



# **CBI's 7<sup>th</sup> Annual Medical Device and Diagnostics Compliance Congress**

**Compliance Risk Areas related to  
Educational Programs and Product Training  
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## Today's Agenda

- Risk Areas
- Relevant Guidance
- Scenarios
- Counseling Tips



## Risk Areas

- General Education Programs
- HCP Faculty Arrangements
- Travel
- Meals and Entertainment
- Other Forms of Remuneration for Attendees
- Sponsorship of Third Party Educational Programs
- Scholarships
- Educational Grants



# OIG Compliance Guidance for Pharmaceutical Manufacturers

- The Anti-Kickback Statute (“AKS”) is implicated if funding is conditioned (even in part) on product purchases, even if there is a legitimate educational purpose.
- If Manufacturer has any influence over substance or presenter, program may be used for inappropriate marketing purposes.
  - Manufacturers should separate grant making function from sales and marketing.
  - Establish objective criteria that do not take into account volume/value of purchases and ensure *bona fide* educational purpose.
  - Have no control over speaker/content.
  - Regularly document and monitor compliance with procedures.



## Key Questions Posited by OIG Guidance

- Do the services provided by the manufacturer eliminate an expense that the physician would have otherwise incurred (i.e., have independent value to the physician)?
  - Under the AKS, neither a legitimate purpose (e.g., physician education), nor a FMV payment, will necessarily protect remuneration if there is also an illegal purpose (i.e., the inducement of business).
- Is educational grant funding based, expressly or implicitly, on the physician's referral of the manufacturer's product?
  - If so, the funding plainly implicates the AKS.



## Key Questions Posited by OIG Guidance

- Is the funding for bona fide educational purposes?
  - Funding educational activities sponsored and organized by medical professional organizations typically raise little risk of fraud or abuse, provided that the grant or support is not restricted or conditioned with respect to content or faculty.
- Has the manufacturer taken steps to ensure that neither they, nor their representatives, are using CME funding to channel improper remuneration to physicians or other business sources or to influence or control the content of the program?



# AdvaMed Code: Company Sponsored Product Training

- Companies have a responsibility to make training and education on their products available to HCPs.
  - “Training” means training on the safe and effective use of Company products.
  - “Education” means communicating information directly concerning or associated with the use of Company products, e.g., information about disease states and the benefits of Company products to certain patient populations.
- It may be appropriate for Companies to conduct general educational sessions.
  - But it is not appropriate to pay for travel to such programs.



# AdvaMed Code: Company Sponsored Product Training

- Companies should adhere to the following principles:
  - Programs and events should be conducted in **settings** that are **conducive to the effective transmission of information**.
  - The training **staff** used by the Company should have the **proper qualifications** and **expertise** to conduct such training.
  - Training staff may include qualified field sales employees who have the technical expertise necessary to perform the training.
  - Companies may provide **modest meals and refreshments** that are **subordinate in time and focus** to the training and/or educational purpose.
  - Where there are objective reasons for out-of-town travel to efficiently deliver Training and Education, Companies may pay for **reasonable travel** and **modest lodging costs** of the attending HCPs.
    - It is not appropriate to pay for the meals, refreshments, travel, or other expenses for HCP guests or for any other person who does not have a *bona fide* professional interest in the information being shared at the meeting.





# AdvaMed: Third Party Conference Grants

- Companies may provide a grant to the conference sponsor to reduce conference costs.
- Grants to a training institution or the conference sponsor to allow attendance by medical students, residents, fellows, and others who are HCPs in training are also permissible.
- Companies may provide grants when:
  - (1) the gathering is primarily dedicated to promoting objective scientific and educational activities and discourse; and
  - (2) the training institution or the conference sponsor selects the attending HCPs who are in training.



## AdvaMed Code: Third Party Educational Conferences

- Grants should be paid only to organizations with ***genuine educational function*** and may be used to reimburse only legitimate expenses for ***bona fide educational activities***.
- Grants also should be ***consistent with applicable standards*** established by the conference sponsor and any accrediting body.
- The conference sponsor should ***independently control*** and be responsible for the selection of ***program content, faculty, educational methods, and materials***.



