



ACOG COMMITTEE OPINION

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Committee on Ethics

This Committee Opinion was developed by the American College of Obstetricians and Gynecologists' Committee on Ethics in collaboration with committee member David I. Shalowitz, MD.

Commercial Enterprises in Medical Practice

ABSTRACT: Monetary reimbursement of physicians in exchange for medical advice and treatment is well established and accepted in medical practice. However, financial pressures and the pervasiveness of entrepreneurial values have led some physicians to widen the scope of activities for which they seek reimbursement. Some of these commercial activities are ethically problematic in the clinical setting. Obstetrician–gynecologists should strive to ensure that commercial enterprises in medical practice do not compromise the patient-focused mission of clinical care. In this Committee Opinion, the American College of Obstetricians and Gynecologists' Committee on Ethics differentiates between commercial activities judged to be generally ethically appropriate for obstetrician–gynecologists and those that are not.

Recommendations

On the basis of the principles outlined in this Committee Opinion, the American College of Obstetricians and Gynecologists (ACOG) provides the following recommendations, which apply regardless of whether sales or promotions are conducted in person, by telephone, online, or by written solicitation:

- Obstetrician–gynecologists should not sell or promote agents or devices as being therapeutic without an adequate evidence base for medical benefit.
- Obstetrician–gynecologists should not use their professional influence or clinical environment to sell or promote nonmedical products or services or to enroll participants into multilevel marketing schemes.
- The sale of prescription or nonprescription medication or devices directly to patients from obstetrician–gynecologists' offices is discouraged when reasonably convenient, alternative vendors exist.
- Obstetrician–gynecologists should be aware that referral of patients to medical facilities in which they or their immediate family have a direct financial stake may create a conflict of interest. Self-referral should be approached with caution and with knowledge of applicable regulations.

Introduction

Monetary reimbursement of physicians in exchange for medical advice and treatment is well established and accepted in medical practice. However, financial pressures and the pervasiveness of entrepreneurial values have led some physicians to widen the scope of activities for which they seek reimbursement. Some of these commercial activities are ethically problematic in the clinical setting. In this Committee Opinion, ACOG's Committee on Ethics differentiates between commercial activities judged to be generally ethically appropriate for obstetrician–gynecologists and those that are not. The role of obstetrician–gynecologists in the provision of cosmetic services is beyond the scope of this document and is addressed in another ACOG publication, *The Role of the Obstetrician–Gynecologist in Cosmetic Procedures* (1).

Ethical Issues and Considerations

The American College of Obstetricians and Gynecologists agrees with the American Medical Association Council on Ethical and Judicial Affairs' statement that physicians should hold patients' interests as paramount in their role as prescribers and dispensers of drugs and devices (2). Commercial activities that call into question

obstetrician–gynecologists’ primary motivation to promote patients’ well-being should be avoided.

Nonmedical Goods and Services

Obstetrician–gynecologists should not sell or promote agents or devices as being therapeutic without an adequate evidence base for medical benefit. Physicians who dishonestly market a product as medically beneficial may compromise public trust in physicians’ clinical advice. Further, obstetrician–gynecologists should not use their professional influence or clinical environment to sell or promote nonmedical products or services or to enroll participants into multilevel marketing schemes. Multilevel marketing schemes are enterprises in which individuals recruit other individuals to sell products and receive a commission on sales made by their recruits. Patients may ascribe clinical benefit to such products or services when none exists, or they may feel pressured to join marketing schemes on physicians’ request. It is manipulative for physicians to exploit patients’ trust to leverage personal financial gain.

Medical Goods and Services

Under most circumstances, the direct sale of products by obstetrician–gynecologists to patients in clinical settings represents an apparent financial conflict of interest that may undermine physicians’ fiduciary responsibility to promote their patients’ best interests. Therefore, the sale of prescription or nonprescription medication or devices directly to patients from obstetrician–gynecologists’ offices is discouraged when reasonably convenient, alternative vendors exist. However, ACOG recognizes that in-office availability of medical goods and services (eg, medication, vaccines, and contraceptive devices) may improve clinical care by, for example, increasing receipt of recommended vaccinations (3) or improving initiation rates of desired methods of contraception (4–6). Additionally, the obstetrician–gynecologist’s office may sometimes be the only point of access for such medically indicated care.

In these cases, or when medically indicated products are not covered by insurance, direct-to-patient sales may be permissible. When offering sale of medical goods or services to patients in the clinical setting, obstetrician–gynecologists should ensure the following: First, the offered product should be clinically indicated and its use should be consistent with current medical practice. Second, if access to equally effective alternative products exists, obstetrician–gynecologists should not restrict patients’ access to alternatives or misleadingly imply that products sold in the office are the best or only available treatment options. Third, obstetrician–gynecologists should not coercively suggest that continued care is contingent upon purchasing medical products directly from the physician or the clinic. Finally, the selling price of all products should not exceed fair market value. If these safeguards are not in place, the therapeutic focus of

the patient–physician relationship may be significantly weakened.

Self-Referral

Obstetrician–gynecologists should be aware that referral of patients to medical facilities in which they or their immediate family have a direct financial stake may create a conflict of interest. Self-referral should be approached with caution and with knowledge of applicable regulations. Self-referral describes referral of patients for medical services (eg, laboratory tests or imaging) at facilities in which referring physicians or their immediate family have a direct financial interest. In general, self-referral represents a potential conflict of interest on the part of physicians who may overprescribe testing or interventions to increase income. In one meta-analysis, for example, self-referrers ordered imaging studies more than twice as frequently as other referrers (7). For this reason, ACOG discourages self-referral, particularly to facilities in which the physician does not directly provide care or services. Further, ACOG agrees with the American Medical Association Council on Ethical and Judicial Affairs’ statement that self-referral to outside facilities is ethical only when criteria for referral are objective and evidence based, referral enhances patient access to high-quality products or services, physicians’ financial interest in products or services are disclosed to patients, and efforts are made to mitigate conflicts of interest (8). In addition, obstetrician–gynecologists are encouraged to be aware of regulations governing self-referral practices, including the federal “Stark Law,” also known as the “physician self-referral law” (9).

Conclusion

Obstetrician–gynecologists should strive to ensure that commercial enterprises in medical practice do not compromise the patient-focused mission of clinical care. As such, it is unethical for obstetrician–gynecologists to use their professional influence or environment to sell or promote nonmedical products and services. Direct sale of medical goods and self-referral for medical services should be approached with caution.

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