

OMIC

OPHTHALMIC MUTUAL INSURANCE COMPANY

(A Risk Retention Group)

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To be eligible for coverage, an outpatient surgical facility must comply with the following underwriting and risk management requirements, which are arranged in alphabetical order for easy reference.

The requirements outlined below are the minimum requirements established by OMIC for underwriting purposes and may not be representative of all requirements applicable to your facility. Outpatient surgical facilities may be subject to more stringent rules as required by law or regulation for such facilities. It is the facility's responsibility to determine whether and which additional rules or restrictions may apply.

ADVERTISING

Advertisements must comply with state law and FDA- and FTC-mandated guidelines. Ads and other patient information materials must not be misleading and must not make statements that guarantee results or cause unrealistic expectations. Similarly, satisfaction guarantees, warranties, and similar contracts are not permitted. Please refer to the attached "Review of Advertisement for Medical Services" form so that you may evaluate and monitor your compliance with OMIC's underwriting requirements with respect to advertising.

ANESTHESIA/SEDATION

MEDICATIONS. Propofol and other similar agents used to induce general anesthesia should only be used by anesthesia personnel. The use of DPT or Lytic cocktails (Demerol, Phenergan, Thorazine) should not be allowed.

MONITORING. All patients must be monitored appropriately for their age, type of anesthesia, level of sedation, and type of surgery performed. If anesthesia providers are present, healthcare providers must have at least Basic Life Support for Healthcare Providers certification; advanced certification is recommended (ACLS, PALS). If no anesthesia providers are present and the patient is receiving moderate sedation (including any pediatric sedation), the physician and monitoring personnel must be ACLS/PALS certified. Personnel skilled in pediatric airway management and cardiopulmonary resuscitation should be present for all procedures performed on children.

PATIENT SELECTION. The ophthalmologist who performs the operation must 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. Operations on **adults** (age 15 or older) must be limited to ASA Physical Status Class I, 2, or 3 patients (see below). Procedures on **pediatric patients** (under age 15) present greater risks depending upon

the patient's age and the presence of disease processes or congenital abnormalities. Operations on **infants** (6 months to 1 year) and **children** (1 to 14 years) must be limited to ASA Physical Status Class 1 and 2 patients. **NOTE: 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 specifically designed for patients of this age or complexity and capable of handling all possible complications.

The American Society of Anesthesiologists (ASA) has a Physical Status Classification System that assigns a category after the physician completes a history and physical examination:

- P1: normal, healthy patient
- P2: mild systemic disease
- P3: severe systemic disease
- P4: severe systemic disease that is a constant threat to life
- P5: a moribund patient who is not expected to survive without the operation
- P6: a declared brain-dead patient whose organs are being removed for donor purposes

RECOMMENDATIONS ON OFFICE-BASED SURGERY (OBS) FOR ADULTS.

OMIC has developed risk management recommendations on written protocols, procedure and patient selection, monitoring, and emergency equipment and response for office-based surgery. See http://www.omic.com/resources/risk_man/forms/medical_office/OfficeBasedSurgery.rtf

CREDENTIALING

Providers who utilize the facility must maintain staff privileges for the same procedures at a local hospital (excluding procedures for which hospital privileges are generally not granted, e.g., laser refractive surgery).

As part of your established credentialing process for granting and removing clinical privileges, you must:

- a) Review and verify the physician's education, training, and experience. Ideally, the physician's current competence should also be verified.
- b) Verify the physician's Board certification status.
- c) Verify the status of the physician's licensure directly with the state medical board.
- d) Obtain evidence of the physician's insurance coverage.
- e) Require that the physician maintains professional liability limits at least equal to the liability limits carried by the surgical facility.
- f) Review the physician's claims experience.

Privileges must be granted for a period of not longer than two years.

The doctor's qualifications must be re-evaluated prior to renewing privileges.

The training, licensure (if applicable), claims experience (if applicable), and current competency of all allied health care personnel (e.g. technicians, first assistants, CRNAs, etc), whether employees of the facility or not, must be verified initially and on a regular basis.

All anesthesia providers, including nurse anesthetists, must maintain professional liability limits of at least a) \$1,000,000 per claim if the outpatient surgical facility's limits are \$1,000,000/

\$3,000,000 or greater or b) equal to the liability limits carried by the surgical facility if the facility carries limits lower than \$1,000,000/\$3,000,000.

