

Government, Industry and Health Profession Compliance Guidance: Welcome to the Era of Ethics and Transparency

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The Perfect Storm for Reform

- Industry, Hospitals and Physicians Under DOJ Scrutiny for Financial Arrangements
- Congressional interest
- Consumer/Patient interest
- Public Health agency interest
- Media interest: NYT, WSJ, NEMJ
- Medical Professional interest
- Industry Code of Ethics
- Transparency Initiatives
- International Anti-Corruption Initiatives





Discussion Agenda

- Industry Codes of Ethics.
- Medical Society Codes of Ethics and Disclosure Initiatives.
- Hospital Conflicts and Access Policies.
- State Marketing Laws.



U.S. Sentencing Guidelines

- Chapt. 8 Organizational Guidelines. Alive and Well As Force in Compliance.
http://www.ussc.gov/Guidelines/2011_Guidelines/index.cfm
- Recent USSG Updates to Corporate Compliance Guidance.
- Emphasis on industry standards and misconduct, not just illegality, to assess effective corporate compliance.



Industry and Professional Codes

- AMA Code of Medical Ethics Opinion 8.061 (1990) – Gifts to Physicians from Industry.
- PhRMA Code – 2002; revised 2009.
- AdvaMed Code – 2003, revised 2009. New Best Practice Guidance in 2011.
- AAOS-2007 Standards of Professionalism and 2010 Disclosure Program.
- Council of Medical Societies – 2010 Code for Interactions with Companies.
- Hospital Conflicts of Interest Policies – 2011.
- Global Codes of Ethics. Eucomed (Europe) MEDEC (Canada)
- Kuala Lumpur Principles – May 2011. Trend to Harmonization.



Regulated Interactions

- Consulting and Royalty Arrangements
- Product Training and Education
- Third-Party Educational Conferences
- Sales, Promotion and Other Business Meetings
- Meals, Gifts, Recreation, Entertainment
- Reimbursement and Economic Information
- Educational Items for Professionals and Patients
- Product Evaluation
- Drug Samples
- Prescriber Data



Scope of Ethics Codes

- Industry Personnel.
- Health Care Professionals.
- Health Care Institutions.
- Office Managers, Receptionist and other Personnel.
- Distributors and Third party agents.



Common Industry Standards

- sales and promotion expenditures should be for bona fide purposes that have patient benefit;
- no cash or cash equivalent gratuities;
- hospitality, travel and lodging expenses should be related to genuine educational, scientific or other independent medical purposes;
- expenses for spouses, children and significant others should not be provided at medical conferences;
- compensation for passive attendance at conferences is prohibited;



Common Industry Standards

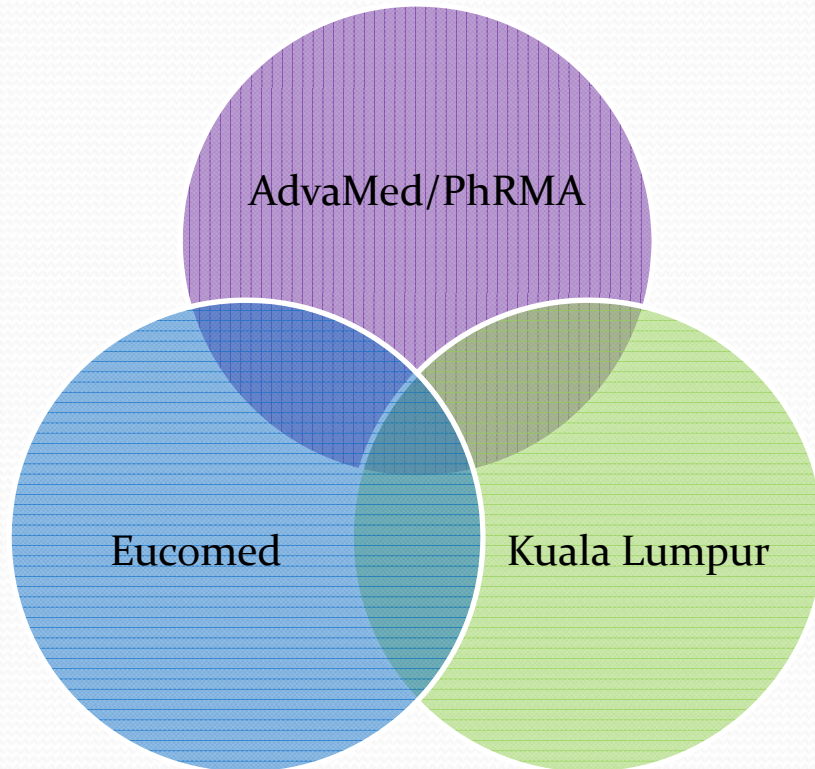
- grants and research funding should be structured to address financial and medical conflict of interest issues;
- switching or tying or other quid pro quo arrangements with physicians or those in a position to influence product use are prohibited;
- business conduct and arrangements should comply with established statutes, such as the federal anti-kickback statute, the PDMA, FDA and other federal regulatory statutes; and
- Recreation and entertainment are prohibited.



