



Review of Advertisements for Medical Services

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PURPOSE OF RISK MANAGEMENT RECOMMENDATIONS

OMIC regularly analyzes its claims experience to determine loss prevention measures that our insured ophthalmologists can take to reduce the likelihood of professional liability lawsuits. OMIC policyholders are not required to implement these risk management recommendations. Rather, physicians should use their professional judgment in determining the applicability of a given recommendation to their particular patients and practice situation. These loss prevention documents may refer to clinical care guidelines such as the American Academy of Ophthalmology's Preferred Practice Patterns, peer-reviewed articles, or to federal or state laws and regulations. However, our risk management recommendations do not constitute the standard of care nor do they provide legal advice. If legal advice is desired or needed, an attorney should be consulted. Information contained here is not intended to be a modification of the terms and conditions of the OMIC professional and limited office premises liability insurance policy. Please refer to the OMIC policy for these terms and conditions.

Version 6/26/07

Regulations and guidelines for advertising for medical services

Physician advertising is regulated by state law, as well as by the Food and Drug Administration (FDA) and the Federal Trade Commission (FTC) under provisions of the Food, Drug, and Cosmetic Act and the Federal Trade Commission Act (FTCA). The American Academy of Ophthalmology (AAO) and the American Society of Cataract and Refractive Surgery (ASCRS) have issued guidelines to advise their members on relevant ethical and professional standards.

Advertising "includes any oral or written communication to the public made by or on behalf of an ophthalmologist that is intended to directly or indirectly request or encourage the use of the ophthalmologist's professional medical services...for reimbursement" (ASCRS Guidelines). These guidelines apply to print, radio, and television advertisements, as well as informational brochures, seminars, videos, and the internet.

Advertising for medical and surgical services must be truthful and accurate. It cannot be deceptive or misleading because of a failure to disclose material facts, or an inability to substantiate claims made explicitly or implicitly by the advertisement. It must balance the promotion of the benefits with a disclosure of the risks, and be consistent with material included in the informed consent discussion. False or misleading advertising could lead to

allegations of lack of informed consent and/or fraud, and result in uninsured risk, denial of a claim, or termination of coverage. Physicians can reduce their liability exposure by identifying and correcting potentially misleading claims, such as those listed below.

Potentially misleading claims

1. Advertises an “off-label” use of an identified drug or device (e.g., Botox Cosmetic, approved for the temporary softening of glabellar lines, cannot be advertised for use on areas other than between the eyebrows)
2. Mentions brand name equipment without disclosing all of the relevant warnings, precautions, contraindications, and side effects for the device’s approved use
3. Misleading because implies the surgery is safe but does not provide material information
 - a. Does not indicate that this is surgery and, like all surgery, has risks and alternatives
 - b. Does not disclose risks and alternatives
4. Misleading because makes a claim about the efficacy of this surgery that cannot be substantiated (e.g., implies can predict a guaranteed 20/20 result)
 - a. No mention that not all patients are candidates for this surgery
 - b. No mention of possible need for glasses for reading or other activities
 - c. No mention of possible future changes in vision requiring glasses or enhancements
 - d. Must have reliable scientific evidence to support any claim: make sure the claim matches the science
5. Misleading because states procedure is “painless”
 - a. All aspects of the procedure must be painless
 1. If pain medications are prescribed, this claim is misleading
 2. If patients experience discomfort, the claim is misleading
 - b. Must be true for all patients
6. Misleading use of patient or physician testimonial
 - a. Makes claim indirectly through testimonial that cannot be substantiated
 - b. Makes claim that is not typical or representative of the physician's outcomes
 - c. Patient should be an actual patient
 - d. Use of testimonials may be prohibited by state law (e.g., Texas, Illinois)
 - e. If the testimonial comes from a physician, must ensure that the physician is a qualified expert, conducts an expert evaluation, is independent, and discloses any personal or financial connection to the sponsor of the advertisement.
7. References to “board certification” must specify the name of the certification board.

