SUPPLEMENTAL QUESTIONNAIRE FOR OUTPATIENT SURGICAL FACILITY

OMIC
OPHTHALMIC MUTUAL INSURANCE COMPANY
A Risk Retention Group

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OPERATIONS/ADMINISTRATION

1 Name of surgical facility: _____

2 Is the surgical facility a separate legal entity? ☐ Yes ☐ No

3 A. Mailing Address: _____

_____

City *State* *County* *Zip code*

B. Physical Address (if different): _____

_____

City *State* *County* *Zip code*

C. Phone: ( ) _____ D. Fax: ( ) _____

4 A. Contact person's name: _____ B. Title: _____

C. Email: _____ D. Phone (if different): ( ) _____

5 Date facility incorporated/opened for operation: _____

6 The facility can best be described as: ☐ Ambulatory surgical center ☐ Refractive center ☐ In-office surgical suite

7 Please list the name, specialty (if physician) or professional designation (if non-physician), and percentage of ownership for each owner of the surgical facility.

Name	Specialty/Designation	Percentage of Ownership

Continue on a separate page, if needed.

8 Medical Director's name: _____ Specialty: _____

9 What are the facility's hours of operation?

☐ Monday	_____	to _____
☐ Tuesday	_____	to _____
☐ Wednesday	_____	to _____
☐ Thursday	_____	to _____
☐ Friday	_____	to _____
☐ Saturday	_____	to _____
☐ Sunday	_____	to _____

10 On the attached chart, please list all health care providers who utilize the surgical facility (other than ancillary support personnel). For each, indicate their specialty, insurance carrier, and limits of professional liability insurance.

11 Which of the following surgical procedures are performed at the surgical facility?

- ☐ Eyelid surgery (e.g. blepharoplasty, ectropion, ptosis, etc)
- ☐ Laser skin resurfacing
- ☐ Orbital surgery
- ☐ Oculofacial plastic surgery
- ☐ Enucleation/evisceration
- ☐ Glaucoma laser treatments
- ☐ Retinal laser treatments
- ☐ Strabismus
- ☐ Vitrectomy
- ☐ Corneal transplant
- ☐ Intraocular lens implants
- ☐ LASIK/PRK
- ☐ Refractive lens exchange
- ☐ Phakic Implants
- ☐ Other intraocular surgery

Other ophthalmic procedures performed (please list): _____

_____

Non-ophthalmic procedures performed (please list): _____

_____

The following procedures are not permitted at OMIC-insured facilities: abortion, cardiac surgery, gender reassignment surgery, infertility treatment, laminectomy, neurosurgery, obstetrics *(caesarian or vaginal delivery),* pain management, 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. Coverage for other non-ophthalmic procedures is subject to underwriting review and approval.

12 Are any "off-label" or "non-approved" laser procedures performed? ☐ Yes ☐ No

If yes, please explain: _____

_____

_____

13 Please specify the annual volume of surgeries performed at the surgical facility:

	By members of the owning practice	By open-access members	Total
Ophthalmic (excluding refractive surgery):	_____	_____	_____
Refractive Surgery:	_____	_____	_____
Non-Ophthalmic:	_____	_____	_____

14 Do you anticipate a significant change:

A. In the volume of procedures to be performed during the next 12 months?

☐ Increase in volume ☐ Decrease in volume ☐ No change expected

B. In the types of procedures to be performed during the next 12 months?

☐ No ☐ Yes (please list new procedures): _____

INSURANCE

15 Does the facility currently maintain professional liability insurance? ☐ Yes ☐ No

If yes, please attach a copy of the declarations page or certificate of insurance indicating the name of the insurance carrier, policy number, policy effective and expiration dates, retroactive date, and limits of liability carried.

16 What is your requested effective date of coverage? _____

17 What limits of liability do you desire? _____

Note: The facility's liability limits can be no higher than the limits carried by its owners or those providers who utilize the facility.

Limits will be “shared” with the owner ophthalmologist/entity unless otherwise specified.

“Separate” limits of liability are available only to separately incorporated surgical facilities.

