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Ophthalmic Risk Management Digest

OMIC DIGEST

Hidden Costs of Non-Traditional Revenue Sources

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

Long before the national presidential debates focused attention on health care, ophthalmologists were experiencing firsthand the many obstacles to quality, affordable medical services. They have watched as increasingly complex health care delivery systems demand more but pay less. Judging by calls to OMIC's Risk Management Hotline, the poster child for the injustices of this medical pressure cooker is the on-call physician, who at times is forced to provide uncompensated back-up for hospital emergency rooms. Drawing upon the innovative and entrepreneurial spirit that has long characterized ophthalmology, some eye surgeons have responded to financial pressures by offering new health care products, such as diagnostic testing or interpretive centers, cosmetic skin care clinics, and "Medispas." Others promote their ability to serve as independent medical examiners (IME) and expert physician witnesses (EW) in professional liability, workers compensation, and disability litigation and disputes. These business ventures tend to be characterized by a more limited physician-patient relationship, fee-for-service payment, and delegation of care—and even operations—to non-physician staff. Eyes fixed on the financial prize, some physicians ignore or remain unaware of the risks and duties these relationships entail. Whether provided in the trenches of a crowded emergency room or amid the soothing luxury of a Medispa, ophthalmic care poses medical-legal hazards, professional liability insurance coverage issues, and patient safety pitfalls.

ER Call

One of the most frequent reasons OMIC policyholders call our Hotline is for clarification of their ER-call duties. They wonder about hospitals where they have no privileges, other hospitals in a hospital system, patients in other states, and days when they are not on call. Their next question involves outpatient care of patients with or about whom they have had no contact, but who may show up, call for an appointment, or simply have discharge documents containing the physician's name. Depending upon the circumstances, your duties range from none to diagnosis, treatment, and follow-up. The **Table** on page 5 and the **Closed Claim Study** provide brief remarks. See "EMTALA: An Overview" and "EMTALA: On-Call Issues" at www.omic.com for detailed answers.

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MESSAGE FROM THE CHAIRMAN

I have often used this Message to point out the many services OMIC provides to its policyholders, and indeed our profession, that other professional liability carriers cannot. Here is another very recent example of the prompt, specialty-specific advice OMIC is poised to provide. Within days of the 18 June 2008 announcement in the American Academy of Ophthalmology's *Academy Express* that the FDA had approved an injectable triamcinolone acetonide suspension (TA) for ophthalmic use, OMIC began to revise its consent form and anticipate associated medicolegal issues.

Trivaris,™ manufactured by Allergan Inc., is the second approved drug; it joins Alcon's Triesence.™ These drug approvals come just 18 months after ophthalmologists received a "Dear Doctor" letter from Bristol-Myers Squibb advising them that Kenalog™ was not approved for ocular use. In 2006, OMIC policyholders called our confidential Risk Management Hotline to ask if their policy would cover them if they still administered Kenalog.™ OMIC reassured ophthalmologists and assisted them by preparing and distributing a sample consent form to help patients understand that the use of an approved drug in an "off-label" fashion is a legal and often necessary aspect of the practice of medicine.

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OMIC

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OMIC
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

Coverage for Legal Costs of Regulatory Investigations

Each year, thousands of physicians are investigated for alleged fraudulent billing practices and violations of HIPAA, EMTALA, DEA, and STARK regulations. To protect insureds who incur legal expenses as a result of regulatory investigations, OMIC purchases a $25,000 Broad Regulatory Protection Policy for each of its physician and entity professional liability policyholders as a benefit of membership. OMIC's BRPP policy extends coverage for fraud and abuse claims related to billing errors and HIPAA privacy proceedings to include fines and penalties (where allowed by law) as a standard policy feature. Coverage also provides legal expense reimbursement for alleged violations of EMTALA, DEA, and STARK regulations.

Several purchasing options are available for policyholders who wish additional supplementary coverage. Limits of $50,000 or $100,000 may be purchased as a standard BRPP upgrade while limits of $250,000, $500,000, or $1 million are available through a BRPP Plus policy.

Because the standard $25,000 coverage is automatically extended to OMIC professional liability insureds, a declarations page is not necessary and is not produced unless higher liability limits are purchased.

Policyholders can review and download BRPP policy documents and upgrade forms at www.omic.com/members/mbrsOnlyBRPP.cfm. Please contact your OMIC underwriter if you wish to have a hard copy of your policy mailed to you. Additional BRPP information, including FAQs, is available at www.omic.com/products/bus_products/BRPP.cfm.

Message from the Chairman

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As a result of the limited indications for which Triesence™ and Trivaris™ were approved, much ophthalmic use of these forms of TA will continue to be "off-label." Moreover, now that there are approved formulations of TA, policyholders are calling the Hotline again to ask, "Can I still use Kenalog™?" Why would physicians want to use a drug off-label if it was available in an approved, single dose form? Retina specialists whose patients were being successfully treated with bevacizumab (Avastin™) grappled with this issue when Genentech got approval for another of its own products, ranibizumab (Lucentis™).

The answer then and now is related to the topics addressed elsewhere in this issue of the *Digest*: the cost of health care and the vagaries of reimbursement. Pharmaceutical companies devote years and considerable capital to research and manufacture new drugs. Thus, it is not surprising that freshly approved drugs are generally more expensive than ones already in use. The dilemma for physicians and patients alike, however, is that these drugs may not now—or ever—be included in the formularies of the patient's health insurance plan. If an ophthalmologist feels the medication is indicated but learns that the cost won't be borne by the insurance company or can't be paid by the patient, what should he or she do?

OMIC's board and committee members are ophthalmologists; we know it is our ethical and professional responsibility to put the patient's interests above our own and provide what we feel is the most appropriate care. So our answer to our policyholders remains the same: discuss the situation openly with your patient, use your medical judgment, document your decision-making process, and know that OMIC will support you if your care is challenged. Be sure to call our Hotline to discuss particular concerns, and download the TA consent form and risk management recommendations at www.omic.com.

Our ability to support your care may, however, be jeopardized if you do not properly evaluate and reduce the risks associated with other health care products, such as Medispas, cosmetic skin care, and forensic consulting. While you may gain needed revenue from this type of professional activity, it may come at too high a cost. Indeed, these services raise a number of questions that are addressed in detail in this *Digest*. Some legal issues can only be resolved by contacting your medical board, practice attorney, or the requesting party. Some malpractice claims coverage questions have clear cut answers, others will depend upon your relationship with the patient and the specific allegations. This issue of the *OMIC Digest* will at least help you begin your risk assessment.

Joe R. McFarlane Jr., MD, JD
OMIC Chairman of the Board