

## Advertising 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 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. Consult an attorney if legal advice is desired or needed. 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.

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Many ophthalmologists advertise their medical services to the public. Following the recommendations included in this document will help ophthalmologists reduce their liability exposure, comply with underwriting requirements, and avoid uninsured risk.

### **What laws and guidelines govern physician advertising?**

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.

The FTCA prohibits deceptive or unfair practices related to commerce, and “prohibits the dissemination of any false advertisement to induce the purchase of any food, drug, or device.” The FTCA and the professional guidelines state unequivocally that advertising for medical and surgical services must be truthful and accurate. It cannot be deceptive or misleading because of 1) a failure to disclose material facts, or 2) an inability to substantiate claims—for efficacy, safety, permanence, predictability, success, or lack of pain—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 and documents.

### **Liability risks associated with false or misleading advertising**

Allegations related to physician advertising have surfaced in medical malpractice claims. The first is lack of informed consent. Aggressive advertising can run the risk of overstating the possible benefits of a procedure, and potentially mislead patients into agreeing to undergo the surgery without fully understanding or appreciating the consequences and alternatives. Unfortunately, stories of physician advertisements being introduced in court to destroy the validity of a consent form are all too often true.

Plaintiff attorneys may try to position ads as unseen “additions” to consent forms that convey unrealistic expectations or describe treatment to which the patient never consented. If the advertisement overstates the benefits, misrepresents any facts, or conflicts with other consent documentation, it can potentially make a jury believe the physician may have over-stepped the line of ethical propriety by creating unrealistic patient expectations. Legally, such a scenario might allow a jury to conclude the patient was not given a full and fair disclosure of the information needed to make a truly informed decision.

### **Fraud: A potentially uninsured risk**

In addition to allegations of lack of informed consent, plaintiffs are also using state consumer protection laws to claim that the physician defrauded the patient. State law may allow the plaintiff to ask for punitive damages, which might double or triple the amount of money awarded to the patient by the jury. Physicians should be particularly concerned about such allegations since most professional liability insurance policies do not pay for such damages.

## OMIC coverage limits

Advertisements must not be misleading, and must not make statements that guarantee results or cause unrealistic expectations. Insureds are required to abide by FDA- and FTC-mandated guidelines and state law. Failure to abide by these requirements could result in uninsured risk, denial of a claim, or termination of coverage. As explained on page 10 of the OMIC policy, while OMIC would defend physicians against allegations of medical malpractice that include misleading advertising, the policy does not provide for indemnity payments for such allegations:

### **B. Conditional Defense - No Payment of Damages or Supplementary Payments**

**OMIC** will defend an **Insured** because of a **Claim** otherwise covered by this policy that arises out of, but is not solely limited to, any of the following; however, under no circumstances will **OMIC** pay any **damages** or supplementary payments except **Claim expenses** resulting from either settlement or judgment attributed to any of the following:

1. **Intentional Acts.** An act, error, or omission intended or expected to cause **injury** or **property damage** committed by the **insured** or at the direction of the **Insured**, including any of the following: intentional infliction of emotional distress; assault or battery, except that a technical battery based upon lack of informed consent is not excluded; false, misleading, or deceptive advertising and marketing; or any other dishonest, fraudulent, malicious, or knowingly wrongful acts, errors, or omissions.

## Review of advertisements for potentially misleading claims

It is prudent to periodically review advertisements for compliance with federal and state requirements. Here is a checklist to help identify problems.

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. Does not 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. May violate anti-kickback, fraud and abuse, state, or federal regulations since it contains an offer of “free” services. Check with your personal attorney before making this offer.
- 13. Misleading and risky since it contains an offer of “free” services based on raffle, drawing, or ophthalmologist’s donation of services to a charity. OMIC strongly discourages this type of offer 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 the treatment is a surgical procedure with risks

- e. Physician who raffles off surgical services may be perceived as unprofessional
- f. OMIC's ability to defend a malpractice claim may be compromised

14. Misleading 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. Marketing of Refractive Eye Care Surgery: Guidance for Eye Care Providers. <https://www.ftc.gov/tips-advice/business-center/guidance/marketing-refractive-eye-care-surgery-guidance-eye-care>; accessed 10/23/20.
- Food and Drug Administration:
  - LASIK guidance for providers and patients: <https://www.fda.gov/medical-devices/surgery-devices/lasik>; accessed 10/23/20.
  - Letter to eye care professionals about advertising: <https://www.fda.gov/medical-devices/lasik/fda-letter-eye-care-professionals-september-23-2011>; accessed 10/23/20.
- American Academy of Ophthalmology and American Society of Refractive Surgery Joint Guidelines for Refractive Surgery Advertising: <https://www.aao.org/ethics-detail/policy-statement--guidelines-refractive-surgery-ad>; accessed 10/23/20.

**OMIC policyholders are invited to contact our confidential Risk Management Hotline. Please call 1.800.562.6642, option 4 or email us at [riskmanagement@omic.com](mailto:riskmanagement@omic.com).**