

9.6.4 Sale of Health-Related Products

The sale of health-related products by physicians can offer convenience for patients, but can also pose ethical challenges. “Health-related products” are any products other than prescription items that, according to the manufacturer or distributor, benefit health. “Selling” refers to dispensing items from the physician’s office or website in exchange for money or endorsing a product that the patient may order or purchase elsewhere that results in remuneration for the physician.

Physician sale of health-related products raises ethical concerns about financial conflict of interest, risks placing undue pressure on the patient, threatens to erode patient trust, undermine the primary obligation of physicians to serve the interests of their patients before their own, and demean the profession of medicine.

Physicians who choose to sell health-related products from their offices or through their office website or other online venues have ethical obligations to:

- (a) Offer only products whose claims of benefit are based on peer-reviewed literature or other sources of scientific review of efficacy that are unbiased, sound, systematic, and reliable. Physicians should not offer products whose claims to benefit lack scientific validity.
- (b) Address conflict of interest and possible exploitation of patients by:
 - (i) fully disclosing the nature of their financial interest in the sale of the product(s), either in person or through written notification, and informing patients of the availability of the product or other equivalent products elsewhere;
 - (ii) limiting sales to products that serve immediate and pressing needs of their patients (e.g., to avoid requiring a patient on crutches to travel to a local pharmacy to purchase the product). Distributing products free of charge or at cost makes products readily available and helps to eliminate the elements of personal gain and financial conflict of interest that may interfere, or appear to interfere with the physician’s independent medical judgment.
- (c) Provide information about the risks, benefits, and limits of scientific knowledge regarding the products in language that is understandable to patients.
- (d) Avoid exclusive distributorship arrangements that make the products available only through physician offices. Physicians should encourage manufacturers to make products widely accessible to patients.

AMA Principles of Medical Ethics: II

Background report(s):

CEJA Report 3-A-16 Modernized *Code of Medical Ethics*

CEJA Report 1-A-99 Sale of health-related products from physicians’ offices

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REPORTS OF COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS

The following reports, 1-6, were presented by Robert M. Tenery, Jr., MD, Chair:

1. SALE OF HEALTH-RELATED PRODUCTS FROM PHYSICIANS' OFFICES

HOUSE ACTION: RECOMMENDATIONS ADOPTED AND REMAINDER OF REPORT FILED

At the 1998 Interim Meeting, the House of Delegates adopted Resolution 7, introduced by the Oregon Delegation, which asked that the American Medical Association "develop ethical guidelines that will discriminate between the legitimate provision of medically necessary goods and services in physicians' offices and physicians' marketing activities that exploit the patient-physician trust."

The Council addressed the ethical issues regarding sales of non-health-related items such as household goods and magazine subscriptions in CEJA Report 5-I-97, "Sale of Non-Health-Related Goods from Physicians' Offices." That report concluded that the sale of non-health-related goods from physicians' offices should be avoided, except for one narrowly delineated exception, namely, physicians may sell non-health-related goods from their offices for the profit of community organizations, provided that a) the goods in question are low-cost, b) the physician takes no share in profit from their sale, c) such sales are not a regular part of the physician's business, d) sales are conducted in a dignified manner, and e) sales are conducted in such a way as to assure that patients are not pressured into making purchases.

This report addresses ethical problems posed by the in-office sale of health-related products.

SCOPE AND DEFINITIONS

Sales of prescription items are not addressed in this report. The Council already discourages this activity in its report "Conflicts of Interest," which states:

Although there are circumstances in which physicians may ethically engage in the dispensing of drugs, devices or other products, physicians are urged to avoid regular dispensing and retail sale of drugs, devices or other products when the needs of patients can be adequately met by local ethical pharmacies.

"Health-related products" are any products that, according to the manufacturer or distributor, benefit health. Vitamins, dietary supplements, over-the-counter medications, safety devices such as child-seats and bicycle helmets, skin-creams, sun block, and special foods are among the many examples. This report only concerns itself with "in-office" sales. For the purposes of this report, "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. Physicians should interpret these definitions judiciously.

SCIENTIFIC VALIDITY OF NON-PRESCRIPTION HEALTH-RELATED PRODUCTS

Non-prescription health-related products can play a role in maintaining patient health. However, the validity of scientific claims made about these types of products is commonly called into question. The Food and Drug Administration (FDA) does not regulate, for instance, dietary supplements, and therefore neither tests nor monitors them for purity, identification, or manufacturing procedures. Often, the manufacturer conducts the clinical trials that validate the scientific claims being made about the product. These tests may be biased. For example, independent studies conducted on the efficacy of several antioxidants against age-related macular degeneration were inconclusive, despite claims by the manufacturer to the contrary. Inconsistencies such as these indicate a need for further studies into the validity of scientific claims made about certain health-related products.