DOCUMENTATION

Accurate and timely documentation about care rendered at the outpatient surgical facility promotes continuity of care and helps defend the ophthalmologist, staff, and the facility itself in the event of a medical malpractice claim. The patient's medical record must include documentation pertaining to:

- a) Verification of patient identity by two methods
- b) Verification that surgeon has obtained informed consent for the procedure
- c) Consent for care provided at the facility
- d) Pre-procedure assessment
- e) Pre-anesthesia or pre-sedation assessment and informed consent for anesthesia care or sedation
- f) Results of "time out" procedure to prevent wrong site/side/implant problems
- g) Monitoring during anesthesia or sedation
- h) Operative report
- i) Post-procedure monitoring
- j) Discharge evaluation and decision
- k) Discharge education and instructions

INSURANCE/REGULATORY ISSUES

The facility must maintain general liability insurance in full force and effect.

The facility must be in compliance with all applicable federal, state, and local laws and regulations (if any) that pertain to surgery centers, laser centers, and/or in-office surgical suites.

If required by law or regulation, the facility must report adverse events involving moderate or deep sedation, general anesthesia, or anesthetic/surgical complications that require resuscitation or emergency transfer to a hospital, or that result in serious bodily harm or death. Such adverse events should also be reported to the OMIC's Claims Department.

LASER EQUIPMENT (if applicable)

The facility must verify that all those who use or assist those who use laser equipment are appropriately trained in the proper operation of each laser in the facility.

The facility must ensure that all laser safety precautions as determined by the laser manufacturer and/or state law are followed.

All laser equipment must be FDA approved and must not be modified.

The laser equipment must be maintained and serviced as recommended by the manufacturer.

MONITORING AND EMERGENCY RESPONSE

Each of the following monitoring/emergency response equipment must be available:

For outpatient surgical facilities in which 1) the only procedures performed are laser refractive surgery, Intacs, Intracorneal inlays, and/or PTK *and* 2) only single oral sedation is used:

- a) Medications to treat anaphylactic reactions. Consult an anesthesiologist or your local hospital's Pharmacy and Therapeutics Committee about the medications you should have on hand to treat your patient population and procedures.
- b) Ambu bag, appropriately sized airway masks, oral or nasal airways, and tongue blades
- c) Blood pressure apparatus
- d) Stethoscope

For all other outpatient surgical facilities:

- a) Medications to treat anaphylactic reactions. Consult an anesthesiologist or your local hospital's Pharmacy and Therapeutics Committee about the medications you should have on hand to treat your patient population and procedures.
- b) Oxygen, suction, and an emergency cart with ambu bag, appropriately sized airway masks, oral or nasal airways, and tongue blades
- c) Blood pressure apparatus
- d) Stethoscope
- e) Pulse oximeter
- f) Emergency power source. Follow your state licensing department or the accreditation organization's regulations on the duration of the emergency power source.

The following additional equipment must be available at all facilities that administer moderate or deep sedation or general anesthesia:

- a) Reversal agents, including naloxone hydrochloride (Narcan) and flumazenil (Romazicon).
- b) Capnography or end-tidal CO₂ detectors (single use/disposable or continuous sampling)
- c) Cardiac defibrillator or AED (automated external defibrillator)

In general, staff must be certified in age-appropriate BLS (basic life support). Certification in age-appropriate advanced cardiac life support (ACLS) is recommended. If no anesthesia providers are present, and moderate sedation (including any pediatric sedation) is administered, the physician and monitoring personnel must have age-appropriate advanced cardiac life support certification (ACLS or PALS).

NON-OPHTHALMIC PROCEDURES (if applicable)

EXCLUDED PROCEDURES. The following procedures are **not** permitted at OMIC-insured facilities: abortion, cardiac surgery, infertility treatment, laminectomy, neurosurgery, obstetrics (*caesarian or vaginal delivery*), pain management, gender reassignment surgery, silicone breast implants, spinal fusion, surgical weight control/obesity, vascular surgery, or any

procedures requiring overnight stays except in accredited ambulatory surgery centers specifically approved for overnight stays.