Payments to Physicians

- Physicians are the gatekeepers and decision makers for the health care industry and the Medicare trust fund.
- Any payments or gratuities by entities in position to benefit from physician decision making are suspect.
- Primary focus of CPG, the industry codes, professional codes, and recent enforcement activity.
- The underlying issue is the potential conflict of interest created by these financial arrangements.

Global Focus on HCP Interactions



- Globalizes medical device sector practices.
- Applies to HCP interactions globally.
- Important effort to harmonize industry codes of ethics.
- Definition of HCP broad. Includes clinical and non-clinical individuals that make product decisions.
- Confirms common elements of independence and transparency of financial relationships.



Consulting Arrangements

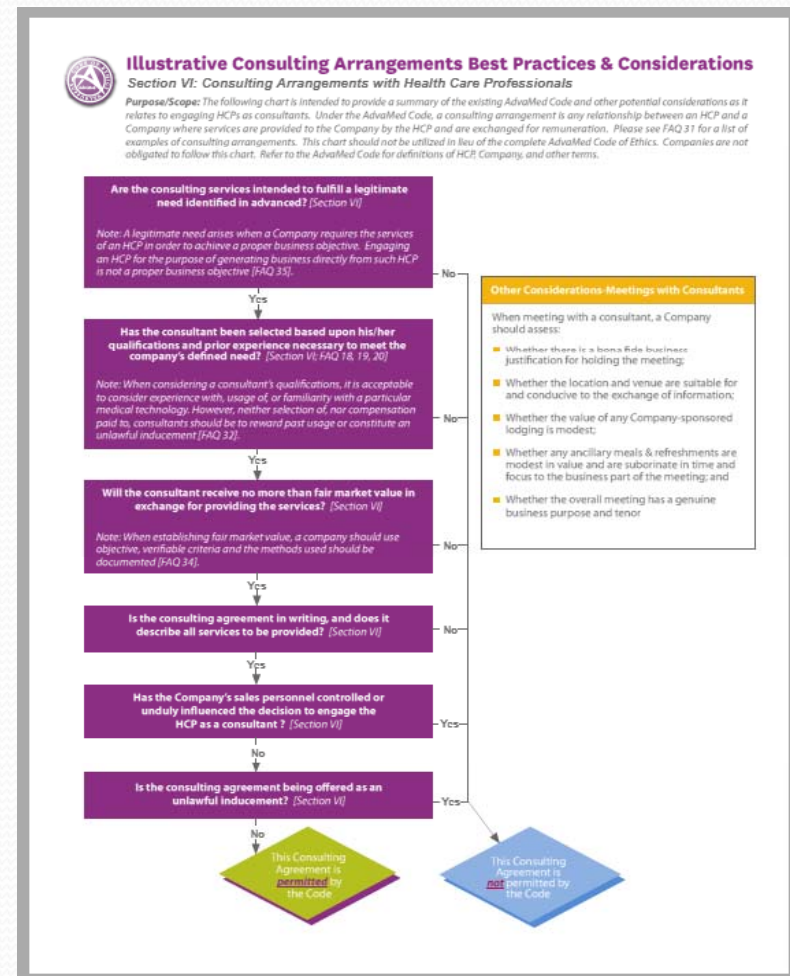


The PhRMA Code-General Approach

- Manufacturers may offer and pay reasonable compensation to consultants (not defined—but, assumed to include medical professionals) who provide services to manufacturers.
- Token consulting arrangements or advisory arrangements should not be used to compensate healthcare professionals for their time or travel, lodging or other out-of-pocket expenses.