According to the Council's Opinion 3.01, "Nonscientific Practitioners," "it is unethical to engage in or to aid and abet in treatment which has no scientific basis and is dangerous, is calculated to deceive the patient by giving false hope, or which may cause the patient to delay in seeking proper care." As an overriding caveat in discussing the appropriateness of in-office sales of health-related products, it should be understood that physicians should neither sell nor recommend the use of non-prescription health-related products that have no scientific basis. Physicians should rely on peer-reviewed literature and other unbiased scientific sources that review evidence in a sound, systematic fashion when judging the efficaciousness of a product.

CONFLICTS OF INTEREST

As stated in the Council's report, "Sale of Non-Health-Related Goods," the in-office sale of products to patients by physicians potentially creates a financial conflict of interest. Patients rely on physicians for objective advice on whether they need a particular item. The Council has stated in Opinion 8.03, "Conflicts of Interest: Guidelines," "Under no circumstances may physicians place their own financial interests above the welfare of their patients." That patients' welfare may be compromised by the sale of unnecessary products is only part of the problem. Any activity that creates a conflict of interest, or the appearance of a conflict of interest, casts doubt on the physician's ability to fulfill fiduciary obligations and undermines the patient's trust.

In-office sales transactions risk exploiting the inherent imbalance of power in the patient-physician relationship. Patients often enter this relationship vulnerable and dependent on the doctor's expertise. In many cases, patients lack the expertise and independent judgement to make a proper determination about their need for the product and have no alternative reliable source of information. This asymmetry of knowledge means that patients may enter into transactions on the basis of subliminal fears or misjudgments about the necessity of making the purchase. Patients mistakenly may feel that purchasing a physician-recommended health-related product is medically necessary. They may feel more inclined or even compelled to buy an item because they wish to secure the doctor's favor, or in the case of a health-related product, because they have placed implicit trust in their doctor's judgment and believe that he or she is acting in their best interest. Indeed, it is often because of these circumstances that manufacturers and distributors are interested in using physicians' offices as sales sites.

Selling health-related products also risks demeaning the profession of medicine. It creates a public image that physicians are merely entrepreneurs trying to increase their income. Financial endeavors by physicians may not be problematic in and of themselves. However, when they are exercised within the patient-physician relationship they potentially create conflicts between the physician and patient, and risk misdirection of the patient. Under these circumstances there is reason for serious concern that patients are being exploited. Because of the risk of patient exploitation and the potential to demean the profession of medicine, physicians should take steps to minimize financial conflicts of interest.

Guidelines to limit conflicts of interest

One mechanism to limit the conflict of interest is to take the element of financial gain out of the transaction. Many physicians distribute health-related products to their patients free of charge. In other cases, physicians sell health-related products to their patients at cost, in order to make useful products readily available to their patients. An "at cost" sale refers to the sale of products at a price that covers the reasonable expense of obtaining, storing, and dispensing the products. Making such items as prenatal supplements, children's bicycle helmets, nicotine patches, and sun-block available in a physician's office at cost may enhance patients' access to such useful products, raise awareness as to their availability, and reinforce the likelihood that patients will use them. When health-related products are offered free or at cost, it removes the element of personal financial gain that may interfere, or appear to interfere, with the physician's independent medical judgement.

Another mechanism to minimize conflicts of interest is to limit the appropriateness of sales to those circumstances that serve the immediate and pressing needs of patients. As with prescription products, if a product is available at a local pharmacy, physicians should avoid selling it from their office. This includes the sale of brand-name products that are available under a different label or that are essentially equivalent to ones sold at a local pharmacy. Exceptions to this policy would include situations where there is an immediate and pressing benefit to the patient. 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 sell the product from the physician's office. These conditions are explicated in more detail in the Council's report "Conflicts of Interest" and are analogous to situations that constitute exceptions to the permissibility of self-referral.

Although a number of guidelines to limit conflicts of interest can be put into place for physicians who sell health-related products from their office, one safeguard—disclosure—is required in all cases. The Council has previously addressed the importance of disclosure. For example, in Opinion 8.032, "Conflicts of Interest: Health Facility Ownership by a Physician," the Council stated that "physicians should disclose their investment interest to their patients when making referrals." The Council explained the utility in disclosing conflicts of interest in the report "Conflicts of Interest in Biomedical Research."

