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THE CODE SAYS

The AMA *Code of Medical Ethics'* Opinions on Physicians' Financial Interests

Opinion 8.0321 - Physicians' Self-Referral

Business arrangements among physicians in the health care marketplace have the potential to benefit patients by enhancing quality of care and access to health care services. However, these arrangements can also be ethically challenging when they create opportunities for self-referral in which patients' medical interests can be in tension with physicians' financial interests. Such arrangements can undermine a robust commitment to professionalism in medicine as well as trust in the profession.

In general, physicians should not refer patients to a health care facility that is outside their office practice and at which they do not directly provide care or services when they have a financial interest in that facility. Physicians who enter into legally permissible contractual relationships—including acquisition of ownership or investment interests in health facilities, products, or equipment; or contracts for service in group practices—are expected to uphold their responsibilities to patients first. When physicians enter into arrangements that provide opportunities for self-referral they must:

- (1) Ensure that referrals are based on objective, medically relevant criteria.
- (2) Ensure that the arrangement:
 - (a) is structured to enhance access to appropriate, high quality health care services or products; and
 - (b) within the constraints of applicable law:
 - (i) does not require physician-owners/investors to make referrals to the entity or otherwise generate revenues as a condition of participation;
 - (ii) does not prohibit physician-owners/investors from participating in or referring patients to competing facilities or services; and
 - (iii) adheres to fair business practices vis-à-vis the medical professional community—for example, by ensuring that the arrangement does not prohibit investment by nonreferring physicians.

(3) Take steps to mitigate conflicts of interest, including:

(a) ensuring that financial benefit is not dependent on the physician-owner/investor's volume of referrals for services or sales of products;

(b) establishing mechanisms for utilization review to monitor referral practices; and

(c) identifying or if possible making alternate arrangements for care of the patient when conflicts cannot be appropriately managed/mitigated.

(4) Disclose their financial interest in the facility, product, or equipment to patients; inform them of available alternatives for referral; and assure them that their ongoing care is not conditioned on accepting the recommended referral.

Issued June 2009 based on the report "Physicians' Self-Referral," adopted November 2008.

Opinion 8.063 - Sale of Health-Related Products from Physicians' Offices

"Health-related products" are any products that, according to the manufacturer or distributor, benefit health. "Selling" refers to the activity of dispensing items that are provided from the physician's office in exchange for money and also includes the activity of endorsing a product that the patient may order or purchase elsewhere that results in direct remuneration for the physician. This Opinion does not apply to the sale of prescription items which is already addressed in Opinion 8.06, "Prescribing and Dispensing Drugs and Devices."

Physicians who engage in in-office sales practices should be aware of the related guidelines presented in Opinion 8.062, "Sale of Non-Health-Related Goods from Physicians' Offices;" Opinion 8.06, "Prescribing and Dispensing Drugs and Devices;" Opinion 8.032, "Conflicts of Interest: Health Facility Ownership by a Physician;" Opinion 3.01, "Nonscientific Practitioners;" Opinion 8.20, "Invalid Medical Treatment;" as well as the reports from which these opinions are extracted.

In-office sale of health-related products by physicians presents a financial conflict of interest, risks placing undue pressure on the patient, and threatens to erode patient trust and undermine the primary obligation of physicians to serve the interests of their patients before their own.

(1) Physicians who choose to sell health-related products from their offices should not sell any health-related products whose claims of benefit lack scientific validity. When judging the efficacy of a product, physicians should rely on peer-reviewed literature and

other unbiased scientific sources that review evidence in a sound, systematic, and reliable fashion.

(2) Because of the risk of patient exploitation and the potential to demean the profession of medicine, physicians who choose to sell health-related products from their offices must take steps to minimize their financial conflicts of interest. The following guidelines apply:

(a) In general, physicians should limit sales to products that serve the immediate and pressing needs of their patients. For example, if traveling to the closest pharmacy would in some way jeopardize the welfare of the patient (e.g., forcing a patient with a broken leg to travel to a local pharmacy for crutches), then it may be appropriate to provide the product from the physician's office. These conditions are explained in more detail in the Council's Opinion 8.06, "Prescribing and Dispensing Drugs and Devices," and are analogous to situations that constitute exceptions to the permissibility of self-referral.

(b) Physicians may distribute other health-related products to their patients free of charge or at cost, in order to make useful products readily available to their patients. When health-related products are offered free or at cost, it helps to ensure removal of the elements of personal gain and financial conflicts of interest that may interfere, or appear to interfere, with the physician's independent medical judgment.

(3) Physicians must disclose fully the nature of their financial arrangement with a manufacturer or supplier to sell health-related products. Disclosure includes informing patients of financial interests as well as about the availability of the product or other equivalent products elsewhere. Disclosure can be accomplished through face-to-face communication or by posting an easily understandable written notification in a prominent location that is accessible by all patients in the office. In addition, physicians should, upon request, provide patients with understandable literature that relies on scientific standards in addressing the risks, benefits, and limits of knowledge regarding the health-related product.

(4) Physicians should not participate in exclusive distributorships of health-related products which are available only through physicians' offices. Physicians should encourage manufacturers to make products of established benefit more fairly and more widely accessible to patients than exclusive distribution mechanisms allow.

Issued December 1999 based on the report "Sale of Health-Related Products from Physicians' Offices," adopted June 1999.

Clarification of Opinion 8.063

Do the guidelines discussing the sale of health-related products (E-8.063) and the sale of non-health-related goods (E-8.062) apply to physicians' practice websites?

Yes. The physician who provides or sells products to patients must follow the above guidelines regardless of whether the products are provided in the physician's office or through a practice website.

Adopted December 2000 as "Addendum III: Council on Ethical and Judicial Affairs Clarification on Sale of Products from Physicians' Offices (E-8.062 and E-8.063)."

Opinion 8.062 - Sale of Non-Health-Related Goods from Physicians' Offices

The sale of non-health-related goods by physicians presents a conflict of interest and threatens to erode the primary obligation of physicians to serve the interests of their patients before their own. Furthermore, this activity risks placing undue pressure on the patient and risks demeaning the practice of medicine.

Physicians should not sell non-health-related goods from their offices or other treatment settings, with the exception noted below.

Physicians may sell low-cost non-health-related goods from their offices for the benefit of community organizations, provided that (1) the goods in question are low-cost; (2) the physician takes no share in profit from their sale; (3) such sales are not a regular part of the physician's business; (4) sales are conducted in a dignified manner; and (5) sales are conducted in such a way as to assure that patients are not pressured into making purchases.

Issued June 1998 based on the report "Sale of Non-Health-Related Goods from Physicians' Offices," adopted December 1997.

Clarification of Opinion 8.062

Do the guidelines discussing the sale of health-related products (E-8.063) and the sale of non-health-related goods (E-8.062) apply to physicians' practice websites?

Yes. The physician who provides or sells products to patients must follow the above guidelines regardless of whether the products are provided in the physician's office or through a practice website.

Adopted December 2000 as "Addendum III: Council on Ethical and Judicial Affairs Clarification on Sale of Products from Physician Office (E-8.062 and E-8.063)."

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