

Virtual Mentor

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THE CODE SAYS

The AMA *Code of Medical Ethics*' Opinions on the Sale and Dispensing of Health-Related Products

Opinion 8.06 - Prescribing and Dispensing Drugs and Devices

(1) Physicians should prescribe drugs, devices, and other treatments based solely upon medical considerations and patient need and reasonable expectations of the effectiveness of the drug, device or other treatment for the particular patient.

(2) Physicians may not accept any kind of payment or compensation from a drug company or device manufacturer for prescribing its products. Furthermore, physicians should not be influenced in the prescribing of drugs, devices, or appliances by a direct or indirect financial interest in a firm or other supplier, regardless of whether the firm is a manufacturer, distributor, wholesaler, or repackager of the products involved.

(3) Physicians may own or operate a pharmacy, but generally may not refer their patients to the pharmacy. Exceptionally, a physician may refer patients to his or her pharmacy in accord with guidelines established in Opinion 8.0321, "Conflicts of Interest: Health Facility Ownership by a Physician." Physicians may dispense drugs within their office practices provided such dispensing primarily benefits the patient.

(4) In all instances, physicians should respect the patient's freedom of choice in selecting who will fill their prescriptions as they are in the choice of a physician and, therefore, have the right to have a prescription filled wherever they wish. (See Opinions 9.06, "Free Choice," and 8.03, "Conflicts of Interest: Guidelines.") Physicians should not urge patients to fill prescriptions from an establishment which has entered into a business or other preferential arrangement with the physician with respect to the filling of the physician's prescriptions.

(5) A third party's offer to indemnify a physician for lawsuits arising from the physician's prescription or use of the third party's drug, device, or other product, introduces inappropriate incentives into medical decision making. Such offers, regardless of their limitations, therefore constitute unacceptable gifts. This does not address contractual assignments of liability between employers or in research arrangements, nor does it address government indemnification plans.

(6) Patients have an ethically and legally recognized right to prompt access to the information contained in their individual medical records. Since a prescription is part of the patient's medical record, the patient is entitled to a copy of the physician's prescription for drugs or devices, including eyeglasses and contact lenses. Therefore,

physicians should not discourage patients from requesting a written copy of a prescription.

This opinion is a consolidation of previous Opinions 6.04, “Fee Splitting: Drug or Device Prescription Rebates;” 8.06, “Drugs and Devices: Prescribing;” and 8.07, “Gifts to Physicians: Offers of Indemnity.”

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.

This opinion is 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 (8.063) and the sale of non-health-related goods (8.062) apply to physicians’ practice web sites? 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 web site. 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)

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