8. Misleading **unless** claim about physician's skill, experience, or outcomes can be substantiated the day the claim is made
 - a. Physician must already have conducted an analysis of outcomes based on review of patient records that supports this claim; copy of analysis must be available
 - b. Claim does not distinguish between experience of laser/surgery center and that of the physician who will be performing the procedure
9. Misleading because makes a comparative claim without substantiating it
 - a. If comparing results to those of a published study
 1. Assure that study is scientifically reliable, AND
 2. Assure that the surgeon is performing the same procedure using the same protocol, AND
 3. Assure that the surgeon's outcomes do not vary significantly from reported results
 - b. If comparing clinical evidence (e.g., different procedures or equipment), must have competent and reliable scientific evidence
 - c. If comparing experience, must have reliable, current evidence of number of procedures performed in claim area
10. Misleading because fee information about procedure or retreatments/enhancements does not fully and specifically disclose all variables and other material factors
11. Misleading offer of "lifetime" guarantee or warranty
 - a. Does not define "enhancement" or "retreatment"
 - b. Does not state that the surgeon has the responsibility and discretion to determine when and if a retreatment is medically indicated
 - c. Does not explain under what medical conditions additional treatment might be indicated, and/or when it could be done (e.g., healing may take ... months)
 - d. Does not explain that some patients are not suitable candidates for retreatment
 - e. Does not explain that only a limited number of retreatments are possible
 - f. Does not clarify other ocular conditions that cannot be treated with this procedure
 - g. Does not explain the risks and benefits of retreatment
 - h. Implies that the causes of unsatisfactory outcomes can always be identified and corrected
 - i. Does not clarify whose "lifetime" is covered by the warranty (the patient's, the surgeon, the laser center, the marketing firm, the equipment) and what to do if the surgeon, center, or firm are no longer in business, or the equipment is no longer in use
 - j. May "toll" or extend the statute of limitations governing when a lawsuit may be filed
12. Offer of "free" services may violate anti-kickback, fraud and abuse, state, or federal regulations. Check with your personal attorney before making this offer.

13. Offer of “free” services based on raffle, drawing, or ophthalmologist’s donation of services to a charity **strongly discouraged by OMIC** for the following reasons
 - a. The patient who wins the free surgery may not be an appropriate candidate for clinical and psychological reasons
 - b. The offer does not clarify what will happen if the winner is not an appropriate candidate
 - c. The offer does not clarify who will pay for enhancements, care related to complications, and follow-up
 - d. Such an offer minimizes the fact that LASIK is a surgical procedure with risks
 - e. Offer of “free” services may violate anti-kickback, fraud and abuse, state, or federal regulations. Check with your personal attorney before making this offer
 - f. A physician who raffles off surgical services may be perceived as unprofessional
 - g. For all of the above reasons, OMIC’s ability to defend a malpractice claim may be compromised

14. Advertisement for a “seminar”
 - a. The advertisement must clarify that the service being discussed is a medical or surgical procedure with risks
 - b. Information presented at the seminar must be consistent with material provided to the patient during the informed consent discussion
 - c. Promotional activities and statements must be balanced by a truthful discussion of the risks, benefits, and alternatives
 - d. All information about fees and promotions must be truthful, and must fully and specifically disclose all variables and other material factors

Sources of guidelines

- Federal Trade Commission: www.ftc.gov/bcp/guides/eyecare2.htm.
- Food and Drug Administration: <http://www.fda.gov/cdrh/lasik/>
- American Academy of Ophthalmology: www.aao.org/aao/member/policy/advertising_refractive.cfm
- American Society of Cataract and Refractive Surgery: <http://www.ascrs.org/advocacy/adguides.html>

Additional resources

- The OMIC web site, www.omic.com, contains risk management articles and closed claim studies on this issue:
 - Comanaging Refractive Surgery Patients
 - CO₂ Laser Skin Resurfacing: Watch Out for Marketing Liability

- Debunking the Exploding Cataract: Why You Shouldn't Sell Surgery
- Ethical and Risk Management Issues Related to Advertising and Marketing
- False Advertising and Misrepresentation Hamper Defense in Laser Facial Surgery Case
- Great Expectations Raise Stakes in Elective Surgery
- Informed Consent and Elective Procedures
- Informed Consent for Refractive Surgery
- Insuring Refractive Surgery: Liability Risks
- Liability Issues Associated with PRK and the Excimer Laser
- Risk Management Issues in Radial Keratotomy Surgery
- Understanding the Basic Rules of Advertising

OMIC policyholders who have additional questions or concerns about practice changes are invited to call OMIC's confidential Risk Management Hotline at (800) 562-6642, extension 641.