Does the facility want “separate” limits of liability? ☐ Yes ☐ No

LICENSURE/ACCREDITATION

18 Is the facility licensed or certified by the state in which it operates? ☐ Yes ☐ No

If yes, provide license/certification number: _____ State: _____

19 Has any investigation, disciplinary action, or negative change in status occurred with respect to the facility’s license within the past 10 years? ☐ Yes ☐ No

If yes, please explain: _____

_____

_____

20 Is the surgical facility certified by Medicare?

☐ Yes ☐ No ☐ Pending (date certification is expected: _____)

21 Is the surgical facility accredited (other than Medicare certification)?

☐ Yes ☐ No ☐ Pending (date accreditation is expected: _____)

If yes,

A. By which agency?

☐ AAAHC ☐ AAAASF ☐ The Joint Commission ☐ HFAP

☐ Other (specify: _____)

B. When does your accreditation expire? _____

22 Is the facility approved by AAAHC, AAAASF, The Joint Commission, or HFAP for overnight stays? ☐ Yes ☐ No

CREDENTIALING

23 Has the facility ever declined a physician’s request for privileges or terminated a physician’s privileges due to claims history, rate of complications, quality of care concerns, or other issues? ☐ Yes ☐ No

If so, please briefly describe the circumstances: _____

_____

_____

24 Who reviews the physician’s credentials and makes the determination whether to grant privileges?

☐ Medical Director ☐ Medical Staff Committee

If other, please explain: _____

RISK MANAGEMENT/QUALITY ASSURANCE

25 Do you have and do you maintain a written risk management program? ☐ Yes ☐ No

If yes, briefly describe the facility’s risk management program: _____

_____

_____

26 As a general rule, peer review is conducted by peers of the same specialty. Does the facility have a structured process of peer review for medical, surgical, and anesthesia services rendered by physicians or other providers at your facility?

☐ Yes ☐ No

A. Who performs peer review for ophthalmic surgery? _____

B. Who performs peer review for anesthesia services? _____

C. Who performs peer review for non-ophthalmic surgery? _____

☐ Not applicable—non-ophthalmic surgery not performed at facility.

D. How often does the committee meet? _____

27 Which forms of corrective action, if any, may be utilized by the surgical facility?

☐ counseling ☐ education ☐ revoking privileges ☐ limiting privileges

☐ proctoring ☐ probation ☐ reprimands ☐ summary suspensions

☐ suspending privileges

ANESTHESIA/SEDATION

28 How many of each does the surgical facility employ or contract with?

	Employ	Contract
Anesthesiologists	_____	_____
CRNAs	_____	_____

29 Submit a Declarations Page or Certificate of Insurance for each of the above.

30 What type(s) of anesthesia/sedation are used on **adult** patients (age 15 and older)?

☐ Topical (non-injection local) ☐ Injection local (e.g. retrobulbar, peribulbar, sub-Tenon's)

☐ Moderate ("conscious") sedation* ☐ Regional (e.g. epidural, cervical, etc.) ☐ General

What type(s) of anesthesia/sedation are used on **pediatric** patients (up to age 15)? In addition to checking the box, please circle the age group(s) of pediatric patients (**N** for neonate: 0 to 30 days, **I** for infant: 31 days to 1 year, and **C** for child: 2 to 14 years old) for which each type of anesthesia may be used.

☐ Topical (non-injection local)	N	I	C
☐ Injection local (e.g. retrobulbar, peribulbar, sub-Tenon's)	N	I	C
☐ Moderate ("conscious") sedation*	N	I	C
☐ Regional (e.g. epidural, cervical, etc.)	N	I	C
☐ General	N	I	C

*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 (Anxiolysis)*** is a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and physical coordination may be impaired, airway reflexes, and ventilator and cardiovascular functions are unaffected.
- ***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."
  - o **NOTE:** Due to the increased vulnerability of pediatric patients, OMIC considers **any** sedation or analgesia administered to **pediatric patients** to be "moderate sedation."

31 Who conducts the pre-anesthesia/sedation assessment when anesthesia providers are present?

☐ Surgeon ☐ Anesthesiologist/CRNA

If no anesthesia provider is present:

A. Who conducts the pre-anesthesia/sedation assessment? _____

B. Who monitors the patient? _____

MONITORING AND EMERGENCY RESPONSE EQUIPMENT

32 Which of the following monitoring and emergency equipment, if any, is available at the facility?

☐ Dantrolene (required if general anesthesia is given)

☐ Medications to treat anesthesia toxicity (diazepam, midazolam, thiopental, etc.)

☐ Medications to treat hypertension and arrhythmias

☐ EKG oscilloscope

☐ Automated external defibrillator (AED)

☐ Full crash cart

☐ End-tidal CO2 detectors (single use/disposable or continuous sampling)

☐ Laboratory tests (e.g., glucose monitoring)

33 Are any staff ACLS (advanced cardiac life support) or PALS (pediatric advanced life support) certified?

☐ ACLS ☐ PALS ☐ No

If **no**, is moderate sedation administered (including any sedation of pediatric patients)? ☐ Yes ☐ No

34 Does the facility have a written transfer agreement with the nearest acute care hospital to transfer patients in the event of an emergency? ☐ Yes ☐ No

If no, explain why not: _____

35 How close is the nearest acute care hospital? _____ miles _____ minutes

36 For emergency situations, how are patients transported to the hospital? _____

UNDERWRITING ISSUES

If you answer "yes" to any of questions 37–40 please provide complete details.

