policy conditions and exclusions). It is your decision whether to seek less responsibility for CRNA supervision at ASCs or hospitals.

Monitoring and Recovery Equipment for Office-Based Anesthesia

If an anesthesia-related emergency arises during ophthalmic surgery, immediate access to the appropriate monitoring and recovery equipment could mean the difference between life and death. All clinical staff should be trained in the proper use of this equipment. The American Society of Anesthesiologists’ (ASA) Guidelines for Office-Based Anesthesia (available at www.asahq.org) include the following provisions about appropriate office-based monitoring and recovery equipment:

1. At a minimum, all facilities should have a reliable source of oxygen, suction, resuscitation equipment, and emergency drugs.
2. There should be sufficient space to accommodate and allow easy access to all necessary equipment and personnel.

3. All equipment should be maintained, tested, and inspected according to the manufacturer’s specifications.

4. Back-up power sufficient to ensure patient protection in the event of an emergency should be available.

5. There should be appropriate anesthesia monitoring equipment consistent with ASA Standards for Basic Anesthetic Monitoring and documentation of regular preventive maintenance as recommended by the manufacturer.

6. Where anesthesia services are to be provided to infants and children, the required equipment, medication, and resuscitative capabilities should be appropriately sized for a pediatric population.

Emergencies and Transfers

In the event of an emergency requiring transfer to a hospital, the office-based facility must have:

1. Written emergency and evacuation protocols, including provisions for cardiopulmonary emergencies and disasters such as fire, weather-related events, and terrorist actions. All staff should be appropriately trained in these protocols.
2. Medications, equipment, and written protocols in place to treat adverse reactions such as malignant hyperthermia.
3. A written transfer agreement with a hospital.