Even when ethically permissible...arrangements exist, safeguards are needed to protect against the appearance of impropriety. Perhaps the best mechanism available to assuage public (and professional) doubts about the propriety of a[n]...arrangement is full disclosure.

Physicians selling health-related products should disclose to the patient their financial arrangements with the manufacturer or the supplier of the product. Disclosure also includes informing patients about the availability of a product or other essentially 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 the aforementioned scientific standards in addressing the scientific validity of the health-related good.

ETHICAL CONCERNS RELATED TO EXCLUSIVE DISTRIBUTORSHIPS

In-office sales of health-related products that offer a unique benefit to patient health and are available only through physicians raise particular concerns. Since patients would be unable to purchase an equivalent product elsewhere, physicians would have a monopoly on the market. Furthermore, patients would serve as a captive consumer population. Exclusive arrangements such as these are troublesome because they force patients either to purchase the product from their physician or to forgo the recommended treatment.

If a physician strongly believes that a patient needs the product that is available only through physician-distributorship, then physicians should encourage manufacturers to make the product accessible through alternative existing structures such as pharmacies. The transfer to pharmacy distribution might require handling through prescriptions since an element of physician oversight may be necessary due to safety concerns.

CONCLUSION

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 the primary obligation of physicians to serve the interests of their patients before their own. When these items offer some health-related benefits the physician's influence over the sale is amplified and makes it even more necessary to place limits on such activities.

RECOMMENDATIONS

The Council recommends that the following be adopted and that the remainder of the report be filed:

"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.

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 8.03, "Conflicts of Interest Guidelines;" Opinion 8.032, "Conflict of Interest: Physician Ownership of

Medical Facilities;” Opinion 3.01, “Nonscientific Practitioners;” Opinion 8.20, “Invalid Medical Treatments;” (see Appendix A) as well as the Reports from which these Opinions are extracted. The following guidelines stem from those Opinions.

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 the primary obligation of physicians to serve the interests of their patients before their own. When these items offer some health-related benefits, the physician’s influence over the sale is amplified and makes it even more necessary to place limits on such activities.

1. Physicians who do sell health-related products from their offices should not sell any health-related good whose claims of benefit lack scientific validity. Physicians should rely on peer-reviewed literature and other unbiased scientific sources that review evidence in a sound, systematic fashion when judging the efficaciousness of the product.
2. Physicians who sell health-related products from their offices should follow these guidelines to limit their conflicts of interest, minimize the risk of brand endorsement, and ensure a focus on benefits to patients.
 - a. Physicians may distribute 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 removes the elements of personal gain and financial conflicts of interest that may interfere, or appear to interfere, with the physician’s independent medical judgement.
 - b. Except under certain circumstances, such as those described in Opinion 8.032, “Conflict of Interest: Physician Ownership of Medical Facilities,” physicians should not sell a health-related good when patients can obtain a product that offers the same medical benefit at a local pharmacy or health-products store.
 - c. 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 understood 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 validity of the health-related good.
3. Physicians should not participate in exclusive distributorships of health-related products, in which the products are available only through physicians’ offices and for which product there is no comparable alternative available at a local pharmacy or health-products store. Physicians should encourage manufacturers to make their products more widely accessible to patients.

(References pertaining to Report 1 of the Council on Ethical and Judicial Affairs are available from the Ethical Standards Division Office.)

APPENDIX A

Opinion 3.01 **Nonscientific Practitioners.** It is unethical to engage in or to aid and abet in treatment which has no scientific basis and is dangerous, is calculated to deceive the patient by giving false hope, or which may cause the patient to delay in seeking proper care.

Physicians should also be mindful of state laws which prohibit a physician from aiding and abetting an unlicensed person in the practice of medicine, aiding or abetting a person with a limited license in providing services beyond the scope of his or her license, or undertaking the joint medical treatment of patients under the foregoing circumstances.

Physicians are otherwise free to accept or decline to serve anyone who seeks their services, regardless of who has recommended that the individual see the physician.

Opinion 8.03 Conflicts of Interest Guidelines. Under no circumstances may physicians place their own financial interests above the welfare of their patients. The primary objective of the medical profession is to render service to humanity; reward or financial gain is a subordinate consideration. For a physician unnecessarily to hospitalize a patient, prescribe a drug, or conduct diagnostic tests for the physician's financial benefit is unethical. If a conflict develops between the physician's financial interest and the physician's responsibilities to the patient, the conflict must be resolved to the patient's benefit.

