

Physician-Industry Transparency

AdvaMed and its members support efforts to provide transparency into our industry's relationships with health care professionals. These relationships form the basis of innovation and technological advancements that benefit patients and improve lives around the world.

- ✓ The **U.S. Physician Payments Sunshine Act** requires medical technology companies to disclose annually most payments and transfers of value provided to U.S. physicians and teaching hospitals.
- ✓ **Interpretations vary** as to whether this includes disclosing (1) educational grants to medical societies and other conference sponsors and (2) the names of individual physicians who benefit from these funds.
- ✓ Until January 1, 2016, the government excluded from Sunshine Act reporting grants in support of accredited medical educational conferences. The government has since modified this exception.
 - Starting in 2016, medical technology companies look to whether grant payments would be considered "**indirect payments**" – a term of art under the Sunshine Act regulations that involves independent legal interpretation.
 - The government has issued some guidance regarding speaker compensation at third-party educational events, indicating that grant funds used to compensate faculty are not reportable if a company does not (1) select or pay a speaker directly or (2) provide the continuing education provider with a distinct, identifiable set of individuals to be considered speakers for the program.
 - **Some companies may interpret the agency's regulations and guidance differently.**

For these reasons, third-party conference organizers might see restrictions in grant agreements regarding the ability to use grant funding for meals or for faculty expenses. Companies may also decline to recommend or suggest faculty.

Society Policies on Conflicts of Interest

Financial arrangements between medical technology companies and HCPs may create a conflict of interest that calls into question the objectivity of an educational program, journal, or clinical standards.

Society and association boards of directors may include clinical experts whose opinions are sought by industry in the course of developing innovative products. These health care professionals may have financial and other relationships with industry. The same is often true of speakers, authors, or journal editors as well as physicians engaged by a society to help set clinical standards.

In order to avoid any actual or perceived bias as a result of these interests, AdvaMed encourages medical societies to:

- ✓ Foster an **environment of transparency** by adopting policies that require physicians that serve as faculty, program directors, and journal editors to **disclose financial interests and relationships with industry**, such as research and development contracts or training arrangements, among others.
- ✓ Develop policies that require program directors, journal editors, and others **to recuse themselves or to divest their interests in companies** if they are planning a conference, editing a journal, or setting standards, the contents of which could be considered favorable to one company or another.

Adopting strong conflict of interest policies with the **key principles of transparency, disclosure, and recusal** will benefit the objectivity, independence, and depth of all medical conference content, journal articles, and clinical standards.



INDUSTRY SUPPORT FOR U.S. MEDICAL EDUCATION CONFERENCES:
A Guide for Medical Technology Companies, Health Care Professionals, and Medical Societies and Associations



This brochure has been designed to assist you and your team in better understanding the rules and guidelines that medical technology companies follow with respect to medical education conferences.

Medical Technology Companies' Considerations in Reviewing & Funding U.S. Educational Grants

The AdvaMed Code of Ethics on Interactions with Health Care Professionals provides compliance guidelines for medical technology companies.

Under the AdvaMed Code, companies can support *bona fide* independent, educational, scientific, and policymaking conferences that promote scientific knowledge, medical advancement and the delivery of effective health care. The AdvaMed Code establishes **criteria for medical technology companies' support** for these conferences.

- ✓ The event must be primarily dedicated to **objective scientific and educational activities**. Companies may consider establishing a threshold for minimum number of hours dedicated to education.
- ✓ The training institution or conference sponsor must select the attending HCPs and have **independent control and responsibility** for the selection of program content, faculty, educational methods, and materials.
- ✓ The grant recipient must be an organization with a **genuine educational function**.
- ✓ The venue must be **conducive to the educational program**.
- ✓ The grant should be **consistent with the applicable standards** established by the conference sponsor and any accrediting body (e.g., ACCME).

Companies may have established grant submission and review processes. Requesters should consult a company's website or other resources and follow the process outlined.

Other Considerations

A company may consider some or all of the following factors when determining whether to support a third-party educational conference:

VENUE	MARKETING MATERIALS
<ul style="list-style-type: none"> Is the venue a resort location? Is the venue easily accessible, centrally located for attendees? Is it a well-known conference location? Will the conference be the attendees' main reason for being at the venue? Is the venue appropriate for attendees/audience? 	<ul style="list-style-type: none"> How does the conference market itself to potential attendees? Is education or recreation the focus?
CONFERENCE TOPIC	BUDGET
<ul style="list-style-type: none"> Is the topic relevant to the business and supportive of business objectives? Is the program accredited? 	<ul style="list-style-type: none"> What is the total budget of the conference? How much of the total budget will go towards educational content and how much is overhead? What percentage of the total budget will the company's grant represent? Are multiple companies providing support, or is one company the sole supporter?
AGENDA	
<ul style="list-style-type: none"> Is the agenda robust? Are there large gaps in the day for recreation? Are sessions mandatory or optional? 	

In addition to the considerations listed in this brochure, additional rules might apply:

PERMISSIBLE UNDER THE CODE	IMPERMISSIBLE UNDER THE CODE
<ul style="list-style-type: none"> Educational items may be provided to attendees Companies may provide meals and refreshments to attendees if provided consistent with the conference sponsor's and accrediting body's standards. Meals should be modest in value, subordinate in time and focus to the purpose of the conference, and must be clearly separate from the continuing medical education portion of the conference. Company sales personnel may provide input about the 	<ul style="list-style-type: none"> Gifts, branded items, entertainment, and recreation may not be provided to attendees – including free passes to attend the conference. Lavish meals or meals and refreshments not offered in of compliance with the sponsor's and accrediting body's standards cannot be provided. Company sales personnel should not control or unduly influence grant decisions, and companies may be required to reject grant requests if

Companies may look at different factors in determining whether to fund Educational Support and Non-Educational Support:

EDUCATIONAL SUPPORT	NON-EDUCATIONAL SUPPORT
<p>Funds granted to a third-party conference sponsor with the intent of reducing conference costs – that is, legitimate expenses and bona fide educational activities.</p> <ul style="list-style-type: none"> Typically reviewed against independent criteria listed in the AdvaMed Code and summarized in this brochure Companies might review Educational Support and Non-Educational Support separately – might require submission of Educational and Non-Educational Support requests separately 	<p>Funds paid to a third-party conference sponsor with the intent of promoting the company. This can include purchasing exhibit space or other advertising during the conference; however, separate policies and procedures may govern, and these costs may be negotiated in a separate agreement.</p> <ul style="list-style-type: none"> Generally considered to be marketing costs that are distinct from Educational Support and may not necessarily be reviewed against the same independent, objective criteria Companies may assess whether the funds paid reflect the fair market value of the exhibit or advertising space provided