

Guidance on Sponsorship Funding Requests

The members of the Contact Lens Institute (CLI) seek to support the needs of the Optometry community, often through their respective professional and medical associations. In connection with these efforts, a number of questions have arisen from time to time regarding the various types of funding requests submitted to commercial companies as well as some of the related reporting requirements under the Open Payments “Sunshine” Law. We hope that the definitions and discussion provided in this **guidance** will give some clarity around the types of requests CLI members receive, as well as some insights into relevant considerations under the AdvaMed Code Of Ethics On Interactions With Health Care Providers and related guidance under that Code.

I. Funding Requests:

Typically, funding can be categorized into 3 types of support including promotional sponsorships, educational grants and charitable contributions. Additionally, companies may be asked to provide support in several other ways, including: providing meals, in-kind services, educational materials, and other items. We will focus on the funding categories.

A. Promotional Sponsorships

Requests for a commercial sponsorship may be requested for promotional opportunities at local, regional or national meetings, or for a healthcare related organization. This type of sponsorship may include but is not limited to:

- Commercial sponsorship of a meeting or conference where Company receives a bonafide promotional return for such sponsorship
- Advertisement sponsorship on program materials or videos or an organization’s website
- Availability to exhibit and promote products at an exhibit or convention booth
- Opportunity for podium time at a non-CE program to provide a promotional discussion on the Sponsor’s products
- Must be requested in writing on the requesting organization’s letterhead, and request must set out the anticipated promotional benefit to the Sponsor
- Must be available to all companies at the same established fees or rates
- Promotional benefit must be Fair Market Value return for sponsorship:

CMS Definition of Fair Market Value: “...the value in arm’s-length transactions, consistent with the general market value. “General market value” means the price that an asset would bring, as the result of bona fide bargaining between well-informed buyers and sellers who are not otherwise in a position to generate business for the other party, on the date of acquisition of the asset.” Usually, the fair market price is the price at which bona fide sales have been consummated for assets of like type, quality, and quantity in a particular market at the time of acquisition, or the compensation that has been included in bona fide service agreements with comparable terms at the time of the agreement, where the price or compensation has not been determined in any manner that takes into account the volume of anticipated or actual referrals.”

B. Educational Grants

Supporting Third-Party Educational Conferences - *Bona fide* independent, educational, scientific, and policymaking conferences promote scientific knowledge, medical advancement and the delivery of effective health care. These typically include conferences sponsored by national, regional, or specialty medical associations and conferences sponsored by accredited continuing medical education providers. Companies may support these conferences in various ways:

Companies may provide a grant to the conference sponsor to reduce conference costs. They may also provide grants to a training institution or the conference sponsor to allow attendance by medical students, residents, fellows, and others who are Health Care Professionals in training. Companies may provide grants when: (1) the gathering is primarily dedicated to advancing objective scientific and educational activities and discourse; and (2) the training institution or the conference sponsor selects the attending Health Care Professionals who are in training. Such grants should be paid only to organizations with a genuine educational function and may be used to reimburse only the legitimate expenses for *bona fide* educational activities. Such grants also should be consistent with applicable standards established by the conference sponsor and the accrediting body for the educational activity. The conference sponsor should independently control and be responsible for the selection of program content, faculty, educational methods, and materials.

Faculty Expenses. Companies may make grants to conference sponsors for reasonable honoraria, travel, lodging, and modest meals for Health Care Professionals who are *bona fide* conference faculty members.

C. Contributions

A Company may make monetary or Medical Technology donations for charitable purposes, such as supporting indigent care, patient education, public education, or the sponsorship of events where the proceeds are intended for charitable purposes. Charitable Donations should be motivated by *bona fide* charitable purposes and should be made only to *bona fide* charitable organizations or, in rare instances, to individuals engaged in genuine charitable activities for the support of a *bona fide* charitable mission. Charitable donations should not be tied to, or conditioned upon, the purchase or recommendation of a Company product by the organization or its supporters. Companies should exercise diligence to ensure the *bona fide* nature of the charitable organization or charitable mission.

II. Physician Payments Sunshine Law

The main purpose of the law is to provide patients with enhanced transparency into the relationships their health care providers have with life science manufacturers, including medical technology companies. The Sunshine Law requires that payments and transfers of value made by life science manufacturers to “Physicians” and “Teaching Hospitals” be reported. Under the Sunshine Law, “physicians” include doctors of medicine and osteopathy, dentists, podiatrists, optometrists and licensed chiropractors. The program is administered by the Centers for Medicare and Medicaid Services (CMS), and is now known as the Open Payments program.