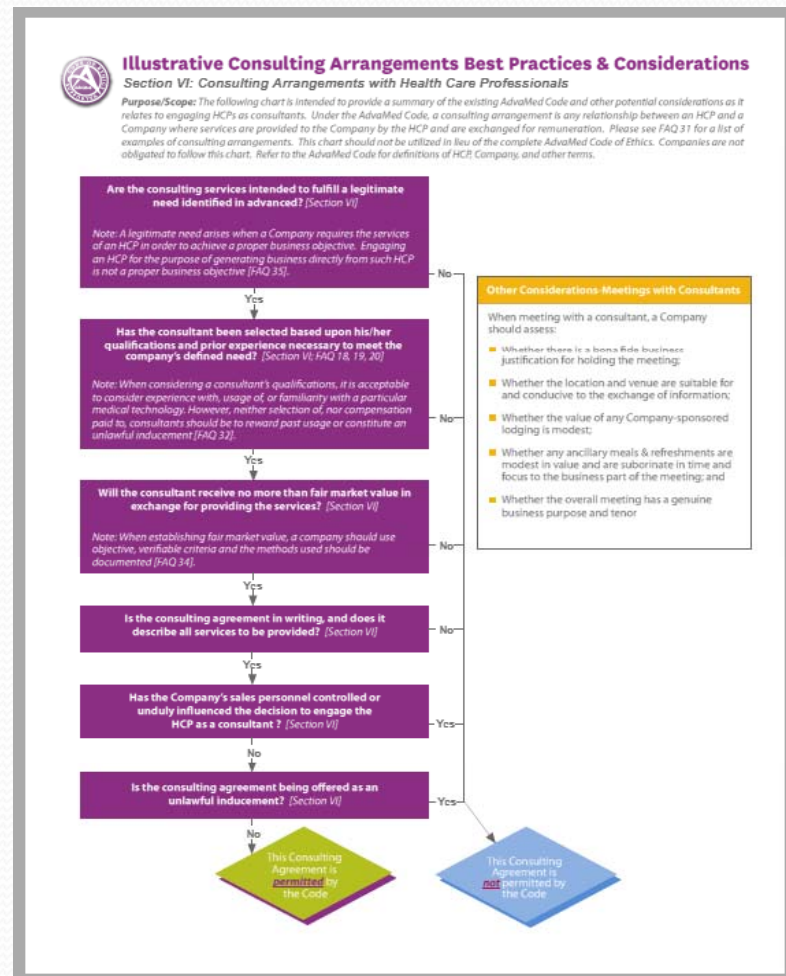
The AdvaMed Code-Specific Approach

- The revised AdvaMed Code includes specific guidance in the following areas:
 - In writing & detail the services. For research, a written protocol is needed.
 - Need for services documented in advance.
 - Consultant selection based on needed expertise & not controlled or unduly influenced by sales staff.
 - Compensation is fair market value and does not factor in the value or volume of business.
 - AdvaMed Consulting Arrangements - Best Practices



The AdvaMed Code

- The revised AdvaMed Code includes specific guidance in the following areas:
 - May reimburse for documented and reasonable expenses incurred in performing services.
 - Meetings should be in a setting appropriate to subject matter.
 - Provision of modest meals and refreshment.
 - Prohibition of entertainment and recreation.
 - Special provisions on royalties.





AAOS Standards of Professionalism

- Industry and Surgeon Collaborations must be lawful and consistent with medical ethics.
- Disclosure of compensated relationships.
- Fair market value and commercial reasonableness.
- Enforcement standards.



Research Grants



Research Grants

- The AdvaMed Code includes:
 - Clinical research should have written contracts and protocols.
 - Not awarded based on past or anticipated referrals.
 - Objective standards for reviewing and awarding grants.
 - Independent of sales force.
 - No unrestricted grants.



