


1

The Revised AdvaMed Code of Ethics

HCCA
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2

Agenda

- The Revised AdvaMed Code of Ethics
- State and Federal Transparency Legislation
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3

Who is AdvaMed?



- World's largest medical technology association



- 1,600+ member companies and subsidiaries
- Members produce 90% of sales in domestic market, 50% of sales in global market







- 70%+ of member companies have less than \$30 million in annual revenue
- 65 staff with global expertise, bi-partisan backgrounds
- 45 member Board of Directors including 5 from smaller companies



4

Who Is AdvaMed?

AdvaMed's Commitment to Compliance Excellence







5

The Device Industry Difference:

Close and ongoing collaboration between health care professionals and medical technology companies is necessary for patient safety and medical innovation


- Medical technologies require hands-on training and practice to assure safe and effective use and retraining as medical technologies undergo repeated changes (short life cycle)
- Physicians bring practical field and other experience vital to continued development and improvement of medical technology



6

AdvaMed Code

- Revised Code effective July 1, 2009
- Purpose is to encourage voluntary, ethical interactions between AdvaMed members and health care professionals
- Interpret Code in light of principle that AdvaMed Members:
 - Encourage ethical business practices and responsible industry conduct
 - Shall not use unlawful inducement to sell, lease, etc. their products
- "Health Care Professionals" defined as:
 - Individuals or entities involved in the provision of health care to patients that purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe Companies' products in the U.S.



7

Sections of the Code

- I. Preamble: Goal and Scope of the AdvaMed Code
- II. Code of Ethics Compliance
- III. Company-Conducted Product Training and Education
- IV. Supporting Third-Party Educational Conferences
- V. Sales, Promotional, and Other Business Meetings
- VI. Consulting Arrangements with Health Care Professionals
- VII. Prohibition on Entertainment and Recreation
- VIII. Modest Meals Associated with Health Care Professional Business Interactions
- IX. Educational Items; Prohibition on Gifts
- X. Provision of Coverage, Reimbursement and Health Economics Information
- XI. Research and Educational; Grants and Charitable Donations
- XII. Evaluation and Demonstration Products

7

8

Preamble

- One of the primary purposes of this section is to differentiate medical devices from pharmaceutical products.
- Interactions with HCPs involving devices are different from, and more extensive than those for drugs, and include those relating to:
 - a) Safe and Effective Use;
 - b) Research and Education;
 - c) Charitable Giving

11

9

Code Compliance

- Companies are strongly encouraged to adopt the Code and implement policies and procedures (including OIG elements of an effective compliance program); non-member device companies are encouraged to do the same.
- Adopting Companies submit annual certifications of compliance signed by the CEO and Chief Compliance Officer
- Public website will identify:
 - the Companies that commit to abide by the Code and
 - contact information for members' Chief Compliance Officers or anonymous reporting hotlines

12

Supporting Third Party Educational Conferences

Companies may support bona fide conferences sponsored by associations and CME providers, and grand rounds, through:

- a) Educational grants to conference sponsors to reduce conference costs, or to training institutions to permit attendance by students, residents, fellows
 - training institution must select attendees
 - sponsor must control content, faculty, materials

- b) Companies can provide modest meals and refreshments directly to all attendees if separate from CME portion of program and consistent with sponsor or accrediting body guidelines;

- c) Faculty expenses including honoraria, travel, lodging and meals (cannot pay directly to Health Care Professionals) 13

Sales & Promotional Meetings

Occasional modest meals and refreshments can be provided during meetings to discuss product features, contract negotiations, and sales terms

Companies can pay reasonable travel costs of attendees when necessary, e.g., for demonstrations of non-portable equipment.

No meals, hospitality, travel or lodging for HCP guests

Consultants

Appropriate to provide reasonable compensation for services intended to fulfill a legitimate business need, including the development and/or transfer of intellectual property.

Factors that support a bona fide consulting agreement:

- Written contract specifies the nature of the consulting services and the basis for payment (for research services, must be written research protocol);
- Legitimate need for the consulting services identified in advance of requesting the services and documented;
- Royalty arrangements should be entered only where the HCP is expected to make or has made a novel, significant, or innovative contribution to the development of a product, process, or method; 15

Factors Con't.

- Selection of consultants should be on the basis of qualifications and expertise to meet the defined need;
- Venue and circumstances of any meeting with consultants should be appropriate to the subject matter of the consultation, including hotel or other commercially available meeting facilities;
- Company-sponsored meals and refreshments should be modest and subordinate in time and focus - no recreational or entertainment events;
- Compensation should be consistent with FMV in an arm's length transaction, not based on consultant's past, present or anticipated business, and
- Should be driven by a process capable of objective evaluation.