37 Within the past 10 years, has any medical professional liability insurer canceled, declined, non-renewed, or otherwise restricted coverage for the facility? ☐ Yes ☐ No

38 Have any professional liability claims been brought against the facility within the past 10 years (regardless of merit)? ☐ Yes ☐ No

39 Are there any older professional liability claims pending against the facility? ☐ Yes ☐ No

40 Are you aware of any facts or circumstances which may give rise to a claim, regardless whether it has been reported to your current or previous carrier? ☐ Yes ☐ No

41 Does the surgical facility advertise? ☐ Yes ☐ No

"I have read and agree to comply with OMIC's underwriting requirements specific to outpatient surgical facilities, including those outlined on pages 6 through 10 of this application. I agree to notify OMIC prior to implementing any intended changes to my responses above, including any changes in the facility's licensure or accreditation status. I understand that failure to comply with OMIC's underwriting and notification requirements may result in uninsured risk or termination of coverage."

_____ _____

Signature of Authorized Representative *Date*

_____ _____

Authorized Representative's Name *Title*

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. Please initial each item to confirm your understanding and agreement to abide by these requirements.

The requirements outlined in this application 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 OMIC's "Review of Advertisement for Medical Services" form, available online at www.omic.com/advertising-medical-services-recommendations, 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, health care 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 1, 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:

- o **P1:** normal, healthy patient
- o **P2:** mild systemic disease
- o **P3:** severe systemic disease
- o **P4:** severe systemic disease that is a constant threat to life
- o **P5:** a moribund patient who is not expected to survive without the operation
- o **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 www.omic.com/office-based-surgery-for-adults-recommendations.

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 OMIC's Claims Department.

LASER EQUIPMENT

☐ Section not applicable — facility does not have laser equipment.

_____ 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 ☐ Section not applicable — facility is ophthalmic-exclusive

_____ 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. ☐ Not applicable

_____ 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. ☐ Not applicable

_____ 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). ☐ Not applicable

_____ 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 www.jointcommission.org/standards_information/up.aspx)

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

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 (Anxiolysis)*** is a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and physical coordination may be impaired, airway reflexes, and ventilator and cardiovascular functions are unaffected.

- ***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."

☐ Section not applicable—facility does not administer sedation as defined above

_____ 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).
☐ Not applicable

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:

The ASA website (www.asahq.org) has many helpful articles, including "Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists." See also the JCAHO Compliance Toolkit, available on the ASA website, for sample policies and procedures for sedation administered by non-anesthesia personnel to adults and children.

ROSTER OF PROVIDERS WHO UTILIZE THE FACILITY

Name of Surgical Facility: _____

Provider's Name	Specialty	Carrier	Limits

HIPAA DISCLOSURE

Under the HIPAA Privacy Regulations, you may disclose protected health information (PHI) without patient authorization to medical professional liability insurers in order to obtain or maintain insurance coverage. OMIC will (1) maintain the confidentiality of PHI you provide to us, (2) use it only for the purposes for which it was disclosed, and (3) notify you of any breach of confidentiality of PHI. If OMIC insures you, OMIC will safeguard PHI you disclose to it in accordance with OMIC's HIPAA Business Associate Agreement.

RISK RETENTION GROUP NOTICE

The policy to which this application applies is issued by Ophthalmic Mutual Insurance Company (A Risk Retention Group). Risk retention groups may not be subject to all of the insurance laws and regulations of your state. State insurance insolvency guaranty funds are not available for risk retention groups.

Wisconsin applicants only: Under the Federal Liability Risk Retention Act of 1986 (15 USC 3901 to 3906), the Wisconsin insurance security fund is not available for payment of claims if this risk retention group becomes insolvent. In that event, you will be personally liable for payment of claims up to your limit of liability under s.655.23 (4), Wis. Stat.

ARBITRATION CLAUSE NOTICE

The OMIC professional and limited office premises liability policy contains an Arbitration Clause. By accepting the policy coverage, you will be bound by the terms of the Arbitration Clause. This Clause states that any dispute you have with OMIC arising out of the policy must be submitted exclusively to final and binding arbitration. Under the Clause, you agree not to proceed against OMIC in state or federal court and specifically acknowledge waiving your right to a jury trial. Any arbitration award rendered will be final and not subject to appeal. Arbitration will take place in any jurisdiction that is convenient to you and agreed to by the parties. Each party pays its own arbitration costs and the fees of its selected arbitrator and they share equally in the fees of the neutral arbitrator and any other arbitration costs. You must keep confidential the nature of the arbitration proceeding and the award.