Physician Training & Education



The PhRMA Code

- No payments to attendees unless for legitimate consulting or speaking services.
- Content must be educational or scientific.
- Modest meals can be provided for off-site company speaker program.
- No entertainment.
- No spouses.
- Field sales staff can only provide meals to health care professionals and staff in the office or hospital and in connection with informational presentation or discussion.



The AdvaMed Code

- Training is instruction on the safe and effective use of medical device.
- Consultant may be retained, but content must be company approved and consistent with on-label indications.
- Content must be educational or scientific.
- Training event location/venue must be appropriate and conducive to the exchange of information (e.g., not a resort location).



The AdvaMed Code

- Companies can pay for attendees travel and lodging for hands on training if an “objective reason” such as limited sites with equipment, centralized location, etc.
- Companies should consider duration of travel needed, alignment with meeting agenda, class of fare, and overall cost.
- Companies can provide modest meals and refreshments with training.
- No entertainment & no spouses.



AMA Ethics Opinion 8.061 Educational Meetings

- Meetings or conferences should be at appropriate location and primarily educational.
- Subsidies to conference sponsor ok to reduce registration fees.
- No payments for travel, lodging, expenses or lost opportunity of attending physicians.
- Ok for faculty honoraria and expenses.
- Scholarships for students, residents, fellows ok but selection by institution.



Evaluation / Demonstration Products

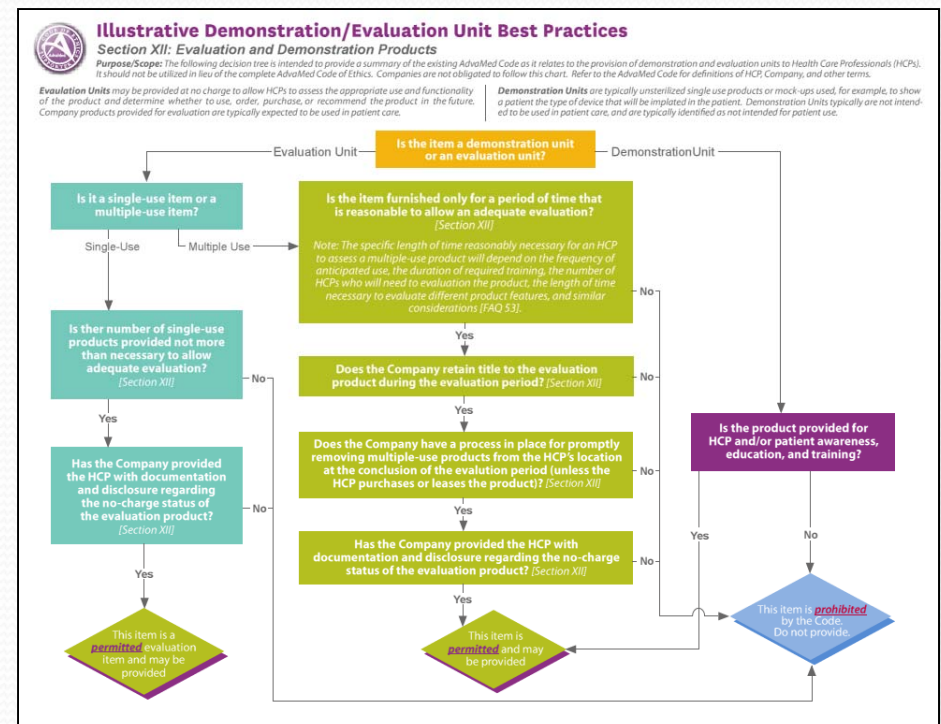


Evaluation / Demonstration Products

- Revised AdvaMed Code adds new section on the provision of evaluation and demonstration products.
 - Evaluation and demonstration products
 - Improving patient care
 - Facilitating safe and effective use of products
 - Improving patient awareness
 - Educating HCPs
 - Single Use
 - Multiple Use/Capital

Evaluation / Demonstration Products

- Evaluation products must be reasonable in number (single use/disposable) or length of loan for evaluation purposes (multiple use/capital).
- Documentation and disclosure regarding no-charge status of evaluation and demonstration products.
- Must have equipment picked up at end of evaluation period.
- AdvaMed
Evaluation/Demonstration Best Practices





Educational Grants for Third Party Conferences



The PhRMA Code

- Companies should separate grant-making from sales and marketing departments.
- Companies should develop objective criteria for making CME grant decisions.
- Companies should not provide any advice or guidance to sponsor regarding faculty or content of particular program.