GASTRO-INTESTINAL PROCEDURES. Gastro-intestinal procedures (including endoscopies) may be performed at OMIC-insured facilities only if the following requirements are met:

- a) The facility must have separate rooms and equipment that are dedicated for GI surgical/endoscopy procedures. The rooms and equipment that are to be dedicated include instrument and equipment storage rooms; “clean” and “dirty” instrument processing rooms; instrument sterilization equipment (autoclaves, gas sterilization equipment, etc.); PACU’s or recovery rooms, and operating suites. These rooms may not be used for GI surgical/endoscopy cases one day and ophthalmic or other non-GI cases another day. Overlap or joint use of rooms on alternate days or weeks is not permitted.
(This requirement does not apply to reception/greeting areas, anesthesia pre-op and surgical holding areas, or areas that are used for “step-down units” for patient discharge.)
- b) Due to the increased risk of infection, separate and appropriate infection control guidelines must be established for the GI unit and other units.
- c) All rooms dedicated for GI use and the GI unit must be labeled as such.

OTHER PROCEDURES. Coverage for other non-ophthalmic procedures is subject to underwriting review and approval.

POST-PROCEDURAL CARE

MINIMUM STAFFING REQUIREMENTS. At least two staff members, one of whom must be a licensed health care provider with ACLS certification (e.g., the surgeon or a registered nurse), must be present at all times 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 certification must be present at all times until the patient is ready for discharge.

CHOICE OF PERSONNEL TO MONITOR THE PATIENT. 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.

RESTRICTIONS ON DRIVING. If anesthesia other than straight local or peripheral nerve blocks is used or if vision is impaired as a result of the surgery or patching, there must be a responsible adult to take the patient home.

PEDIATRIC PATIENTS (under age 15). After the procedure, children should rest/recover in a quiet monitored area even if they seem completely awake. This is especially important when using medications with long half-lives (such as chloral hydrate, promazine, promethazine, chlorpromazine, phenobarbital).

MONITORING AND DISCHARGE CRITERIA. The patient must meet all written, age-appropriate discharge criteria prior to discontinuation of monitoring and discharge (e.g., stable and satisfactory cardiovascular function and airway patency with stable vital signs, easily awakened by normally spoken verbal commands with intact protective reflexes, oriented when

awake, able to maintain pre-procedure mobility with minimal assistance, and minimal nausea and/or dizziness, etc). All patients who receive oral or IV medications that alter or have the potential to alter the state of alertness of the patient must be discharged in the care of a responsible adult.

DISCHARGE DECISION. The decision to discharge a patient may be made only by the surgeon, the anesthesiologist/CRNA, or the post-anesthesia care registered nurse. The decision to discharge should be based upon established and pre-written discharge criteria.

DISCHARGE EDUCATION. Prior to discharge, the patient and the responsible caregiver (if applicable) must be educated about postoperative care and be given a copy of the discharge instructions. The instructions must address pain relief, activity, special diet requirements (if any), wound care, and follow-up care, including the name of the physician providing follow-up care and the date of the appointment. The instructions must also clearly explain the symptoms of complications and instruct the patient when and how to contact the physician if any noted symptoms arise.

RISK MANAGEMENT/QUALITY ASSURANCE

There must be a written quality assurance program to provide peer review services and evaluate the quality of medical care.

- a) Cases must be reviewed on both a random and problem-oriented basis.
- b) Individual cases must be reviewed.
- c) Clinical records must be reviewed.
- d) Data must be collected periodically and evaluated to identify unacceptable or unexpected trends or outcomes.
- e) The quality assurance program must address clinical and results-of-care issues. Ideally, it should also address administrative and cost-of-care issues.

This requirement does not apply to in-office surgical suites used exclusively by the owners of the facility and their employees.

The facility must have a structured process of peer review. This requirement does not apply to in-office surgical suites used exclusively by the owners of the facility and their employees.

At least two physicians must serve on the peer review committee.

Disciplinary actions, when taken, must be reported to the appropriate federal licensing agency, state licensing agency, and/or state medical board, as required by law.

Informed consent must be obtained prior to each surgical procedure by the physician who will be performing the procedure and must be documented on an informed consent document.

The surgical facility must verify that the physician has obtained informed consent from the patient by reviewing a copy of the signed informed consent document before surgery begins.

The facility must obtain general consent for the care provided at the surgical facility by staff and independent contractors. This is usually done by having the patient sign a form provided by the

surgical facility.

The facility must implement the JCAHO “Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery™,” or its equivalent, for all procedures. (available online at <http://www.jointcommission.org/PatientSafety/UniversalProtocol/>)

NOTE: If the anesthesia is administered outside of the operating room, or before all members of the team are assembled, the protocol must be implemented **both** before anesthesia and again before the procedure starts.