# AdvaMed Code: Conference Meals and Refreshments

- Companies may provide funding to the conference sponsor to support the provision of meals and refreshments to conference attendees.
- Companies may directly provide meals and refreshments for HCP attendees if such meals and refreshments are provided:
  - (1) to ***all HCP attendees***, and
  - (2) in a manner ***consistent with applicable standards*** of the conference sponsor and accrediting body.
- Any meals and refreshments should be ***modest in value, subordinate in time and focus*** to the purpose of the conference, and clearly ***separate*** from the continuing medical education portion of the conference.



## AdvaMed Code: Third Party Educational Conferences

- Companies may make grants to conference sponsors for reasonable honoraria, travel, lodging, and modest meals for HCPs who are *bona fide* conference **faculty members**.
- Companies may purchase **advertisements** and **lease booth space** for Company displays at conferences.
- A Company should **not** provide or pay for any **entertainment or recreational event** or activity for any non-employee HCP.



## AdvaMed Code: Modest Meals Associated with HCP Business Interactions

- Modest meals may be provided as an ***occasional*** business courtesy consistent with the following limitations:
  - The meal should be ***incidental*** to the *bona fide* presentation of scientific, educational, or business information and provided in a manner conducive to the presentation of such information.
  - The meal should ***not*** be part of an entertainment or recreational event.
  - Meals should be in a ***setting*** that is conducive to *bona fide* scientific, educational, or business discussions.



## AdvaMed Code: Modest Meals Associated with HCP Business Interactions

- A Company may provide a meal only to HCPs who actually attend the meeting.
  - A Company may not provide a meal for an entire office staff where everyone does not attend the meeting.
  - A Company also may not provide a meal where its representative is not present (such as a “dine & dash” program).
  - A Company may not pay for meals 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.



## AdvaMed Code: Educational Items; Prohibition on Gifts

- A Company occasionally may provide items to HCPs that benefit patients or serve a genuine educational function for HCPs.
- Other than medical textbooks or anatomical models used for educational purposes, any such item should have a fair market value of less than \$100.
- A Company may not provide items that are capable of use by the HCP (or his or her family members, office staff or friends) for no educational or non-patient-related purposes, for example, a DVD player or MP3 player/I-Pod.
- Non-educational branded promotional items and gifts are never appropriate.



## AdvaMed Code: Educational Grants

- Educational grants may be provided for legitimate purposes. For example:
  - A Company may make educational grants to conference sponsors or training institutions.
  - A Company may not make educational grants to individual HCPs.
- A Company may make grants to support the genuine medical education of medical students, residents, and fellows participating in fellowship programs that are charitable or have an academic affiliation, or other medical personnel.
- A Company may make grants for the purpose of supporting education of patients or the public about important health care topics.





## Lessons Learned from Recent Cases: Education as a Vehicle for Off Label Marketing

Recent enforcement actions demonstrate that the following practices are fraught with compliance risk:

- Providing educational grants to fund CME programs that disseminate messages to use products for unapproved uses.
- Paying KOLs to lecture at CME programs about off label uses.
- Advisory board educational meeting as an excuse for all expense paid trips to resort locations.
- Scripting supposedly independent CME programs and journal articles to promote off label uses.

# Scenario 1: Resident Training Program

<b>Curriculum for 4<sup>th</sup> Annual XYZ Co Cardiology Resident Training Program Ritz Carlton Key Biscayne</b>	
8 – 8:15	Welcome – XYZ Co CEO
8:15 – 9	Key Note Speaker: Sanjay Gupta, M.D.
9 – 10	Indications for ABC surgery
10 – 11	ABC surgical techniques
11 – 12	Post surgical rehabilitation options
Lunch – Music provided by University Trio	
12:30 – 3:30	Cadaver Lab
3:30 – 4	Break
4 – 5	Thinking ahead: Pitfalls in recruitment arrangements and employment agreements
6 – 7	Cocktail Party – Main Ballroom
7 pm	Meet in lobby, board busses for dinner at Joe's Stone Crab



## Issues and Potential Pitfalls

- Is the venue appropriate?
- Are any elements of the curriculum problematic?
- Can the resident bring family if there is no additional charge?
- What if there is an “up charge” for a child in the room?
- Is it OK to have music during lunch?
- What if the resident skips the afternoon lab for golf or sight-seeing?
- Is it ok to host a cocktail party?
- Can guests attend the cocktail party if they promise not to drink?
- Is the dinner appropriate?
- How are faculty selected?



