Board Statute Regarding Gifts to Physicians

KRS 311.595(9), as illustrated by KRS 311.597(4), provides that it is a statutory violation, and a basis for disciplinary action against a license, for a licensed physician to "depart...from or fail...to conform to the principles of medical ethics of the American Medical Association or the code of ethics of the American Osteopathic Association."

AMA Code of Ethics

Current 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 presentations(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 cost 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 outof-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 if they are 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, updated June 1996 and June 1998)

An addendum of questions and answers that adds clarity to this Current Opinion can be found at <u>www.ama-assn.org</u>.

AOA Code of Ethics

Section 17. From time to time, industry may provide some AOA members with gifts as an inducement to use their products or services. Members who use these products and services as a result of these gifts, rather than simply for the betterment of their patients and the improvement of the care rendered in their practices, shall be considered to have acted in an unethical manner. (Approved July 2003)

Board Opinion Regarding Gifts to Physicians

Legal Authority

The following is a Board opinion issued pursuant to the Board's statute, KRS 311.602, to further assist licensees in determining what actions would constitute unacceptable conduct under the provisions of KRS 311.595. The Board has decided to publish this opinion because it addresses issues of significant public and medical interest. Unlike the statute quoted above, this opinion is not a statute or administrative regulation, and does not have the force of law. The Board has determined that the following principles supplement the considerations outlined in the Code of Ethics published by each professional association.

Opinion

Patients should be confident that they are receiving their physician's best care, uninfluenced by the interest of third parties. They

trust that personal or financial benefits will not influence the medical decisions regarding the care they receive. Traditionally, many gifts given to physicians by industry serve an important and socially beneficial function. For example, industry has long provided funds for educational seminars and conferences. In the last several years, however, many troubling practices have been occurring. Industry money and influence has permeated virtually all levels of physician CME in the form of complimentary meals and entertainment, consultation fees, "shop and dash" functions and pseudo-CME courses. The "gifts" give rise to some notion of reciprocity, which would likely undermine trust and weaken the patient-physician relationship.

Congress developed an interest in these activities and began to investigate them in the early 1990's. The Justice Department, along with other investigative agencies, has again recently expressed concern about the relationship between industry representatives and physicians. In the hope of averting government intervention, the American Medical Association and American Osteopathic Association developed ethical opinions to address these issues. The Association's codes of ethics are based on the following principles:

- Gifts should be a benefit to patients.
- Gifts should be of educational value.
- Gifts should be related to the physician's work.
- Gifts need to be of modest value and not cash payments or equivalent payment.
- There should be no strings attached. (Physicians should not require a thing of value from the representative).
- The educational value of the activity must be the primary consideration in the physician's decision to attend.

It would be unrealistic to propose that all meals, entertainment or CME funding provided by pharmaceutical companies are unethical. The practice should be judged by degree. The concern is the pursuit of these practices to excess. When the influence created by the meal, the entertainment or any other activity, in and of itself, has the potential to alter the physician's prescribing patterns rather than the efficacy of the particular product being touted, it should be considered inappropriate. It may also be considered illegal since federal law prohibits a physician from giving or receiving "anything of value" in exchange for a "referral". In determining whether to accept compensation and reimbursement for expenses incurred to serve as a consultant, speaker board, or speaker bureau, and the reasonable amounts to accept, a physician should consider the following defining questions:

- Who is providing input and who is receiving it?
- Will input actually impact the company's decision-making?
- Is feedback provided to the physician that indicates true consulting activity?
- Is the company providing training to influence the content of the presentation?
- Will the invited physician truly be bringing expertise to the activities?
- Is the amount of genuine work greater than the amount of promotional or social time?
- Is there a notion of reciprocity?

Physicians do not belong to a trade but to a profession and, as such, have an obligation to uphold this standard of ethics and to ensure they are properly enforced. The Kentucky Board of Medical Licensure will use these principles as a supplemental basis for deliberating on any complaint received regarding physician activities in this area.

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