

Ophthalmic Risk Management Digest

OMIC DIGEST

New Safety Rules for Outpatient Surgery

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When outpatient surgical facilities (OSFs) first opened, physicians frustrated with the heavily regulated world of hospitals opted to perform low-risk procedures there or in their offices. Partly in response to encouragement from health care insurers, the volume, scope, and complexity of procedures performed outside of hospitals grew, and many physicians became owners and directors of ambulatory surgery centers (ASCs). Just as in hospitals, adverse outcomes inevitably occurred in outpatient settings, and states and regulatory agencies predictably responded by introducing laws and regulations to oversee them. Many states now require freestanding ASCs to be licensed. Texas and California permit only certain types of procedures to be performed in office settings, and Florida suspended all office surgery for a period of 90 days in order to evaluate the safety risks.

OMIC's exposure to malpractice claims at outpatient facilities has increased over the years, a result both of the shift toward expanded and riskier outpatient care and of insuring a larger number of such facilities. Whereas there were 27 OSFs insured by OMIC in 2000, today there are more than 130. After paying out on several large claims, OMIC's Board set a goal of improving patient safety in OSFs and asked the authors of this article to initiate a study to determine steps facilities should take to reduce the number and severity of future claims. The following case study highlights the risks of outpatient surgery and illustrates the main concerns the study identified: patient selection, sedation, and perioperative monitoring.

An 81-year-old female presented for upper eyelid functional blepharoplasty for bilateral ptosis at an ASC. She had a history of systemic and pulmonary hypertension, COPD, coronary artery disease, stent placement x 2, carotid artery disease, and peripheral vascular disease, and was on beta-blockers,

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MESSAGE FROM THE CHAIRMAN



The hurricane season of 2005 is behind us but the destruction wrought by Katrina and Rita lingers. Many survivors who lost homes and jobs are still displaced as they continue to try to pick up the pieces of their former lives and livelihoods. Some of our colleagues and fellow OMIC insureds who live and practice along the gulf coast sustained damage not only to their personal property but to their medical practices as well. In addition to wind and water damage to their office structure and contents (including medical records), some lost staff members and patients as a result of the massive relocation of residents from the hardest hit areas. Fortunately for most ophthalmologists, the disruption in practice was temporary but others have themselves been forced to relocate and rebuild their practice.

In the days and weeks following Katrina, OMIC monitored the situation closely to determine the best way to support our member-insureds in need and was one of the first physician-owned

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ace-inhibitors, statin drugs, calcium, and aspirin. As instructed, she took her antihypertensive medications the morning of surgery. The planned local anesthesia was to be administered by the ophthalmologist, with minimal sedation given by a registered nurse. Preoperatively, the patient's O₂ saturation was 99% but blood pressure was elevated at 168/92, so she was given two doses of oral Valium and sublingual Procardia (nifedipine). The surgery was uneventful and, after a 30-minute stay in the recovery room, the patient was discharged home with a BP of 109/59 and an O₂ saturation of 94%. She later became incontinent of urine, experienced a right-side facial droop, difficulty swallowing, and inability to ambulate without assistance. By the time her family called the surgeon, the patient was sluggish and hard to arouse. She was diagnosed in the emergency room with a cerebrovascular accident, or stroke. Subsequent strokes left her paralyzed on the right side, unable to speak, and in need of a wheelchair, feeding tube, and nursing home care.

The lawsuit alleged negligent prescription and administration of Procardia, negligent choice of anesthesia, negligent monitoring during sedation and in the recovery room, and negligent discharge. Expert witnesses for both the plaintiff and the defendant physician raised concerns about the dosage of Valium in an elderly patient and the administration of Procardia, which carried a "black box" warning that it should not be used sublingually to control blood pressure because of reports of strokes. Given the patient's complex medical comorbidities, it was hard to support the choice of a registered nurse to provide the sedation and monitor the patient. Similar criticisms emerged about the response to the drop in blood pressure, especially the decision to discharge the

patient before the pressure returned to pre-procedure levels. Although defense experts felt the stroke was due to the patient's known, severe, cardiovascular disease and not the Procardia, the insureds and OMIC agreed to settle the case because of the numerous concerns about her care. The \$750,000 indemnity payment was split equally between the ophthalmologist and the ASC.

The defense attorney for the ophthalmologist and the ASC readily acknowledged that this surgeon was highly respected and that the ASC was by far the best he had ever seen. As this case shows, even the most competent and caring providers are at times involved in medical errors. The physician and nurse in this case deeply regretted the patient's poor outcome and were determined to evaluate the entire care process to ensure that similar problems did not recur. OMIC worked with them to help revise protocols and later incorporated the lessons learned from this case into the new requirements for patient selection, sedation, monitoring, and emergency response that apply to outpatient surgical facilities. These "Outpatient Surgery Facility Risk Management Requirements" are included in OMIC's new application for coverage and also can be found in the **Risk Management Recommendations** section of www.omic.com. OMIC is developing guidelines for pediatric office-based care.

and for the care provided by their staff. Policyholders will complete the simpler "Outpatient Surgical Facility Application" (OSFA) and be expected to comply with the listed underwriting and risk management requirements by their 2006 renewal date.

