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Ophthalmic Mutual Insurance Company

Ophthalmic Risk Management Digest

Fear and Loathing of Malpractice Litigation

By Paul Weber, JD

Mr. Weber is Vice President of OMIC's Risk Management/ Legal Department. edia coverage of the impact of malpractice litigation typically focuses on multimillion dollar jury awards, skyrocketing insurance premiums, and physicians who decide to relocate or retire early because an unfavorable malpractice climate has made it too expensive to continue practicing in their state. Regrettably, scant coverage is given to the pervasive negative impact that fear of litigation has on the decision making of physicians and the delivery of health care services.

In March 2002, a Harris poll was conducted by phone and online of more than 300 physicians to provide insight into the impact that fear of litigation has on the practice of medicine and the delivery of medical care. (The results of the Harris poll, as well as other polls relating to the medical liability crisis, can be found on the Common Good web site at http://cgood.org/medicine/related/item?item_id=30218.)

OMIC interspersed many of the Harris poll questions throughout its recent *Mock Litigation* interactive presentation before more than 230 ophthalmologists in Anaheim. The results of OMIC's informal "poll" are strikingly similar to the Harris poll. Both polls indicate that fear of litigation influences all aspects of health care decision making, from ordering tests, prescribing medications, and making referrals to a reluctance to discuss adverse events with colleagues. (Complete OMIC poll results, along with a comparison to the Harris poll, can be found in a PowerPoint slide show on OMIC's web site at www.omic.com.)

That many medical professionals' behavior is clearly influenced by their fear of litigation can perhaps be explained by the finding that the overwhelming majority of physicians (85% in the OMIC poll and 83% in the Harris poll) do not believe they can trust the current system of justice to achieve a reasonable result if

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Eye on OMIC

OMIC

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ΟΜΙΟ

655 Beach Street San Francisco, CA 94109-1336

PO Box 880610 San Francisco, CA 94188-0610

 Phone:
 800-562-6642

 Fax:
 415-771-7087

 Email:
 omic@omic.com

 Web:
 www.omic.com

RISK MANAGEMENT COMMITTEE: B. Thomas Hutchinson, MD Chairman

Tamara R. Fountain, MD James J. Salz, MD John W. Shore, MD

Timothy J. Padovese Editor-in-Chief Paul Weber, JD Executive Editor Linda Radigan Managing Editor Anne Menke, RN, PhD Associate Editor Kimberly Wittchow, JD Associate Editor Stoller Design Group Production

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LASIK, PRK Study Identifies Malpractice Predictors

igher surgical volume and a history of prior claims or lawsuits are the primary predictors of whether a refractive surgeon will be sued in the future. Additional medical-legal risk factors for surgeons who perform more than 100 LASIK or PRK procedures a year include advertising use, comanagement with optometrists, preoperative time spent with patient, and physician gender.

These are the findings of a retrospective cohort study presented by Richard L. Abbott, MD, professor of clinical ophthalmology, University of California San Francisco, at the American Academy of Ophthalmology Annual Meeting in Anaheim. Dr. Abbott, who is chairman of OMIC's Underwriting Committee, compared physician characteristics of 100 consecutive OMIC LASIK and PRK claims and lawsuits to demographic and practice pattern data for all active refractive surgeons insured with OMIC between 1996 and 2002.

The study, which also looked at informed consent issues in LASIK and PRK, found that patients who sued were often presented with informed consent for the first time on the day of surgery and many had no consent note written by the surgeon in the patient record.

These findings, published in *Ophthalmology* (November 2003), will be useful in improving the quality of care for patients undergoing refractive surgery. In addition, OMIC will incorporate the data in its underwriting criteria and risk management protocols to help insureds who perform refractive surgery manage and reduce their risk of claims and lawsuits.