**SEDATION ADMINISTERED BY NON-ANESTHESIA PROVIDERS:
MODERATE (“CONSCIOUS”) SEDATION FOR ADULTS OR ANY PEDIATRIC SEDATION**
(if applicable)

All sedation must be administered by a qualified practitioner. Special risk management precautions are required when non-anesthesia personnel (i.e., ophthalmologists, registered nurses, and physician’s assistants) administer and monitor moderate sedation to adults, or any sedation to pediatric patients (children under 15). The American Society of Anesthesiologists’ (ASA) document, “Continuum of Depth of Sedation: Definition of General Anesthesia and Levels of Sedation/Analgesia,” provides useful guidance on patient safety issues. Per the ASA, sedation and analgesia comprise a continuum of states ranging from minimal sedation (anxiolysis) through general anesthesia.

- ***Minimal sedation*** includes peripheral nerve blocks, local or topical anesthesia, or a single, ORAL sedative or analgesic medication administered in doses appropriate for the unsupervised treatment of insomnia, anxiety, or pain.
- ***Moderate (“conscious”) sedation*** is a “drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully (NOTE: reflex withdrawal from a painful stimulus is NOT considered a purposeful response) to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patient airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.”
 - NOTE: Due to the increased vulnerability of pediatric patients, OMIC considers any sedation or analgesia administered to patients under 15 to be “moderate sedation.”

PERSONNEL QUALIFICATIONS. Non-anesthesia personnel [i.e., ophthalmologists, registered nurses (RN), or physician assistants (PA)] who prescribe, administer, or monitor the effects of moderate sedation (including any pediatric sedation) must: 1) demonstrate an understanding of the pharmacological agents/reversal agents and recognize the associated complications of each, 2) be able to rescue patients who enter a state of deep sedation/analgesia, 3) be capable of establishing an airway and/or provide positive pressure ventilation, and 4) have advanced age-specific cardiopulmonary resuscitation skills (ACLS or PALS).

SURGEON’S RESPONSIBILITIES. The surgeon must determine if the patient is an acceptable candidate for sedation, order the medication and dosage, and obtain and document the patient’s or parent’s informed consent. The surgeon must directly supervise the RN or PA who administers or monitors the patient.

NPO PERIOD. To prevent aspiration and regurgitation, patients undergoing sedation may not eat or drink for an age-appropriate interval prior to sedation. The ASA recommended fasting protocols are available in "Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologist" (see below).

MODERATE SEDATION OF ADULTS. In order to respond to emergencies, all adults receiving moderate sedation must have either an IV or IV access (heparin lock).

SEDATION OF PEDIATRIC PATIENTS (UNDER AGE 15).

- a) Sedative and anxiolytic medications should only be administered by, and in the presence of, personnel skilled in pediatric airway management and cardiopulmonary resuscitation.
- b) Sedation should be administered **only** at the facility where the procedure will be performed.
- c) All pediatric patients receiving IV sedating medications for a procedure must have an IV or IV access (heparin lock) throughout the procedure and recovery period. Personnel skilled in establishing IV access, as well as appropriate equipment and supplies, must be readily available for all patients receiving sedation by other routes (oral, nasal, rectal).
- d) Pediatrics patients must be monitored
 - (1) With pulse oximetry
 - (2) And by a registered nurse skilled in pediatric airway management and cardiopulmonary resuscitation

ADMINISTRATION OF MEDICATION. All forms of sedation must be administered by qualified practitioners (a surgeon, RN, or PA). RNs and PAs who administer sedation operate under the direct supervision of the surgeon, must be credentialed in sedation, and have advanced age-appropriate certification (ACLS or PALS).

MONITORING DURING PROCEDURE. The patient must be continuously monitored by someone, other than the surgeon, who is skilled in age-appropriate airway management and cardiopulmonary resuscitation. A nurse may not simultaneously circulate or assist the surgeon and at the same time monitor the patient receiving moderate sedation. The monitoring function must be separate and independent from all other duties.

RESOURCES:

"Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists" is available from the ASA website at <http://www.asahq.org/publicationsAndServices/sedation1017.pdf>. The ASA website (www.asahq.org) has many helpful articles.

See also the JCAHO Compliance Toolkit at <http://www.asahq.org/clinical/toolkit/toolkithome.htm> for sample policies and procedures for sedation administered by non-anesthesia personnel to adults and children.