There are numerous ways in which CLI companies compensate physicians, academics and healthcare professionals for their time, expertise and intellectual property, in connection with the development of new technologies, the improvement of existing technologies, and training and education of other health care professionals in the safe and effective use of medical technology, among other beneficial services.

These arrangements fuel advances in medical technology, and improve medical care and the quality of healthcare available to patients and consumers. Specific examples under the Sunshine Nature of Payment Categories include: Consulting Fees, Honoraria, Education, Research, Royalty or license, and Direct compensation for serving as a faculty or a speaker.

Under the Open Payments program, CLI Companies are required to report certain value transfers made by them through third parties if the Company directs, instructs, “or otherwise causes” (e.g., through an agreement) the third party to make such a transfer. These are known

as “indirect payments.” This includes suppliers that facilitate speaker programs or advisory boards, provide meals at company sponsored events, or distribute educational items such as text books. Additionally, value transfers provided through organizations that provide continuing medical education are reportable. Payments for educational programs accredited by one of five designated accreditation or certification organizations are currently exempt from reporting. This exemption will not apply after 2015. Specifically, COPE certified education does not qualify for the current exemption, and as such, certain value transfers supported through educational grants are now, and will continue to be, reportable, pending further guidance from CMS.

III. AdvaMed Code Considerations

The Advanced Medical Technology Association (“AdvaMed”) represents companies that develop, produce, manufacture, and market medical products, technologies and related services and therapies used to diagnose, treat, monitor, manage and alleviate health conditions and disabilities (“Medical Technologies”) in order to enable patients to live longer and healthier lives (collectively “Companies,” and individually “Company”). AdvaMed is dedicated to the advancement of medical science, the improvement of patient care, and, in particular, the contributions that high quality, innovative Medical Technologies make toward achieving these goals.

AdvaMed recognizes the obligation to facilitate ethical interactions between Companies and those individuals or entities involved in the provision of health care services and/or items to patients, which purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe Companies’ Medical Technologies in the United States (“Health Care Professionals”).

AdvaMed recognizes that Health Care Professionals’ first duty is to act in the best interests of patients. Companies can serve the interests of patients through beneficial collaborations with Health Care Professionals. To ensure that these collaborative relationships meet high ethical standards, they must be conducted with appropriate transparency and in compliance with applicable laws, regulations and government guidance. AdvaMed recognizes the obligation to facilitate ethical interactions between Companies and Health Care Professionals in order to ensure that medical decisions are based on the best interests of the patient. The ethical principles that govern these interactions are reflected in the AdvaMed Code of Ethics.

IV. Funding Considerations and Reporting Requirements for Medical and Professional Societies

It is important that Companies typically have different internal processes for each type of funding and requests from organizations should be sent by type and not combined. As mentioned previously, the CLI Companies are all committed to meet the reporting requirements under Open Payments.

When requesting funds, consider the reporting implications that these requests might have on companies required to report under Open Payments. Such as the CLI Companies, as well as the data gathering that would be required of your organizations to meet these reporting requirements.

Currently, the requirements for Continuing Education programs (CE) for optometrists are the same as non CE programs. This is because COPE accredited programs are not exempt from Open Payment as per CMS, as COPE is not one of the five recognized accreditation organizations listed in the current exemption (which expires at the end of 2015).

A. Request submissions

As you submit requests for funding, consider the following as you submit to companies:

- Requests should be consistent with the respective commercial supporter's area of interest
- Request should be submitted on respective Organization's letterhead
- Provide detailed budget for entire activity
 - Provide specific funding for faculty and attendees
- Clarify if funding is being requested for a specific value transfer to the attendees or faculty
 - In general, funding of large scale events where meals are open to all attendees, reporting may not be required
 - For smaller closed meetings; detailed information as above
- Funding should be paid to the organization and not an individual / officer of the organization

B. Reporting Considerations

The following are criteria that will be evaluated to determine if a value transfer needs to be reported:

- Will funding ultimately provide a value transfer to either the faculty members or the attendees of a program
- Does the organization have the ability to track all participants
 - Buffet lunch for a meeting with 3000 attendees vs a plated meal with 100 attendees
- Is funding requested/provided by a single commercial sponsor?
- Are commercial supporters requested to provide funding for specific line-items of a budget?
 - Speaker honorarium and /or travel
 - Meals for attendees
- Does the organization have the capabilities to provide all the required fields of information to the commercial supporter?

C. Reporting Fields Required

If it is determined that a value exchange will be provided as part of the commercial support, the following information will need to be provided by the respective Professional and Medical Society:

- Doctor Name including middle initial
- NPI number
- Practice Address
- License Number
- Nature of payment (meal, honorarium, etc.)
- Date of exchange
- Amount of payment
- Form of payment
- Associated product (if any)