Coverage for Phakic Implants

In early October, the FDA's Ophthalmic Devices Advisory Panel recommended approval with conditions for use of the Staar Implantable Contact Lens for the treatment of myopia. It is anticipated that many ophthalmologists, including those who may have never previously performed refractive surgery, may be interested in offering this procedure to their patients once the lenses have gained final FDA approval. OMIC is in the process of developing a special questionnaire and underwriting guidelines, similar to other refractive surgery procedures, so that coverage may be offered to qualified ophthalmologists for their performance of phakic implants. The questionnaire and guidelines will address training, patient selection criteria, informed consent, operative procedures, postoperative care, and advertising. If approved, coverage for phakic implants will be endorsed to the policy at full policy limits. No additional premium will apply.

Please note that OMIC's standard policy excludes coverage for all refractive surgery procedures unless specifically added by endorsement. Each type of refractive surgery procedure must be *separately endorsed* for coverage to apply. While the technique for phakic implants is very similar to that for intraocular lens implants, phakic implants are considered to be refractive surgery and, therefore, are not automatically covered by OMIC. No coverage will extend for any phakic implant procedures performed unless the physician has specifically applied and been approved for coverage and the policy has been amended accordingly.

Other procedures for which coverage is available by endorsement following review and approval of a supplemental questionnaire are radial and astigmatic keratotomy, PRK, LASIK (including LASIK variations such as epi-LASIK, LASEK, IntrLase, and Custom-Cap procedures), CK, LTK, Intacs, and clear lens extraction (refractive lensectomy).

How to Reach OMIC

If you have called the OMIC office recently, you probably noticed that we have a new phone system. While our toll-free 800 number is the same, phone extensions for individual departments have changed. Please remove and save the phone card included with this issue of the *Digest*. It lists new extensions for the most frequently called OMIC departments and gives contact information to reach OMIC by mail, fax, and email.

Toll-free numbers also are provided for Medical Risk Management Insurance Services and Marsh Affinity Group Services, which are the contacts for information about Academysponsored business insurance and life and health insurance programs.

Policy Issues

Shared Liability for ROP Screening

By Kim Wittchow, JD OMIC Staff Attorney

xamining premature infants for retinopathy of prematurity (ROP) is an important aspect of ophthalmic care. Ophthalmologists who perform this critical consultative function are providing a tremendous service to these infants and to the neonatal intensive care units (NICU) and supporting institutions that care for them. Because these institutions and ophthalmologists work together to reduce the likelihood that significant ROP will develop, they also should share the medical malpractice liability risk should a case of ROP advance to vision loss or blindness. If you perform ROP screening, you should know how your hospital handles this shared risk and take steps to limit your liability in the NICU.

Hold Harmless/Indemnification

One approach is to ask the hospital to hold you harmless and indemnify you for any liability you incur in performing ROP screening in the NICU. This means the hospital promises to absolve you of any responsibility for damages or other liability and to reimburse you for any loss you suffer arising from your provision of services in the NICU. This would be accomplished by inserting a hold harmless/indemnification clause in your ROP service contract with the hospital. Note, however, that many states limit the types of risks that can be transferred from one party (you) to another party (the hospital). Any indemnification agreement that you and the hospital enter into should be reviewed and/or drafted by legal counsel. Contact OMIC's Legal/Risk Management Department for sample language.

An additional safeguard is for you to be named an "Additional Insured" under the hospital's liability policy. This gives you direct access under the hospital's policy to defense coverage for insured claims whether or not the hold harmless/indemnification provision is legally enforceable. However, "Additional Insured" status should not be obtained in lieu of a hold harmless/indemnification provision because the hospital's insurance policy may not cover the loss.

