

Advanced Medical Technology Association (AdvaMed)

Overview of the Revised Code of Ethics on Interactions with Health Care Professionals

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Overview

- Effective July 1, 2009.
- Revisions include both new sections and expanded sections contained in the current version of the Code.

I. Preamble

- Replaces references to “Members” with references to “Companies.”
- States that medical devices — now referred to as “Medical Technologies” — are distinct from drugs and biologics.

II. Code Compliance (NEW)

- Companies “strongly encouraged” to adopt the Code and to implement an effective compliance program.
- Companies “strongly encouraged” to submit an annual certification of compliance, signed by the CEO and Chief Compliance Officer.
- Companies “strongly encouraged” to follow the seven core elements of an effective compliance program as outlined by the OIG.
- AdvaMed will publish on its website companies that submit annual certification and companies’ compliance program contact information.

III. Company-Conducted Product Training & Education

- Expanded from current version.
- Includes definitions of “training” and “education.”
- Recognizes that training staff “may include qualified field sales employees who have the technical expertise necessary to perform the training.”
- Payment for HCP out-of-town travel expenses permissible where supported by objective reasons.

IV. Supporting Third-Party Educational Conferences

- Expanded from current version.
- Changes references to “hospitality” to “meals and refreshments.”
- Permissible for companies to provide meals and refreshments directly to conference attendees, with certain restrictions.
- Permissible to sponsor off-site sales, promotional or other business meetings ancillary to a third-party educational conference.
 - There must be a legitimate business purpose.
 - Off-site meeting must comply with conference sponsor’s guidelines.

V. Sales, Promotional and Other Business Meetings

- Remains substantially the same as the current version.
- FAQ makes clear that that venue should be appropriate/conducive to accomplishing the purpose of the meeting.
 - Selection of a resort location may give rise to an appearance of impropriety.

VI. Consulting Arrangements

- Expanded from current version.
- Provides greater clarification regarding standards for consulting agreements.
 - Role of sales: sales personnel may provide input as to the suitability of a proposed consultant but cannot control or unduly influence the decision of whether to engage a consultant.
 - Consultant's qualifications: assessing a potential consultant's expertise and qualifications could include experience with, usage of, or familiarity with a specific Medical Technology.

VI. Consulting Arrangements (cont'd)

- Adds new section on royalty payments to HCPs.
 - Royalty arrangements must meet the same standards as other consulting arrangements (*e.g.*, written contract, services clearly specified, etc.)
 - Permissible only when an HCP is “expected to make or has made a novel, significant or innovative contribution to the development of a product, process or method associated with a company’s product.”
 - Royalties should not be conditioned on an HCP’s marketing of products.
 - Companies “strongly encouraged” to consider whether it is appropriate and practicable to exclude from royalty calculations the number of units of a product purchased, used or ordered by the HCP or his/her practice.

VII. Prohibition on Entertainment and Recreation (NEW)

- Strict prohibition on all entertainment and recreation.
- Includes theater tickets, sporting events, golf, skiing, hunting, sporting equipment, vacations and similar items.

VIII. Modest Meals Associated with HCP Business Interactions (NEW)

- Meals can be provided to HCPs in conjunction with the presentation of scientific, educational or business information.
- No restriction that meals must be provided exclusively in the office or hospital setting.
- Off-site meals are permitted if on-site setting is not conducive to the presentation of scientific, educational or business information or if it is impractical/inappropriate to provide meals there.
 - Examples of when off-site meals are permitted:
 - Technology cannot be transported easily to the HCP's location.
 - Confidential product information being discussed.

IX. Educational Items: Prohibition on Gifts

- Expanded from current version.
- Prohibits non-educational, branded promotional items (pens, notepads, mugs, “reminder” items).
- Only educational or patient-benefit items are permitted, subject to \$100 cap.
- \$100 cap does not apply to textbooks or anatomical models.
- No gifts to office staff.
- No cookies, wine, flowers, food baskets, etc.

X. Provision of Coverage, Reimbursement and Health Economics Information

- Expanded from current version.
- Identifies several permissible activities:
 - Providing clinical value of a company's product;
 - Collaborating with HCPs on joint advocacy for coverage, reimbursement and health economics concerns;
 - Providing accurate and objective coverage, coding and billing information; and
 - Providing information/training on payor policies and procedures for obtaining prior authorization (includes providing sample letters and information on medical necessity and appeals of denied claims).
- Prohibits services that would eliminate an HCP's overhead or other expenses.

XI. Research and Educational Grants and Charitable Donations

- Expanded from current version.
- Companies should implement procedures to ensure no unlawful inducement via grants and donations.
- Companies should develop: (a) objective criteria for making grant and donation decisions and (b) ensure appropriate documentation of grants and donations.
- For charitable donations, companies should exercise diligence to ensure the *bona fide* nature of the charitable organization or mission.
- Sales personnel may provide input about the suitability of a grant or donation recipient or program but may not control or unduly influence the decision of whether a particular HCP will receive a grant or donation or the amount.

XII. Evaluation and Demonstration Products (NEW)

- Permits companies to provide products to HCPs for evaluation and demonstration purposes at no charge.
- Includes guidelines specific to single-use products (consumable or disposable items), multiple use products (capital equipment) and demonstration or unsterilized products.
- Includes standards for determining:
 - Duration of the demonstration and evaluation period, and
 - Appropriate amount of product that should be provided to customers (reasonable amount for adequate evaluation).
- Companies should provide documentation to HCPs of the no charge status of evaluation and demonstration products.



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