The PhRMA Code

- CME and other third-party scientific and educational conferences or professional meetings are appropriate if (a) the subsidy is given directly to the conference's sponsor, (b) the sponsor uses the subsidy to create an overall reduction in conference registration fees for all attendees, and (c) the physician does not receive the subsidy directly.
- Manufacturers are instructed not to offer or pay for the costs of travel, lodging, or other personal expenses of non-faculty health care professionals attending CME or other third-party scientific or educational conferences or professional meetings, either directly to the individuals attending the conference, or indirectly to the conference's sponsor.

The AdvaMed Code

- Funding of educational grants or sponsorships must comply with AKS and FDA requirements.

Program eligibility -

- Dedicated to objective scientific and educational activities.
- Conference sponsor is a medical association, accredited CME provider or an organization with an educational purpose (e.g., university).
- Conference sponsor has independent control and responsibility for the selection of program content, faculty, educational methods, and materials.
- Venue is conducive to the educational program.
- Grant recipient is not an individual healthcare professional.

The AdvaMed Code

Objective Criteria

- Venue
- Agenda (e.g., meaningful curriculum)
- Use of Funds (e.g., reduce overall conference costs, faculty costs, travel costs)
- Conference Topic
- Marketing Materials
- Budget

Supporting Documentation

- Brochure
- Agenda
- Budget

Award of an educational grant is not unduly influenced by sales personnel



Educational Grants for Third Party Conferences (CME)

- AMA takes the position that to the extent that an industry organization subsidizes or otherwise pays for costs associated with medical conferences or lectures, the responsibility for and control over the selection of content, faculty, educational methods, and materials should belong to the organizers of the conferences or lectures.



Educational Grants for Third Party Conferences (CME)

- AMA takes the position that a subsidy provided directly to a physician by an industry representative could influence the use of the industry company's products.



Scholarships & Fellowship Grants

The PhRMA Code

- Manufacturers may offer financial assistance for scholarships or other educational funds to permit:
 - medical students;
 - residents;
 - fellows;
 - and other medical professionals in trainingto attend carefully selected educational conferences provided that the selection of the individuals who will receive the funds is made by the academic or training institution.
- The term “carefully selected educational conferences” means “the major educational, scientific, or policy-making meetings of national, regional, or specialty medical associations.”

The AdvaMed Code

- Funding of fellowship grants or sponsorships must comply with AKS and FDA requirements.

Program eligibility -

- Support of genuine medical education of a fellow participating in a fellowship program.
- Fellowship grant recipient is an organization with an academic affiliation.
- Fellowship grant recipient has independent control and responsibility for the selection of candidate selection.
- Grant recipient is not an individual healthcare professional.

The AdvaMed Code

Objective Criteria

- Program accreditation status (as applicable)
- Faculty qualifications or expertise (i.e., board certified in certain specialty)
- Program has well established curriculum with defined goals and objectives
- Use of funds for appropriate educational/research purposes
- Funding request is commercially reasonable and proportional to the cost, requirements and quality of the program

Supporting Documentation

- Funding request
- Budget
- Candidate selection criteria
- Faculty qualification
- Approval

Award of an fellowship grant is not unduly influenced by sales personnel



Scholarships & Fellowship Grants

AMA

- Scholarship funds and other special funds to permit medical students, residents, and fellows to attend carefully selected educational conferences may be appropriate where the selection of the recipients is made by the academic institution.



Gifts & Educational Items



AMA Ethics Opinion 8.061 – *Gifts*

- No cash.
- Gifts should benefit patients.
- Gifts should not have substantial value.
- Textbooks and meals are okay if they serve educational value.
- Reminder items of nominal value are okay as long as related to physician's work (e.g., pens and note pads).
- AdvaMed and PhRMA are consistent except pens and notepads.

Gifts & Educational Items

PhRMA

- Manufacturers may offer to physicians and other medical professionals items that primarily benefit patients if they are not of substantial value (i.e., \$100 or less).
 - An anatomical model for use in an examination room primarily involves patient benefit, whereas a VCR or CD player does not.