

Question:
What is AdvaMed?

Answer:

The Advanced Medical Technology Association (AdvaMed) is a global trade association of Companies that develop, produce, manufacture, and market Medical Technologies. We are dedicated to advancing medical science; developing high quality, innovative Medical Technology; and improving patient care



Question:
What is the purpose of the AdvaMed Code?

Answer:

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Question:
What are the elements of an effective compliance plan?

Answer:

An effective compliance plan begins with a commitment to an ethical culture and includes the following elements: effective lines of communication (including an anonymous reporting hotline); effective training and education; appropriate oversight and management of the compliance program; standards enforced through disciplinary action; prompt response to detected problems and corrective action undertaken; written policies and procedures that incorporate and foster compliance with the Code; and Internal risk assessments, monitoring, and auditing.



Question:
What are the main ethical principles for retaining the services of an HCP?

Answer:

Legitimate Need - for HCP's Services.
Consultant Selection - must be based on qualification.
Number of Consultants – must be reasonable.
Fair Market Value Compensation – must be provided for services.
Expenses – must be reasonable and modest
Written Agreement – must describe scope of services.
Sales Involvement – must not influence or control hiring decision.



Question:

What other arrangements are treated similar to HCP Consultants?

Answer:

Arrangements involving the payment of royalties to a Health Care Professional should meet the standards listed in this section of the Code.

Arrangements that involve clinical research services by a Health Care Professional in return for compensation are also a type of consulting arrangement, subject to the principles in this section of the Code.



Question:

List the principles a Company must follow in offering training and education on its medical device products?

Answer:

Setting – must be conducive to the effective transmission of information.

Faculty – must be qualified to conduct the training or education.

Attendees – must have a legitimate need to attend training.

Travel & Lodging – must be modest under AdvaMed Code Section VI.

Meals & Refreshments – must be modest under Section VII of the Code.



Question:

List the principles a Company must follow in hosting business meetings?

Answer:

Legitimate Need - must exist for meeting.

Setting - must be conducive to the discussion of relevant information.

Attendees – must have objective, legitimate need to attend.

Travel & Lodging – must be modest under AdvaMed Code Section VI.

Meals & Refreshments – must be modest under Section VII of the Code.



Question:

When may a Company provide an Educational Grant in support of a Third-Party Program?

Answer:

A Company may use an Educational Grant in support of a Third-Party Program directly to the Third-Party Program Organizer or (other entity in Code) under the following conditions: 1) to defray or reduce the costs of conducting the educational component of the seminar; 2) to allow HCPs to attend the training; 3) to cover the reasonable compensation of HCPs serving as bona fide faculty; and 4) to provide HCP attendees with items of value permissible under the Code, such as modest meals, refreshments, and educational items.



Question:

Under what conditions may a company support a third-party training program?

Answer:

A Company may provide Educational Grants to medical schools and teaching hospitals and others in support of their legitimate educational programs and activities.

A company may not determine which HCPs would be able to benefit from those training programs and the sales team in the Company may not influence or control which institution receives the financial support.



Question:

In what ways may a Company support independent, third-party research.

Answer:

A Company may provide in-kind or monetary research grants for research following specific protocols with defined objectives and milestones. Research grants may include in-kind or monetary support, including no-charge product for the limited duration of the research. The recipient should retain independent control over the research.

A Company should establish controls for reviewing requests for research grants in order to ensure sales personnel do not control or influence selection of recipient organizations.



Question:

Under what conditions may a Company donate to charity or sponsor a charitable activity?

Answer:

Charitable or Philanthropic Mission - Donations should be made for bona fide charitable purposes.

Use of Funds – must be for charitable purposes.

Indigent Care Donations – must be used for indigent patients.

Charitable Events not Permitted – a Company may not pay for or provide tickets to HCP for golf outings or other events.

Sales Involvement – Sales Personnel may not influence choice of charity



Question:

What the restrictions on a jointly conducted marketing and educational program?

Answer:

There must be a bona fide Need for the Company to engage in the activity.

A Company must have controls to ensure that decisions to engage in these arrangements are not unlawful inducements

Health Care Professionals must comply with Company guidelines on providing information related to a product's labeling and guidelines for furnishing appropriate health economics information, among other controls.

The programs must be balanced and promote both the Company and HCP interests.



Question:

Does the Code permit Companies to pay for travel to attend Company-conducted training or education program?

Answer:

Yes. The Code contemplates that a Company may bring Health Care Professionals together at a central location to deliver training and education concerning Medical Technologies, which may make out-of-town travel necessary.



Question:

Does the Code permit a Company to pay for travel to a Company-conducted general educational program not concerning a Medical Technology?

Answer:

No. It may be appropriate for a Company to conduct a general educational session not concerning a Medical Technology, but it is not the type of program for which Company-supported travel would be appropriate under the Code.



Question:

When is it inappropriate for Company to provide a meal to an HCP at a meeting?

Answer:

A Company may not provide a meal or refreshments: 1) for an entire office staff where everyone does not attend the meeting; 2) if a Company representative is not present (such as a “dine & dash” program); or 3) for guests of HCPs or for any other person who does not have a bona fide professional interest in the information being shared at the meeting.



Question:

A Company needs to meet which three criteria in order to offer meals to HCPs?

Answer:

The meal or refreshment must be subordinate in time and value to the bona fide discussion or training offered. The setting must be conducive to a bona fide scientific, educational or business discussions. The participants in the meal, must participate in the bona fide scientific, educational or business activity.



Question:

May a Company or its representative provide a gift to recognize a life event for an HCP, such as a wedding, birth, anniversary, etc.?

Answer:

No. A Company or its representative acting on the Company's behalf may only provide items to Health Care Professionals that are intended for the benefit of patients or serve a genuine educational function for the Health Care Professional. Gifts such as flowers, fruit baskets, etc. do not meet this requirement, even if provided to recognize a significant life event.



Question:

What is an item for the benefit of patients?

Answer:

Items considered to be intended for the benefit of patients could include starter kits, and educational brochures, for example. With respect to starter kits, a Company should adopt appropriate safeguards regarding the provision of such kits to ensure they are not offered as an unlawful inducement.



Question:

Under what circumstances, may a Company provide entertainment or recreation to an HCP?

Answer:

A Company may not provide or pay for any entertainment or recreational event for an HCP under any circumstance. Prohibited activities could include theater, sporting events, golf, skiing, hunting, or vacation trips.



Question:

Provide an example of a permissible role for a Company representative in a clinical setting.

Answer:

Company representatives may assist the clinical/operating room team to ensure that the appropriate range of necessary devices and accessories are available during a procedure, especially when dealing with Medical Technology that involves multiple devices and/or accessories.



Question:

List the five principles for a Company representative in a clinical setting.

Answer:

1. Company representatives should be under the supervision of an HCP.
2. Company representative should be transparent that they are acting on behalf of the Company in a technical support capacity.
3. Company representatives should not interfere with a Health Care Professional's independent clinical decision-making.
4. Company representatives should comply with applicable hospital or facility policies and requirements, including patient privacy and credentialing requirements.
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AdvaMed
Code of Ethics