Hospital-Provided or Funded Insurance

Another approach is for the hospital to provide you with additional insurance. Again, the specific provisions would be spelled out in your ROP service contract with the hospital. This hospital-provided insurance would coincide with your primary OMIC professional liability insurance. If you negotiate a primary or contributory policy with the hospital, then OMIC and the hospital most likely would share and cooperate in your defense and payment of any (covered) indemnity. (The OMIC policy describes how losses are apportioned when the OMIC policy and other insurance apply to the loss on the same basis.) However, if you negotiate an excess policy with the hospital, the hospital would not generally participate in the defense of the claim unless it is likely you will exceed your primary limits with OMIC. The excess limits would be available, though, if a judgment against you exceeds your policy limits with OMIC. Keep in mind that all determinations of coverage are case specific.

Another alternative is for the hospital to contribute toward payment of your insurance premiums. The AMA reports that hospitals are increasingly helping physicians pay their medical malpractice premiums to ensure that physicians continue to provide services at hospital facilities. As an OMIC insured, one option for you is to raise your professional liability limits and ask the hospital to reimburse you for the difference in premium. You should seek legal counsel when entering into these arrangements to ensure compliance with federal and state laws regulating hospital payments to physicians.

Damage Caps and Punitive Damages

When considering any of these options, you should be aware of state laws, such as those governing damage caps and the availability of punitive damages awards, because they will affect how much and what type of liability coverage you should seek. For example, if the state's damage cap is \$1 million and you have \$2 million per occurrence/\$4 million in the aggregate coverage, you can feel more secure that your limits will not be exceeded because of a jury award against you. However, if your state allows punitive damages awards, you might want to negotiate additional insurance from or indemnification by the hospital since the OMIC policy does not cover punitive damages. Your attorney should recommend the most appropriate and viable coverage alternatives and work with the hospital to draft the applicable terms.

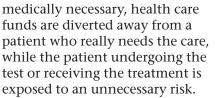
You also should note that if a patient files a lawsuit, conflicts of interest may arise between you, the hospital, and other codefendants such as subsequent treating physicians. For example, you might disagree as to whose responsibility it was to provide follow-up ROP exams to a baby you examined once who was then transferred to another facility. In this situation, OMIC might exercise the right to separate counsel for its insured while still focusing on a unified defense.



continued from page 1

they are sued. This widespread mistrust contributes to feelings of apprehension of possible lawsuits and encourages the practice of defensive medicine rather than care based on medical need.

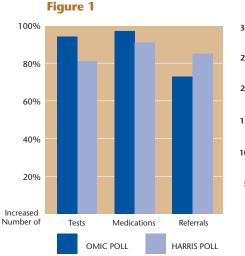
The Harris and OMIC polls asked the following question concerning three areas of medical care: "Based on your experience, have you noticed fear of malpractice liability causing physicians to (1) order more tests; (2) prescribe more medications; and (3) make more referrals than they would based on professional judgment of what is medically needed?"



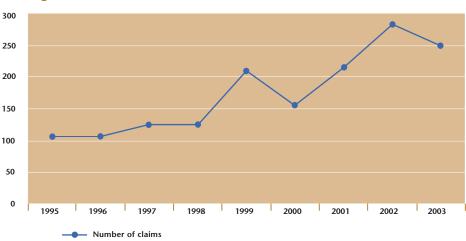
A paradox can be observed here. Even though physicians are increasingly using tests and referrals to avoid malpractice litigation, claims and lawsuits continue to rise. As **Figure 2** shows, OMIC claims frequency has been rising steadily and substantially since 1998.

Apparently for OMIC insureds, more treatment does not result in fewer claims. Indeed, as **Figure 3**

The increase in frequency and severity of OMIC claims is not due to a decline in the quality of ophthalmic care. It remains constant that year after year, the vast majority of OMIC claims (over 78%) are disposed of without an indemnity payment to the patient. It is commonly accepted that most claims and lawsuits are attributable to a combination of unmet patient expectations regarding a procedure or course of treatment and poor doctor-patient communication. Throw the following technological and societal dynamics into the mix and you have a recipe for claims:







OMIC Claims

Claims frequency has been rising steadily and substantially since 1998.

