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# Adhering to Industry Codes of Conduct

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# Industry Code of Ethics Overall Categories

(All applicable to AdvaMed but not all are comparable to PhRMA Code)

- Code Compliance
- Company-sponsored training and education
- Third-party educational conferences
- Sales, promotion, and other business meetings
- Consulting arrangements with HCPs
- Entertainment and recreation
- Meals associated with HCP interactions
- Educational items/no gifts
- Provisions of coverage/reimbursement information
- Grants
- Charitable donations
- Evaluation/demonstration products

# Code Compliance

## AdvaMed, Sec. II & PhRMA

- Companies “strongly encouraged” to
  - adopt the Code and to implement an effective compliance program.
  - submit an annual certification of compliance, signed by the CEO and Chief Compliance Officer.
  - follow the seven core elements of an effective compliance program as outlined by the OIG.
- AdvaMed & PhRMA publish on their websites companies that submit annual certification, public commitment and companies’ compliance program contact information.
- Is there a gap in monitoring compliance?
- Neither AdvaMed or PhRMA independently verifies or audits a company’s compliance with their Code—do you think that 3<sup>rd</sup> Party auditing should be incorporated into each Association’s Code of Ethics?

# Company-Conducted Product Training and Education

AdvaMed, Sec. III (*no comparable PhRMA Code provision*)

- Includes definitions of “training” and “education.”
- 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 *[note MA prohibits]*.
- There are no time limits or length restrictions regarding how long a training/education must last in order for an HCP to obtain reimbursement for travel.
- Should there be a continuing education component to the training?

# Training and education (cont'd)

AdvaMed, Sec. III

- Example: Grand Rounds
  - Who has control of program? If they do, look at third-party conference standards
  - Is the setting conducive to transmission of information?
  - Are the trainers appropriate?
  - Are modest meals subordinate in time and focus?

## Supporting Third-Party Education Conferences

### AdvaMed, Sec. IV

- 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.
- Overall event dedicated to objective scientific/educational activity
- Distinguish educational/non-educational support
- Who is selecting faculty/HCPs?
- Is venue conducive to education?
- Is agenda robust – or too much down time?
- Consider overall budget issues

## Supporting Third-Party Scientific/Education Conferences and Accredited CME Events

### PhRMA

- Financial support *should not* be offered for the costs of travel, lodging, or other personal expenses of non-faculty HCP's, either directly to individuals participating in the event or indirectly to the event's sponsor.
- Funding *should not* be offered to compensate for the time spent by HCPs attending the conference.
- Control over content and materials belongs to the organizers of the conference .
- Distinguish CME providers – can, at its own discretion, apply financial support provided by a company for meals for all participants.
- Separate CMI grant-making functions from sales and marketing departments.

## Potential Gaps in the Codes Support for 3<sup>rd</sup> Party Educational Conferences

- Should the Codes actually parse out the difference between an education and non-educational conference?
- Do the limits and restrictions actually hinder the innovative flow of information that 3<sup>rd</sup> Party Educational Conferences inherently provide?
- What happens to rural HCPs who may be unable to afford the costs associated with 3<sup>rd</sup> Party Educational Conferences but who have legitimate medical education needs?
- Is it AdvaMed & PhRMA's responsibility to the healthcare industry to take a stance on these issues?

# Training and Education (cont'd)

AdvaMed, Sec. IV

- Example: Plant Tours
  - Does HCP have *bona fide* professional interest in training?
  - Is tour reasonable/*bona fide*? (non-portable equipment, exposure to quality/manufacturing processes)
  - Modest meals subordinate in time + focus?
  - No guests; no entertainment
  - Consider limiting extensions



## How to Handle Sales and Business Meetings

AdvaMed, Sec. V & PhRMA

- Both Codes allow companies to conduct sales and business meetings and allow reasonable travel expenses within certain limits, including:
  - No guests
  - No “dine & dash” or take-out meals
  - Limits to office settings
  - May not be apart of entertainment of recreation
- Location must actually be conducive to effectively communicating information
- Both Codes allow travel expenses when necessary for meetings such as plant tours, or demos of non-portable equipment
- Does providing travel expenses for this style of education contradict the company’s not being allowed to pay for HCP travel to 3<sup>rd</sup> Party Education Conferences, where arguably the HCP will arguably have greater access to multiple products—not just the company specific products that are showcased at a business meeting?

## Consulting Arrangements with Health Care Professionals

### AdvaMed, Sec. VI

- Provides 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.
- Royalty payments to HCPs
  - [Suggested exclusion for self-referrals involving royalties]

### PhRMA

- Provides factors that support a *bona fide* consulting agreements.
  - Written contract, legitimate need for consultation services - identified in advance.
  - Selecting consultants: persons responsible for selecting have the expertise necessary to evaluate whether the particular HCPs meet identified purpose; number of HCP's retained is not greater than number reasonably necessary to achieve the identified purpose.
- Compensation & Reimbursement
  - Reasonable & based on fair market value.