## Scenario 2: Off-Site Cadaver Lab

- Your Company's Director of Education develops a plan to offer off-site cadaver labs at six locations spread throughout the country.
  - Four of the locations are academic medical centers (AMCs) that are major customers. They have “great” facilities but they are more expensive than the non-AMC-owned facilities.
  - One of the AMCs is insisting that all faculty be members of its medical staff.
  - Another is demanding a \$250k educational grant in lieu of a facility fee.
  - A distributor wants to use its private plane to fly HCPs from its region to the program.
- What aspects of this plan present potential compliance issues and how should you address them?



## Scenario 3: Distributor Business Plan

- A distributor's business development plan includes the following:
  - Monthly “lunch and learn” programs for key physician practices
  - Patient activation programs with HCP speakers
  - Scholarships for junior physicians to attend Company's annual leadership development symposium in Switzerland
  - Sponsorship of grand rounds at key hospital clients
  - Quarterly CME programs for area HCPs
  - Giving thumb drives with patient education materials to practices that are high-volume users of company products
  - Renting space within physician offices for Company patient education kiosk
- Spot the issues.



## Scenario 4 – Professional Society Annual Symposium

- Your VP of Marketing proposes to sponsor a professional society's annual symposium.
  - Sponsorships are more expensive than for the competing professional society's annual symposium, which you have sponsored in the past.
  - You would be able to sponsor the key note speaker luncheon with prominent signage.
  - You would have a trade show booth and a room in which you could host a breakfast on day 2 of the conference.
  - The sponsorship requires the donation of a raffle prize.
  - Your logo would be included on the binder and on the tote bag provided to carry the course binder.
- Again, spot the issues.



# Ensuring Educated Educational Decisions: Counseling Tips

- Conduct a “gap” analysis to identify discrepancies between Company practice/ policy and best practices
- Require Compliance review of agendas/ curriculum for product training (to ensure that it is product training)
- Require Compliance review of general education provided by the Company to ensure against AKS pitfalls
- Conduct periodic distributor audits to ensure against inappropriate funding of educational programs
- Subject HCP faculty at Company-sponsored training programs to needs assessment and qualification review
- Track the frequency of educational programs/ meetings at HCP offices and facilities to ensure that they are occasional and appropriate



# Counseling Tips: Policies

Develop/ review policies to ensure that business has clear guidelines to ensure that:

- Sales and marketing plays no role in educational grant function
- Grants do not take into account the volume/ value of actual or potential business generated by the recipient or HCPs affiliated with the recipient
- Company-sponsored product training has appropriate focus on Company products and takes place in an appropriate venue
- Only reasonable travel expenses of attendees who have a need for product training are paid
- Only appropriate educational items are provided to attendees
- Company does not pay for travel to general education programs
- Meals are modest and in an appropriate venue
- Educational meetings with HCPs are appropriate in terms of frequency, attendees and meals provided
- No entertainment or gifts are provided in connection with Company or third-party programs
- Company does not influence content, materials or faculty at third-party programs



# Appendix





# OLG Compliance Guidance for Pharmaceutical Manufacturers

- While educational funding can provide valuable information to the medical and health care industry, manufacturer grants to purchasers, GPOs, PBMs and similar entities raise concerns under the anti-kickback statute.
  - Funding that is conditioned, in whole or in part, on the purchase of product implicates the statute, even if the educational or research purpose is legitimate.
  - Furthermore, to the extent the manufacturer has any influence over the substance of an educational program or the presenter, there is a risk that the educational program may be used for inappropriate marketing purposes.