As **Figure 1** shows, both polls overwhelmingly demonstrate that the omnipresent fear of having to deal with litigation results in excessive treatment. Not surprisingly, physicians were nearly in unanimous agreement in both polls (99% of OMIC respondents; 94% of Harris respondents) that these extra tests, medications, and referrals contribute in a significant way to health care costs. The fact is that every time a test is ordered or a treatment is rendered that is not

OMIC and Harris Polls Percentage of physicians who say

medications, and referrals.

that fear of claims leads to more tests,

demonstrates, some of the OMIC claims that have resulted in the largest payouts to patients are in fact related to allegations of failure to order a test leading to failure or delay in diagnosis or allegations of failure to make a timely referral leading to delayed treatment. The number of large payout cases (\$500K and above) has increased severely since 1998. From the company's inception in 1987 to 1998, there were only five large losses; there have been ten large losses in the ensuing five years.

- Improved outcomes leading to unrealistic patient expectations.
- A large population of lawyers practicing in a litigious society.
- HMOs and other managed care entities contributing to real and perceived perceptions of problems with access to health care.

As a result of the current dysfunctional litigation system, there is an unfortunate sense of futility among physicians that there is little they

Figure 3

Sta	te Indemni	ty Year	Allegation
RI	\$500K	2003	Failure to diagnose brain tumor
СТ	\$500K	2003	Failure to diagnose retinal melanoma (patient died)
IL –	\$1M	2002	Steroid mismanagement (joint degeneration)
ТХ	\$850K	2002	Failure to diagnose lung cancer
ТХ	\$500K	2002	Negligent retrobulbar to treat pain
ΤX	\$500K	2002	Numbness OS post retrobulbar to treat pain
AZ	\$1.8M	2001	Failure to diagnose/treat pediatric glaucoma
IL –	\$1M	1999	Failure to treat pediatric corneal ulcer in the ER
MA	\$1M	1999	Stroke post strabismus surgery
AZ	\$740K	1999	Negligent administration of marcaine via catheter (patient died)
GA	\$575K	1996	ROP lost to follow up
ТХ	\$735K	1995	Failure to diagnose endophthalmitis post cataract surgery
FL	\$656K	1995	Corneal perforation during blepharoplasty
FL	\$500K	1995	Garamycin toxicity causing blindness
FL	\$790K	1993	Failure to diagnose pituitary tumor (patient died)

OMIC Large Losses

Large payout cases have doubled in number since 1998.

can do to avoid being named in a malpractice suit. This sentiment is often expressed by OMIC insureds in surveys conducted by the Claims Department after a claim or lawsuit has been closed. One of the comments most frequently heard by insureds is that the claim was frivolous and there was nothing they could have done to avoid it. The following comment by one insured sums up the frustration felt by many with a tort system that seems unjust.

"It appears that plaintiffs have unlimited rights and the accused have no rights. In the eyes of Medicare, state licensing boards, and hospital boards, doctors are presumed guilty and must prove their innocence. Reports of staggering malpractice jury awards add to the fear that regardless of the facts, regardless of guilt or innocence, doctors are at risk of losing everything they own with any lawsuit brought against them. These outrageous awards also encourage a 'win the lottery' type of mentality on the part of plaintiffs and a feeding frenzy for lawyers hungry for cases. The current liability system is terribly unfair to doctors and in no way helps us take better care of our patients, which should be our primary goal as physicians."

Physicians in both the OMIC and Harris polls agree that 95% of malpractice claims arise as a result of adverse results rather than actual error. However, in a litigious society, the priority is to find "fault" and not to be unduly concerned with whether it was an "adverse result" or an "error." An emerging patient safety movement is critical of the current system of health care delivery for being overly complex, ineffective, and intrinsically hazardous. It proposes shifting the focus of malpractice litigation from finding fault to scientific and analytical review of medical errors with the goal of preventing such errors in the future.