## Prohibition on Entertainment and Recreation

AdvaMed & PhRMA

- Both Codes strictly prohibit *all* entertainment and recreation.
- Includes theater tickets, sporting events, golf, skiing, hunting, sporting equipment, vacations and similar items.
- However, both Codes permit “modest meals” is offered in appropriate circumstances and venues.
- Does permitting “modest meals” (where “modest” is undefined) allow some companies to push the boundaries of what is allowed in both Codes for purchasing meals?

# Handling Modest Meals

AdvaMed, Sec. VIII & PhRMA

- Meals can be provided to HCPs in conjunction with the presentation of scientific, educational or business information.
- PhRMA limits meals to only in the office or hospital setting
- AdvaMed permits off-site meals 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. Off-site meals are permitted:
  - Technology cannot be transported easily to the HCP's location.
  - Confidential product information being discussed.
- Both Codes permit “modest” meals with “modest” being judged by a local standard
- No spouses/guests or “dine & dash” meals.

## The Prohibition of the Pen: Educational Items & Prohibition on Gifts

AdvaMed, Sec. IX & PhRMA

- Promotional non-educational items (ie pens, notepads, mugs, etc.) are absolutely prohibited
- Only educational or patient-benefit items are permitted, subject to \$100 cap—but cap does not apply to textbooks or anatomical models
- Samples are allowed for patient use only
- No gifts to office staff.
- No cookies, wine, flowers, food baskets, sports tickets, golf balls, sports bags etc.
- Do some of these prohibitions take the human side out of the relationships that are cultivated between companies and HCPs?
- Is there a chance that the gift prohibition goes too far? Or is it not strict enough? What would the benefit be if the gift prohibition was more strict?

# Provision of Coverage, Reimbursement, and Health Economics Information

*AdvaMed, Sec.X (no comparable PhRMA Code provision)*

- Identifies several permissible activities:
  - Providing information on 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.

# Research and Educational Grants and Charitable Donations

## AdvaMed, Sec. XI

- 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.

## PhRMA

- No separate section in the Code on research grants or charitable donations
- Educational grants covered as a part of CME section and excludes sales and marketing personnel from CME grant-making functions
- Grants, scholarships, subsidies, support, consulting contacts, and education or practice related items provided should be in exchange for prescribing products

# Evaluation and Demonstration Products

AdvaMed, Sec. XII (*no comparable PhRMA provision*)

- 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.



# Evaluation and Demonstration Products (cont'd)

AdvaMed, Sec. XII

- Investigative and enforcement activities have focused on:
  - Free goods.
  - Swapping/quid pro quo.
  - Absence of documentation.
  - Failure to enforce “terms.”

# Considerations on Evaluation Units (cont'd)

AdvaMed, Sec. XII

- Must determine whether the product is single-use or multi-use?
- How many single use products will allow an adequate evaluation? Consider the number of users.
- Is documentation and disclosure provided regarding the no charge status of the products? Is it a product or part of procedure?
- What period of time is necessary for a reasonable evaluation?
- Who maintains title?
- Consider procedure for removal of device at end of demonstration (absent purchase or lease).

## Difficult Choice # 1

Your medical science liaison wants to hold a meeting of your scientific advisory board here. You say ***no way*** – but then she returns and says:



## Difficult Choice # 2 (cont'd)

Here's the website for "Beyond the Ivy," the official rooftop meeting rooms of the Chicago Cubs.



## Difficult Choice #2: Answer

- Section VI of Code – prohibition on entertainment/recreation activities
- May be nice meeting rooms, but BAD optics.
- Section III – settings have to be conducive to the effective transmission of information (also Section VIII)
- Best Answer: Compliance needs to investigate further into the details of the environment and setting of the meeting



## Difficult Choice # 3



A busy physician practice is having trouble getting claims paid for your diagnostic procedure, and wants you to place a billing assistant in the office to take care of the backlog of appeal letters.

## Difficult Choice #3: Answer

- Section X of Code generally permits a manufacturer to provide accurate and objective coverage, coding, and billing information, and provide information on payor policies and procedures – including sample letters
- The issue is whether you can provide patient-specific letters (differences of opinion on this point) – should not place staff in physicians' offices (Code prohibits services that would eliminate an HCP's overhead or other expenses).
- Best Answer: Provide objective information but nothing more

## Difficult Choice # 4

Your company's top sales rep has dinner with a friend from childhood who is now a physician who prescribes your company's products. The physician pays for his own meal, and the rep submits an expense voucher for her expenses.