Opinion 8.032 Conflict of Interest: Physician Ownership of Medical Facilities. Physician ownership interests in commercial ventures can provide important benefits in patient care. Physicians are free to enter lawful contractual relationships, including the acquisition of ownership interests in health facilities, products, or equipment. However, when physicians refer patients to facilities in which they have an ownership interest, a potential conflict of interest exists. In general, physicians should not refer patients to a health care facility which is outside their office practice and at which they do not directly provide care or services when they have an investment interest in that facility. The requirement that the physician directly provide the care or services should be interpreted as commonly understood. The physician needs to have personal involvement with the provision of care on site.

There may be situations in which a needed facility would not be built if referring physicians were prohibited from investing in the facility. Physicians may invest in and refer to an outside facility, whether or not they provide direct care or services at the facility, if there is a demonstrated need in the community for the facility and alternative financing is not available. Need might exist when there is no facility of reasonable quality in the community or when use of existing facilities is onerous for patients. Self-referral based on demonstrated need cannot be justified simply if the facility would offer some marginal improvement over the quality of services in the community. The potential benefits of the facility should be substantial. The use of existing facilities may be considered onerous when patients face undue delays in receiving services, delays that compromise the patient's care or affect the curability or reversibility of the patient's condition. The requirement that alternative financing not be available carries a burden of proof. The builder would have to undertake efforts to secure funding from banks, other financial institutions, and venture capitalists before turning to self-referring physicians.

Where there is a true demonstrated need in the community for the facility, the following requirements should also be met: (1) physicians should disclose their investment interest to their patients when making a referral, provide a list of effective alternative facilities if they are available, inform their patients that they have free choice to obtain the medical services elsewhere, and assure their patients that they will not be treated differently if they do not choose the physician-owned facility; (2) individuals not in a position to refer patients to the facility should be given a bona fide opportunity to invest in the facility on the same terms that are offered to referring physicians; (3) the opportunity to invest and the terms of investment should not be related to the past or expected volume of referrals or other business generated by the physician investor or owner; (4) there should be no requirement that a physician investor make referrals to the entity or otherwise generate business as a condition for remaining an investor; (5) the return on the physician's investment should be tied to the physician's equity in the facility rather than to the volume of referrals; (6) the entity should not loan funds or guarantee a loan for physicians in a position to refer to the entity; (7) investment contracts should not include 'noncompetition clauses'

that prevent physicians from investing in other facilities; (8) the physician's ownership interest should be disclosed to third party payers upon request; (9) an internal utilization review program should be established to ensure that investing physicians do not exploit their patients in any way, as by inappropriate or unnecessary utilization; (10) when a physician's commercial interest conflicts to the detriment of the patient, the physician should make alternative arrangements for the care of the patient.

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: (a) the goods in question are low-cost; (b) the physician takes no share in profit from their sale; (c) such sales are not a regular part of the physician's business; (d) sales are conducted in a dignified manner; and (e) sales are conducted in such a way as to assure that patients are not pressured into making purchases.

Opinion 8.20 Invalid Medical Treatments. The following general guidelines are offered to serve physicians when they are called upon to decide among treatments:

(1) Treatments which have no medical indication and offer no possible benefit to the patient should not be used. (Opinion E-2.035)

(2) Treatments which have been determined scientifically to be invalid should not be used. (Opinion E-3.01)

(3) Among the treatments that are scientifically valid, medically indicated, and offer a reasonable chance of benefit for patients, some are regulated or prohibited by law; physicians should comply with these laws. If physicians disagree with such laws, they should seek to change them. (Principles of Medical Ethics III, IV)

(4) Among the various treatments that are scientifically valid, medically indicated, legal, and offer a reasonable chance of benefit for patients, the decision of which treatment to use should be made between the physician and patient. (Fundamental Elements of the Patient-Physician Relationship)

2. THE ETHICS OF HUMAN CLONING

HOUSE ACTION: RECOMMENDATIONS ADOPTED AND REMAINDER OF REPORT FILED

INTRODUCTION

In early 1997, a research team in Scotland cloned a sheep, Dolly, by modifying technology developed some decades previously with amphibians. Then, in July of 1998, researchers at the University of Hawaii produced mouse clones and developed a process by which mass cloning could occur. The technique used in both cases, somatic cell nuclear transfer, involves taking a nucleus from a somatic cell, placing it in an enucleated ovum, and implanting the ovum into a host uterus.