16

Prohibition on Entertainment

- Companies should not provide any entertainment or recreational items.
- Recreational items should not be offered regardless of their value, whether the HCP is a speaker or consultant, or whether the entertainment is secondary to an educational purpose.

17

Modest Meals

- **PURPOSE:** Modest meals may be provided if they are incidental to a *bona fide* scientific, educational, or business discussions.
- **SETTING:** In some cases, an HCP's place of business may not be available for, or conducive to, such discussions. Reasons for this include:
 - Where the Medical Technology cannot easily be transported to the HCP's location;
 - When it is necessary to discuss confidential product information; or
 - Where a private space cannot be obtained on-site.
- **PARTICIPANTS:** Meals may be provided only to HCPs who attend the meeting—not to others without a *bona fide* professional interest in the information being shared at the meeting. The company representative must also be present.

18

Prohibition on Gifts

- Appropriate to provide modest educational items that are intended for the benefit of patients or serve genuine educational function, such as textbooks and anatomical models.
- No items that can also be for the personal benefit of HCPs (such as DVD player or MP3 player).
- Only educational items are appropriate; no non-education reminder items such as branded promotional items like pens and notepads.

Provision of Coverage, Reimbursement and Health Economics Info.

- May provide accurate and objective information on their products and related procedures, services, and therapies, and collaborate with HCPs.
- Permissible activities identified include:
 - Collaborating with providers and HCPs;
 - Promoting accurate and responsible billing;
 - Providing factual information on economically efficient product use;
 - Providing information on reimbursement and costs;
 - Providing information on coverage;
 - Providing technical and other support;
- Companies cannot interfere with HCP decision-making, such as proving a free service that materially eliminates an HCP's overhead or other expense.

Research & Educational Grants & Charitable Donations

- Companies should:
 - Develop objective criteria and implement procedures to ensure no unlawful inducement for making grant and donation decisions.
 - Ensure appropriate documentation.
- With appropriate procedures, sales personnel may provide input, but may not control or unduly influence the decision of recipient or amount.
- Companies:
 - May support research with scientific merit, well-defined objectives and milestones, and no direct or indirect link to purchases.
 - May provide educational grants for advancement of medical education and public education; no grants may be given to individual HCPs.
- Monetary or product donations may be made when motivated by bona fide charitable purposes and made to charitable organization. New FAQ permits contributions to charitable events such as gold tournaments or galas but states that Companies may not pay for individual HCPs to play or participate.

Evaluation and Demonstration Products

•Companies may provide reasonable quantities of products at no charge to HCPs for evaluation and demonstration purposes.

•Consumable and multiple use products expected to be used in patient care can be provided only for a reasonable time necessary to evaluate them, and only in quantities necessary for adequate evaluation, with the terms set forth in a written agreement and the Company retaining title to the products.

•Demonstration products which typically are not used in patient care may be provided for patient awareness, education and training.

•Companies should provide HCPs with documentation of the no charge status of evaluation products.

AdvaMed Code
Device Industry Response

2006 PWC / Compliance Alliance /
King & Spalding Survey:

- Nearly 100% Adoption of AdvaMed Code Among Companies Surveyed
- Best Practices Noted in Code - Specific Sections



2. State and Federal Transparency
Legislation

Grassley-Kohl Legislation (S.301)

- Similar to a bill introduced last year
- Requires all manufacturers of drugs, devices, and medical supplies, with annual gross revenues of more than \$100 million, to disclose *any* payment quarterly and in an annual summary report if payments exceed \$100.
- Must disclose all payments, including compensation, food, entertainment, gifts, trips or travel, discounted products, continuing medical education, product rebates, consulting fees or any other economic benefit as defined by the Secretary. Product rebates and discounts specifically included.
- Covered health care professionals include physicians or an entity a physician is employed by, has tenure with or an ownership interest.
- Exceptions include free drug samples for patients, payments for clinical trials.
- Penalties for non-compliance: minimum \$10,000 up to \$100,000 per violation.

State Legislation

- Potentially more important and burdensome than federal law
- Massachusetts
 - Disclosure Requirements PLUS Standardized Code of Conduct
- Other States
 - Vermont, Texas, New Mexico, New York, Colorado, Minnesota
 - Combination of Disclosure Requirements and Marketing Restrictions
 - Some go so far as to ban all payments—including discounts (VT)

Thank You!

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