The patient safety movement understands that as medical care becomes increasingly complex, there are many opportunities to improve quality and safety and reduce costs. Failures of the system occur as a result of a combination of multiple small failures, each individually insufficient to cause an accident but when combined, capable of leading to catastrophic injuries. Since fault is not the focus of the patient safety movement, it fosters among health care providers an open and ongoing analysis of the latent and active errors that contribute to incidents and near misses. There already exists in medicine a collaborative inclination to openly discuss and consider ways to reduce errors. Both polls found that physicians strongly agree that open communication and analysis of incidents, adverse events, and errors helps them avoid similar mistakes. However, a significant barrier to information sharing among physicians is the fear that this information will somehow be used to prepare a lawsuit against them.

There is no one quick fix to remedy the negative impact and detrimental effects that fear of litigation has wrought on health care providers and, consequently, on patient care. Reversing this trend will require a strong, sustained effort to raise awareness among patients and providers of the seriousness of the situation and the efforts being made in health care to improve patient safety.



Patient Mix-up in the Laser Suite

By Ryan Bucsi, OMIC Senior Claims Associate, and Anne M. Menke, RN, PhD, OMIC Risk Manager

Allegation

Case Summary

Incorrect LASIK procedure performed on the wrong patient.

Disposition

Case settled on behalf of the ophthalmologist and surgery center. A4-year-old male truck driver presented at a local eye surgery center for bilateral LASIK correction of hyperopia. He was scheduled to have the second procedure of the day. When the first patient canceled, the truck driver was moved into the first time slot. In the laser suite, staff members addressed him, reportedly more than once, as the patient who had canceled; he did not correct them. He was already positioned for surgery when the insured ophthalmologist entered and was handed the first patient's medical record, which he used to verify the laser settings.

The next day following surgery, the patient reported significant visual difficulties, which examination revealed were due to high hyperopia and astigmatism. The ophthalmologist realized what had happened, informed the patient of the error, and explained that retreatment alone could not correct the problem. After unsuccessful trials of contact lens and glasses, the patient elected to have clear lens extraction with toric intraocular lens insertion, followed by bilateral LASIK retreatment for residual refractive error, all performed free of charge. The patient's corrected visual acuity the day after retreatment was 20/20 OU. He did not return for additional follow-up.

An Independent Medical Evaluation (IME) was obtained to evaluate complaints of severe sensitivity to bright light, glare, difficulty focusing, and headaches. UCVA was 20/60 OD, 20/40 OS; pinhole 20/50, 20/30; with refraction, 20/70, 20/60; hard contact lens over refraction, 20/80, 20/100; and near vision 20/25 -2 OU. It was the IME physician's opinion that the patient could read and see better than the measured UCVA or BSCVA.

Analysis

The surgery center did not have adequate systems in place to prevent this communication breakdown and error. The person who took the cancellation message claimed to have told the technician, but the chart and laser cards for the first patient were not removed from the suite. The facility did not give patients name tags or name bracelets, and this patient was apparently too anxious to notice that he was being addressed incorrectly. Plaintiffs have an easy time winning these cases since wrong patient, wrong procedure, and wrong site outcomes are generally considered to be the result of negligence; claims resolution thus focuses on the amount of damages to be awarded. As in this case, the facility and the surgeon are usually named as codefendants and each contributes to the settlement. Although the insured did not own the surgery center or employ the staff there, he was determined to have the primary responsibility for preventing the error and compensating the plaintiff.

Risk Management Principles

Excellent protocols exist for preventing errors of this type. The American Society of Ophthalmic Registered Nurses, in cooperation with the American Academy of Ophthalmology, produced Patient Safety Bulletin Number 1: Eliminating Wrong Site Surgery in 2001 (available at www.asorn.org). In July 2003, the Joint Commission on Accreditation of Healthcare Organizations released its Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery (available at www.jcaho.org). Recommendations include a preoperative verification process, marking the operative site, and a "time out" immediately before starting the procedure. The "time out" involves the patient and the entire surgical team; a checklist is used to verify the identity of the patient, the correct site and side, the procedure, the patient's position, laser settings, and any implants or special equipment.