CLAIMS MADE AND REPORTED POLICY DISCLOSURE

Your policy is a claims made and reported policy. It applies only to claims made against you and reported to OMIC during the policy period or within five days after the end of the policy period arising from professional services incidents that occur on or after the policy retroactive date. A claim is considered made when it is received by you and reported when it is received by OMIC. Upon termination of your policy, an extended reporting period may be available. Carefully review the extended reporting period policy provisions and when you must purchase or accept any offered extended reporting period endorsement.

WARRANTY AND ACCEPTANCE OF POLICY TERMS

I understand that for purposes of insurance coverage all statements contained in this application and all supplemental questionnaires are considered material to the issuance of coverage. I warrant that the information I have provided is true to the best of my knowledge and is given in good faith and that I have not withheld any material information.

I agree to update this application while it is pending should there be any change in the information provided and to update such information if and after OMIC extends insurance coverage. I understand that failure to comply with the above may result in a declination or termination of coverage or denial of coverage for a claim based on the false or undisclosed information. (Denial of coverage does not apply to Wisconsin Injured Patients and Families Compensation Fund participants.)

I understand that this application and any other documents submitted to OMIC for insurance coverage, together with the policy, the Declarations, and any endorsements, will constitute the contract of insurance between OMIC and the outpatient surgical facility.

I acknowledge that as part of the ongoing underwriting review of the facility's insurance coverage with OMIC, certain information pertaining to any open or closed claim made under the facility's OMIC policy may be reviewed in determining whether coverage may be continued, and I consent to the communication of summary information between the claims and underwriting departments.

I understand that the facility is not insured and coverage is not effective until this application is approved, any required premium for the insurance has been paid, and Declarations listing the facility as an insured are issued.

Once insured, the facility will be bound by the terms of the insurance policy issued to it. I have read the policy included in the application materials carefully to determine the facility's rights and duties. I understand that I should discuss the coverage with my attorney, insurance advisor, or risk management consultant.

By my signing this application as the facility's authorized representative, the facility agrees to be bound by the terms, conditions, exclusions, restrictions, and definitions of the OMIC professional and limited office premises liability insurance policy.

_____ _____

Signature of Authorized Representative *Date*

_____ _____

Authorized Representative's Name *Title*

AUTHORIZATION TO RELEASE INFORMATION

I consent to the communication of information and documents between OMIC and other insurance companies, credentialing organizations, certification organizations, professional associations, licensing agencies, and other persons who may have information pertaining to this application, the facility's qualifications for insurance, or claims under review.

I release from liability, to the fullest extent allowed by law, OMIC and its agents and representatives for their acts performed in connection with evaluating this application, the facility's qualifications for insurance, or claims under review.

I release from liability, to the fullest extent allowed by law, all individuals and organizations who provide information and documents to OMIC or its agents or representatives concerning this application, the facility's qualifications for insurance, or claims under review.

_____ _____

Signature of Authorized Representative *Date*

_____ _____

Authorized Representative's Name *Title*

MEMBERSHIP APPLICATION AND AGREEMENT—OUTPATIENT SURGICAL FACILITY

For and in consideration of the benefits to be derived therefrom, the Applicant hereby applies for membership in the Ophthalmic Mutual Insurance Company (a Risk Retention Group) ("OMIC"), the principal office being located in the state of Vermont; and the main business office being located at 655 Beach Street, San Francisco, California 94109-1336.

The Applicant hereby acknowledges that:

1. The undersigned surgical facility, hereafter referred to as "the Applicant," represents and warrants that it provides predominantly eye care-related surgery services.
2. The Applicant understands that this membership is subject to acceptance by OMIC.
3. Membership begins with the commencement of the policy period of a claims made and reported insurance policy issued by OMIC, and ends upon the cancellation or other termination of that policy. The period of membership shall not include any period of coverage under extended reporting or tail coverage endorsements. After termination of membership, the member shall have no further right to participate in any distribution of savings to members or in any distribution of assets upon the dissolution of OMIC, except for amounts that may be due to the member for loans or surplus contributions under separate instruments issued by OMIC.
4. The Applicant, through its authorized representative, has read the Bylaws of OMIC and agrees that if its application for insurance is accepted by OMIC, the Applicant shall at such time become a member of OMIC. Membership shall, among other things, evidence ownership in OMIC to the extent required by Vermont law governing mutual insurance companies and risk retention groups. As a member of OMIC, the Applicant will be bound by the terms and conditions of the Bylaws of OMIC, as such may be amended from time to time.

_____ _____

Signature of Authorized Representative *Date*

_____ _____

Authorized Representative's Name *Title*