## Difficult Choice #4: Answer

- Section XIII of Code permits modest meals in connection with HCP business interactions, and off-site meals are permitted if impractical/inappropriate to provide meals in the HCPs office or hospital setting (note that PhRMA permits no off site meals for sales reps of their immediate supervisors – and some hospital systems may prohibit meals altogether, and some states prohibit them)
- Best Answer:
  - If this is truly an old friend dinner, everyone should pay for himself/herself.
  - If this is truly a business dinner, the company may be expensed--but consider the questionable optics

## Difficult Choice # 5



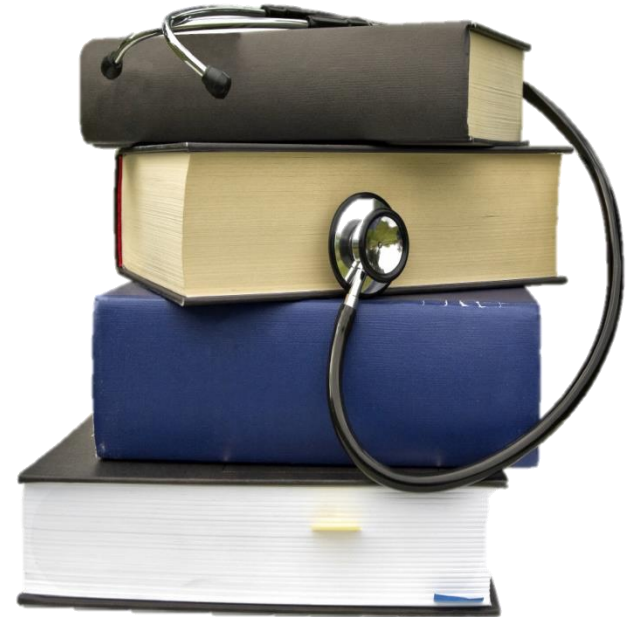
A physician consultant for your company has developed a new surgical technique using your product. He asks you to sponsor a dinner for primary care physicians in his area, and pay him to present on the new technique.

## Difficult Choice #5: Answer

- Section XI of the Code permits educational grants provided pursuant to objective grant-decision making criteria and appropriate documentation.
- Is this program designed to provide legitimate education to HCPs who need it, or is it “practice building” for the surgeon? Does he want you to subsidize HIS marketing efforts?
- Consider the OIG’s answer re improperly providing freebies to docs – see also: In a 2006 advisory opinion requested by a device manufacturer, the OIG found the advertising, promotional, and call center assistance offered by the manufacturer its referral sources -- in that case, medical equipment suppliers that provided the manufacturer's products to beneficiaries -- constitute prohibited remuneration under the federal anti-kickback statute.

## Difficult Choice # 6

During a conversation between your rep and two fellows from the University of X, the fellows request that the rep provide each of them with four key medical text books.



## Difficult Choice #6: Answer

- Section IX of Code permits giving HCPs items that serve “a genuine educational function.”
- Should be \$100 or less except medical textbooks & anatomical models.
- Best Answer: Here, a request for 4 medical textbook makes the quantity appear excessive, unnecessary. Requests always need to be within reason.

## Difficult Choice # 7



Your marketing staff is attending a three-day medical convention, and wants to raffle off one iPad to a randomly selected HCP who has registered at your booth.

## Difficult Choice #7: Answer

- Section IX would prohibit giving this to an HCP in the normal course - does not serve a genuine educational function – and FAQ41 says you can't give away as part of a raffle at a trade show an item you couldn't give away in the normal course.
- Best Answer: Compliance should not allow items to be raffled which would not be allowed to be given directly to an HCP

## Difficult Choice # 8

Your sales rep is scheduled to provide a lunch-time presentation on a new product for two physicians at a hospital. The receptionist will not let the rep set up the meeting unless he brings food for the entire office staff, including the receptionist and two nurses.





## Difficult Choice #8: Answer

- Section V – during sales meetings, it is not appropriate to pay for meals for anyone without a bona fide professional interest in the information being shared
- Section VIII – not appropriate to provide meals for the entire staff where everyone doesn't attend the meeting.
- May be able to make a case that the nurses could benefit from the education, but probably not the receptionist.
- Best Answer: Compliance needs to explain to the rep that if the entire staff does not have a bona fide professional interest then the entire staff cannot be provided food. Suggest to the rep that they take the 2 HCPs for an information dinner.

## Difficult Choice # 9



Your sales rep sends you an email saying “Dr. Jones’ practice group is the biggest in my territory – we need to provide them with a grant.”

## Difficult Choice #9: Answer

- The devil is in the details
- Are you giving them a grant BECAUSE the practice group is the biggest (i.e., is this a reward for purchases or an inducement) or is there a clinical/scientific reason that the practice group has (i.e., conduct the most comprehensive and effective clinical trial)?
- Best Answer: Compliance should ask the following questions to determine the true reason behind the grant
  - What kind of a grant – educational, research?
  - Are this being contemplated as a CME-accredited program?
  - Does the company have a policy that sets out objective criteria for grant giving – or is this like the Neurontin case (“please don’t switch to another drug – if you agree, we’ll give you a \$300K educational grant that you can use for anything you want”)

*Thank you.*

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