A second issue raised by this case is the judiciousness of bilateral simultaneous procedures. Advantages to the patient include decreased cost and time off work and increased convenience. However, surgery performed on different days prevents the occurrence of sight-threatening complications in both eyes at the same time and may promote greater accuracy through modification of the treatment plan for the second eye. Further, the patient retains visual function in the unoperated eye while the first eye heals.



Acute Postoperative Endophthalmitis

By Anne M. Menke, RN, PhD OMIC Risk Manager

everal policyholders have called with concerns about protocols they use for endophthalmitis prophylaxis before ocular surgery. They have heard rumors that it is below the standard of care not to use the latest topical fluoroquinolones. Currently, there is no basis for this claim. The fact that prevention and treatment of this rare but devastating complication remains the object of ongoing controversy contributes to the confusion. Two sources of information can help allay concerns and provide direction for sound therapeutic choices: OMIC claims experience and evidence-based studies.

Q What is the source of infection in postoperative endophthalmitis?

A In most cases, the causative organism is introduced into the eye at the time of surgery. Studies have identified the eyelids and conjunctiva as the primary source, so prophylactic measures are directed there. Other sources of contamination include secondary infection from sites such as the lacrimal system; contaminated eye drops, surgical instruments, intraocular lenses, or irrigation fluids; other agents introduced into the eye; and major breaches in sterile technique.

What standards exist for prophylaxis?

A There are currently no definitive standards. The latest evidence-based study by Drs. Cuilla, Starr, and Masket (*Ophthalmology*, January 2002) gave no prophylactic technique the highest clinical rating; however, an intermediate rating was given to preoperative preparation of the eyelids and conjunctiva with a 5% povidone-iodine solution just before surgery. Because of weak and conflicting evidence, all other reported prophylactic interventions received the lowest recommendation; of these, postoperative subconjunctival antibiotics had greater supporting evidence than the rest.

Q In the absence of standards for prophylaxis, what should I do?

A Base your treatment protocol on sound medical judgment. Tailor your treatment to the patient by taking into account known risk factors such as diabetes or immunosuppression, as well as the risks and benefits of the proposed treatment. Carefully document discussions with the patient, and provide clear, written instructions for pre- and postoperative care. Stay informed by reading peer-reviewed journals, and keep a risk management file of the articles that form the basis for your infection prevention protocol.

What is the greatest malpractice risk associated with endophthalmitis?

A Without exception, OMIC claims experience shows that liability arises from a delay in diagnosis or treatment, including a delay in referring the patient to a retina-vitreous specialist.

What can I do to reduce the risk of delay in diagnosis?

A If the surgery was complicated (e.g., capsular tear), took a long time, or required extensive instrumentation, you should have a higher index of suspicion for the development of endophthalmitis. Give all patients written discharge instructions stating the symptoms that warrant contacting you (blurred vision, red eye, pain, photophobia). Educate your staff members who handle telephone calls about the risk of endophthalmitis and train them to always ask patients who have these complaints if they have had eye surgery or trauma. Instruct them to schedule emergent appointments for such patients. Use the same screening criteria yourself when fielding after-hours calls (call OMIC for sample screening guidelines and contact forms). Err on the side of patient safety when deciding to treat over the phone versus examining the patient. Document your decisionmaking process in the medical record, especially when the patient calls with symptoms of a possible infection. Obtain a thorough interval history, and perform and document a careful examination, noting the presence or absence of the signs of endophthalmitis (the cardinal sign is intraocular inflammation greater than expected for that point in the recovery process). If in doubt, consult with and/or refer patients to retina-vitreous specialists for culture and management.