OMIC-insured physicians who do surgery in their own offices and do not allow "outside utilizers" need not complete the OSF application, since they do not have the peer review exposure and their policy provides coverage for them, their staff, and their practice or entity. (If the ophthalmologist does not want to share the limits of his or her coverage with the entity, an additional premium is charged.) While they are not bound by these risk management requirements, policyholders who perform office-based surgery nonetheless face the same clinical risks. To assist them in promoting patient safety, OMIC has developed *voluntary* guidelines, "Office-Based Surgery for Adults," which can be found in the **Risk Management Recommendations** section of www.omic.com. OMIC is developing guidelines for pediatric office-based care.

Patient Selection

Unlike hospitals, OSFs do not usually have critical care specialists available to respond to emergencies. The case discussed earlier and our analysis of all outpatient surgery claims convinced us that proactive steps must be taken to ensure that patients selected for outpatient procedures can be safely cared for if adverse events develop. The surgeon must carefully evaluate the patient's overall condition and risk and be satisfied that the procedure is within the facility's capabilities and scope of practice and competency of the health care providers who work there. The American Society of Anesthesiologists established a physical status (PS) classification system to help assess the patient's

Facilities Affected by New Rules

There is no change in the facilities that must comply with the requirements, as insured ophthalmologists who operate ambulatory surgery centers or refractive surgery centers and those whose in-office surgical suites allow "outside utilizers" already must apply for coverage by submitting a surgery center application. These OSFs have liability exposure for activities such as credentialing, quality assurance, and peer review,



risk during operative procedures. We combined the patient's PS classification and age in order to determine which patients can be selected for surgery at OMIC-insured outpatient surgical facilities:

- Adults (age 15 and older) who are healthy (PS 1), have mild systemic disease (PS 2), or severe systemic disease that is not a constant threat to life (PS 3) are, as a rule, appropriate candidates for outpatient procedures. Patients with systemic disease that is a constant threat to life, or who are moribund, not expected to survive the procedure, or declared brain-dead (ASA PS 4, 5, and 6) may not have surgical procedures performed at OMIC-insured outpatient facilities.
- Neonates (0 to 30 days), infants under 6 months of age, and ASA PS 3 pediatric patients of any age should receive care only in centers that are specifically designed for patients of this age or complexity and that have equipment and qualified providers immediately available to handle all possible complications.
- Infants aged 6 months to 1 year and children age 1 to 14 years with PS 1 or 2 status can, as a general rule, be provided safe care at OSFs. Those in these age groups with PS 3, 4, 5, or 6 must be referred to centers that specialize in complex pediatric care.

Sedation Administered by Non-anesthesia Personnel

Sedation can pose significant risks for the ophthalmic patient because, in general, eye patients tend to be older than other surgical patients and may have comorbid diseases that complicate their anesthesia care. That risk is amplified when non-anesthesia personnel (i.e., ophthalmologists, registered nurses, and physician's assistants) administer and monitor moderate ("conscious")

sedation to adults, or when any sedation is provided to pediatric patients (children under 15).

Patients receiving moderate sedation and all children can slip into deeper levels of sedation that approach general anesthesia and compromise their protective reflexes. To ensure that patients can be rescued from deeper levels of sedation, non-anesthesia providers who prescribe, administer, or monitor the effects of moderate sedation (including any pediatric sedation) must demonstrate an understanding of the pharmacological agents/reversal agents and recognize the associated complications of each, be able to rescue patients who enter a state of deep sedation, be capable of establishing an airway and/or providing positive pressure ventilation, and have advanced age-specific cardiopulmonary resuscitation skills (ACLS or PALS).

Monitoring Post-procedure Care

Ophthalmic personnel are highly skilled in the technical aspects of patient care. Many, however, do not have the licensure, training, or expertise needed to administer sedation, monitor and manage patients, and effectively respond to complications during the perioperative period. To protect patients, at least two staff members, one of whom must be a licensed health care provider with ACLS/PALS certification (e.g., the surgeon or a registered nurse), must be present until all patients have been discharged from the surgical facility. If moderate or deep sedation or general anesthesia are administered, at least two staff members with ACLS/PALS certification must be present at all times until the patient is ready for discharge. If anesthesia other than straight local or peripheral nerve block is used, the patient must be monitored after the procedure/ anesthesia and up until discharge by a registered nurse

or other licensed health care provider whose scope of practice includes post-anesthesia care for that age group.

The patient must meet all written, age-appropriate discharge criteria prior to discontinuation of monitoring and discharge. The decision to discharge a patient may be made only by the surgeon, the anesthesiologist/CRNA, or the post-anesthesia care registered nurse and should be based upon established and pre-written discharge criteria. Prior to discharge, the patient and the responsible caregiver (if applicable) must be educated about postoperative care and given a copy of the discharge instructions. The instructions must address pain relief, activity restrictions, special diet requirements (if any), and wound and follow-up care, including the name of the physician providing follow-up care and the date of the appointment. The instructions also must clearly explain the symptoms of complications and instruct the patient when and how to contact the physician if any noted symptoms arise.

Support Available for OMIC-insured Facilities

OSFs presently licensed and/or accredited may already meet or exceed these requirements. We anticipate, however, that some OSFs may not yet meet all of the requirements and may need additional time or assistance to implement them. If your OSF will need more time to comply, please contact your underwriter to request an extension. As always, OMIC's risk manager is available for confidential advice and assistance, and resources to help with implementation are included at the end of the OSFA. While we recognize that change can be difficult, we are convinced that the practices we are requiring will reduce the liability risk of our policyholders and ultimately result in better, and safer, care of patients.