# OIG Compliance Guidance for Pharmaceutical Manufacturers

- To reduce the risks that a grant program is used improperly to induce or reward product purchases or to market product inappropriately, manufacturers should separate their grant making functions from their sales and marketing functions.
  - Effective separation of these functions will help insure that grant funding is not inappropriately influenced by sales or marketing motivations and that the educational purposes of the grant are legitimate.
  - Manufacturers should establish objective criteria for making grants that do not take into account the volume or value of purchases made by, or anticipated from, the grant recipient and that serve to ensure that the funded activities are bona fide.
  - The manufacturer should have no control over the speaker or content of the educational presentation.
  - Compliance with such procedures should be documented and regularly monitored.



# AdvaMed Code: Prohibition on Entertainment and Recreation

- Company interactions with HCPs should be professional in nature and should facilitate the exchange of medical or scientific information that will benefit patient care.
- To ensure the appropriate focus on an educational and/or informational exchange and to avoid the appearance of impropriety, *a Company should not provide or pay for any entertainment or recreational event or activity for any non-employee HCP.*
  - Such activities include, for example, theater, sporting events, golf, skiing, hunting, sporting equipment, and leisure or vacation trips.
  - Such entertainment or recreational events, activities, or items should not be provided, regardless of:
    - their value;
    - whether the Company engages the HCP as a speaker or consultant; or
    - ***whether the entertainment or recreation is secondary to an educational purpose.***



## AdvaMed Code: Educational Items; Prohibition on Gifts

- A Company may not give HCPs any type of non-educational branded promotional items, even if the item is of minimal value and related to the HCP's work or for the benefit of patients.
  - Examples of non-educational branded promotional items include pens, notepads, mugs, and other items that have a Company's name, logo, or the name or logo of one of its Medical Technologies.
- Companies also may not provide HCPs with gifts such as cookies, wine, flowers, chocolates, gift baskets, holiday gifts or cash or cash equivalents.



# AdvaMed FAQs on Company-Conducted Product Training and Education

- Why may it be appropriate under the Code for Companies to pay for travel to attend training and education sessions?
  - In order to efficiently deliver training and/or education at appropriate facilities, the Code contemplates that a Company may bring HCPs together at a central location, which may make out-of-town travel necessary. Note that this section deals only with meetings focused on training and education on Medical Technologies, and only for persons who could legitimately benefit from the training and education.



# AdvaMed FAQs on Company-Conducted Product Training and Education

- May a Company pay for travel to a Company-sponsored general educational program (not related to a Medical Technology)?
  - It may be appropriate for a Company to conduct a general educational session, but it is not the type of program for which Company-supported travel would be appropriate under the Code. In contrast, paying for a HCP's travel may be appropriate when the Company is conducting training and education on the safe and effective use of its Medical Technologies.



# AdvaMed FAQs on Supporting Third-Party Educational Conferences

- May a Company designate attendees or faculty who will speak at a third-party educational conference?
  - No. The Code contemplates that an independent third party will select faculty and attendees. The Code does not preclude a Company from recommending a knowledgeable faculty member, where the recommendation is permitted by the conference sponsor's guidelines. The ultimate selection should be made by the conference sponsor.





## AdvaMed FAQs on Supporting Third-Party Educational Conferences

- May a Company provide an educational grant to support the attendance of a HCP at a third-party educational conference?
  - The Code contemplates that grants would be made to the conference sponsor or training institution, which will select the attendees. Furthermore, the Code contemplates that the benefited attendees would be medical students, residents, fellows, or other HCPs in training.



# AdvaMed FAQs on Supporting Third-Party Educational Conferences

- If a Company provides a grant for a medical student to attend an educational conference, may the funds be used to cover both travel expenses and registration fees?
  - Yes, provided that the grant is given directly to a training institution or a third party educational conference sponsor.
- May a Company sponsor an off-site sales, promotional, or other business meeting that is ancillary to a third-party educational conference?
  - Yes, provided that the sales and promotional meeting or other activity has a legitimate business purpose and meets all applicable requirements of the Code. The Company also should comply with applicable conference sponsor guidelines.