Q Are there other measures I can take to reduce endophthalmitis liability?

During the informed consent discussion, warn patients about the risk of endophthalmitis and the possibility of vision loss. Emphasize the risk if the patient has diabetes, is immunosuppressed, or is having cataract surgery. Have a prudent follow-up plan, especially in symptomatic patients, and ensure that the patient makes the appointment before leaving your office. Diligently follow up on all patients who miss or cancel appointments, again ensuring that they understand that not receiving appropriate treatment could result in blindness. Carefully instruct patients to call you immediately if vision loss, pain, or other ocular problems develop before their next scheduled visit.



Calendar of Events

OMIC, continues its popular seminar series, Professional Liability Issues in Ophthalmology, in 2004 in conjunction with state, regional, and subspecialty ophthalmic society meetings. OMIC-sponsored seminars and exhibits provide an opportunity for current and prospective policyholders to talk to OMIC representatives who can provide rate and coverage information on the entire universe of business, life and health insurance programs available to members of the American Academy of Ophthalmology.

CME credit and OMIC's risk management premium discount are available for attending most OMIC-sponsored seminars or for participating in one of OMIC's two online courses (*Ophthalmic Anesthesia Risks* and *EMTALA and ER-Call Liability*) at www.omic.com. Registration for certain seminars is free for OMIC insureds. Seminars that qualify for OMIC's 10% double risk management discount are indicated with an asterisk. OMIC insureds must be a member of the cosponsoring society to earn the special 10% discount.

January

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The Risks of Telephone Screening and Treatment* Colorado Society of Eye Physicians and Surgeons Manor Vail Resort, Vail, CO 10:15-11:15 am Register with CSEPS, (303) 832-4900

February

28 The Risks of Telephone Screening and Treatment* Illinois Association of Ophthalmology Hyatt Lodge at Hamburger University, McDonald's Campus, Oak Brook, IL Time TBA Register with IAO, (847) 680-1666

March

27-31 OMIC Course TBA* American Association of Pediatric Ophthalmologists and Strabismus (AAPOS) Grand Hyatt Hotel, Washington DC Date and time TBA Register with Maria Schweers, (515) 964-7835

May

1-4 Academy/OMIC Insurance Center Exhibit American Society of Cataract and Refractive Surgery/American Society of Ophthalmic Administrators (ASCRS/ASOA) San Diego Convention Center, San Diego, CA

1-5 OMIC Course TBA ASCRS/ASOA San Diego Convention Center, San Diego, CA Date and time TBA Register with ASCRS, (703) 591-2220

1-5 OMIC Course TBA Joint Commission on Allied Health Personnel in Ophthalmology/ASCRS Location TBA, San Diego, CA Date and time TBA Register with JCAHPO, (800) 284-3937

- 14-15 OMIC Course TBA* Texas Ophthalmological Association Hilton Hotel, Austin, TX Date and time TBA Register with TOA, (512) 370-1504
- 21-22 OMIC Course TBA* Missouri Society of Eye Physicians and Surgeons Country Club Hotel, Lake of the Ozarks, MO Date and time TBA Register with MoSEPS, (847) 680-1666
- 21-23 OMIC Course TBA* Tri-State Meeting (AZ, NV, NM) Loretto Inn, Santa Fe, NM Date and time TBA Register with individual state society

This schedule is subject to change. Please call OMIC's Risk Management Department to confirm dates and times.



Ophthalmic Mutual Insurance Company

(Å Risk Retention Group) 655 Beach Street San Francisco, CA 94109-1336

PO Box 880610 San Francisco, CA 94188-0610

 Phone:
 800-562-OMIC (6642)

 Fax:
 415-771-7087

 Email:
 omic@omic.com

The OMIC office will be closed for the Christmas and New Year's holidays December 24 through 26 and January 1 and 2. We will be open December 29 through 31, and will reopen January 5. Have a safe and joyous holiday season!