

Virtual Mentor

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THE CODE SAYS

The AMA *Code of Medical Ethics*' Opinions on Physicians' Relationships with Drug Companies and Duty to Assist in Containing Drug Costs

Opinion 8.061 - Gifts to Physicians from Industry

Many gifts given to physicians by companies in the pharmaceutical, device, and medical equipment industries serve an important and socially beneficial function. For example, companies have long provided funds for educational seminars and conferences. However, there has been growing concern about certain gifts from industry to physicians. Some gifts that reflect customary practices of industry may not be consistent with the Principles of Medical Ethics. To avoid the acceptance of inappropriate gifts, physicians should observe the following guidelines:

- (1) Any gifts accepted by physicians individually should primarily entail a benefit to patients and should not be of substantial value. Accordingly, textbooks, modest meals, and other gifts are appropriate if they serve a genuine educational function. Cash payments should not be accepted. The use of drug samples for personal or family use is permissible as long as these practices do not interfere with patient access to drug samples. It would not be acceptable for non-retired physicians to request free pharmaceuticals for personal use or use by family members.
- (2) Individual gifts of minimal value are permissible as long as the gifts are related to the physician's work (e.g., pens and notepads).
- (3) The Council on Ethical and Judicial Affairs defines a legitimate "conference" or "meeting" as any activity, held at an appropriate location, where (a) the gathering is primarily dedicated, in both time and effort, to promoting objective scientific and educational activities and discourse (one or more educational presentation(s) should be the highlight of the gathering), and (b) the main incentive for bringing attendees together is to further their knowledge on the topic(s) being presented. An appropriate disclosure of financial support or conflict of interest should be made.
- (4) Subsidies to underwrite the costs of continuing medical education conferences or professional meetings can contribute to the improvement of patient care and therefore are permissible. Since the giving of a subsidy directly to a physician by a company's representative may create a relationship that could influence the use of the company's products, any subsidy should be accepted by the conference's sponsor who in turn can use the money to reduce the conference's registration fee. Payments to defray the costs of a conference should not be accepted directly from the company by the physicians attending the conference.

(5) Subsidies from industry should not be accepted directly or indirectly to pay for the costs of travel, lodging, or other personal expenses of physicians attending conferences or meetings, nor should subsidies be accepted to compensate for the physicians' time. Subsidies for hospitality should not be accepted outside of modest meals or social events held as a part of a conference or meeting. It is appropriate for faculty at conferences or meetings to accept reasonable honoraria and to accept reimbursement for reasonable travel, lodging, and meal expenses. It is also appropriate for consultants who provide genuine services to receive reasonable compensation and to accept reimbursement for reasonable travel, lodging, and meal expenses. Token consulting or advisory arrangements cannot be used to justify the compensation of physicians for their time or their travel, lodging, and other out-of-pocket expenses.

(6) Scholarship or other special funds to permit medical students, residents, and fellows to attend carefully selected educational conferences may be permissible as long as the selection of students, residents, or fellows who will receive the funds is made by the academic or training institution. Carefully selected educational conferences are generally defined as the major educational, scientific or policy-making meetings of national, regional, or specialty medical associations.

(7) No gifts should be accepted if there are strings attached. For example, physicians should not accept gifts given in relation to the physician's prescribing practices. In addition, when companies underwrite medical conferences or lectures other than their own, responsibility for and control over the selection of content, faculty, educational methods, and materials should belong to the organizers of the conferences or lectures.

Issued June 1992 based on the report "Gifts to Physicians from Industry," adopted December 1990; updated June 1996 and June 1998.

Opinion 8.135 - Cost Containment Involving Prescription Drugs in Health Care Plans

When health care plans, whether publicly or privately financed, establish drug formulary systems, physicians are obligated to advocate for formularies that meet the medical needs of their patients.

(1) Physicians should maintain awareness of plan decisions about drug selection by staying informed, where appropriate, about pharmacy and therapeutics (P&T) committee actions and by ongoing personal review of formulary composition. P&T committee members should include independent physician representatives. Mechanisms should be established for ongoing peer review of formulary policy. Physicians who perceive inappropriate influences on formulary development should notify the proper regulatory authorities.

(2) When scientifically based evidence is available, physicians are ethically required to advocate for changes to the formulary that would benefit the patient. Physicians

also should advocate for exceptions to the formulary on a case-by-case basis when justified by the health care needs of particular patients. Mechanisms to appeal formulary exclusions should be established. Other cost-containment mechanisms, including prescription caps and prior authorization, should not unduly burden physicians or patients in accessing optimal drug therapy. Quality improvement rather than cost containment should be the primary determinant for formulary exclusions. In order to be cost efficient, however, physicians should select the lowest cost medication of equal efficacy for their patients.

(3) Physicians should advocate that limits be placed on the extent to which health care plans use incentives or pressures to lower prescription drug costs. Financial incentives are permissible when they promote cost-effectiveness, not when they require withholding medically necessary care. Physicians should not be made to feel that they jeopardize their compensation or participation in a health care plan if they prescribe drugs that are necessary for their patients but that may also be costly. There should be limits on the magnitude of financial incentives, which should be calculated according to the practices of a sizeable group of physicians rather than on an individual basis, and incentives based on quality of care rather than cost of care should be used. Prescriptions should not be changed without the physician's knowledge and authorization. This affords the physician the opportunity to discuss the change with the patient.

(4) Physicians should encourage health care plans to develop mechanisms to educate and assist physicians in cost-effective prescribing practices, including the availability of clinical pharmacists. Such initiatives are preferable to financial incentives or pressures by health care plans or hospitals, which can be ethically problematic.

(5) Physicians should advocate that methods to limit prescription drug costs within health care plans in which they participate be disclosed to patients. In particular, they should encourage health care plans to inform patients upon enrollment concerning:

- (a) the existence of formularies,
- (b) provisions for cases in which the physician prescribes a drug that is not included in the formulary,
- (c) incentives or other mechanisms used to encourage formulary compliance by physicians,
- (d) relationships with pharmaceutical benefit management companies or pharmaceutical companies that could influence the composition of the formulary.

If physicians exhaust all avenues to secure a formulary exception for a significantly advantageous drug, they are still obligated to disclose the option of the more beneficial drug to the patient, so that the patient can consider whether to obtain the medication out-of-plan. Under circumstances in which the health care program will not subsidize the drug, physicians should help patients by identifying alternative forms of financial assistance, such as those available through pharmaceutical companies' assistance programs.

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