Triple Compliance Jeopardy:
Hot Issues and Practical Advice for Hospitals, Physicians and their Suppliers

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I. Medical Device Manufacturer Grants and Charitable Donations to Hospitals

As health care margins decline, not-for-profit health care providers are increasingly dependent on the ability to raise charitable donations to meet their mission of service to the community. Not-for-Profit providers continue to struggle to identify sources of funding for community or physician education. On a larger scale, with the aging of the baby-boomer population, there is an impending growing need for additional hospital in-patient beds in the next 20 years.\footnote{Under-bedded? What a difference a decade makes: Empty wings and shuttered facilities are now giving way to a demand for more hospital beds. Sharon M. Ruff Richter The Journal of Health Care Contracting, http://www.jhconline.com/article-marapr2005-construction.asp.} Along with this, the changing nature of medical care is causing hospitals to branch out into outpatient centers for cancer, diagnostic services and surgery. The pressure for capital investment in facilities will also bring opportunities for for-profit Medical Device Manufactures to partner with not-for-profit health care providers to meet the growing demand for health care services, improve health care quality and access to care, and demonstrate the social responsibility of the for-profit corporation by supporting the community benefit initiatives of the not-for-profit sector. This new opportunity also brings with it corresponding legal and ethical challenges compliance officers of both constituencies.

Without a doubt, strong social goals can be met medical device manufacturers and hospitals and hospital foundations partnering through charitable donations and grants. Not-for-Profit providers can gain access to capital investment they would not otherwise have that will allow them to expand and improve services, and meet the increasing need for traditional and new health care services. For-Profit corporations can demonstrate their “good corporate citizenship” (while at the same time achieving name recognition and public good-will). Meeting this social goal, can directly conflict with other social goals protected by Federal statute, i.e. the protection of independence of medical decision-making and avoiding unnecessary health care costs though the elimination of the undue influence of financial relationships on providers participating in Federal Health Care Programs.

To meet both of these goals, compliance officers and legal counsel will need to develop polices, procedures and controls addressing charitable donations from vendors, especially those that provide health care items or services. These policies should take into account relevant statutory authorities, legal guidance from enforcement authorities, and the latest in industry guidance and trends. This first portion of the presentation is intended to review the important aspects of the main legal authorities and enforcement and industry guidance that come to bear on this issue. The handout materials provide relevant quotations from these authorities.
A. The Anti-Kickback Statute

Under the Federal Anti-Kickback Statute, it is a criminal offense to knowingly and willfully offer to pay, solicit or receive any remuneration with the intent of inducing referrals of items or services reimbursable by Federal healthcare programs. 42 U.S.C. §1128(b). In other words, the Statute makes it illegal for a person or entity to offer to give something of value in order to cause another person to provide the offeror a business opportunity that will be paid for through the Medicare or Medicaid programs. A violation of the Statute is a criminal offense, and as such a violation occurs only where remuneration is paid with the intent of inducing the referral of items or services reimbursable by a federal healthcare program. The Statute provides penalties for both the person offering the inducement and the person accepting the inducement.2

The United States Court of Appeals for the Third Circuit has interpreted the Statute to cover any arrangement where only one purpose of the remuneration is to obtain money for referral of service or items. United States v. Greber, 760 F.2d 68 (3rd Cir.), cert. denied, 476 U.S. 988 (1985). Violations of the Statute constitute a felony and can result in criminal penalties, including a maximum fine of $25,000, and five years imprisonment or both. A provider can also be excluded from participation in federal healthcare programs for a violation of the Statute.

B. OIG Application to Donations

In a series of guidance publications, the Office of Inspector General for the United States Department of Health and Human Services has discussed the application of the Anti-Kickback Statue to charitable donations by vendors of health care providers participating in Federal Health Care Programs.

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2 Under the Statute, the term “remuneration” is very broadly defined and includes any benefit in any form, with no minimum value required. Remuneration can be presented as a payment, rebate or a benefit of any kind, including the transfer of anything of value, “in cash” or “in-kind”, directly or indirectly, covertly or overtly. The basic test of whether remuneration is involved in a transaction is whether the benefit offered has materially influenced the professional clinical judgment of the other party. See Letter dated May 20, 1991 from Richard P. Kusserow, Inspector General to Paul C. Rettig, Executive Vice President of the American Hospital Association (asserting that case law “makes it clear that the Statute’s prescriptions apply to those who can materially influence the flow of Medicare or Medicaid business”).

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1. The Charitable Golf Outing

In OIG Advisory Opinion 01-02, the OIG used the vehicle of a charitable golf outing to expressed its opinion that contributions by a vendor to a health care provider’s charitable fundraising initiative clearly implicates the Statue.

This Office's concern with the provision of monetary donations to actual or potential referral sources is longstanding and clear: such arrangements are suspect and may violate the anti-kickback statute if one purpose is to induce or reward referrals of Federal health care program business. Those concerns are not necessarily ameliorated when the donation is in the form of sponsorships or participation in a charity golf tournament that would benefit the Requester, an actual or potential source of Federal health care program business for some sponsors and participants.3

OIG recognizes that that most donations made by vendors are for true charitable purposes.

We accept that the majority of donors who make contributions to tax-exempt organizations, including donors with ongoing business relationships with the donees, are motivated by bona fide charitable purposes and a desire to help their communities. Substantial numbers of health care providers are not-for-profit organizations, many of which are community-based service providers, and depend on tax-deductible charitable donations to fund all or part of their operations. We recognize that soliciting donations is vital to these providers’ viability and that the potential donor pool will include many persons and entities in the local community with which the soliciting entity has past, present, or potential business relationships. Invariably, some of the persons or entities solicited will be in a position to receive referrals or business from the soliciting provider. This business relationship does not make a tax-deductible donation automatically suspect under the anti-kickback statute. 4

While the bon-fide purposes do not make the donation exempt under the statute, the OIG cited the following safeguards in making the determination not to apply sanctions:

First, the golf tournament appears to be a bona fide charitable event intended to provide benefits to the community, in particular, to the local Hispanic community with an emphasis on underserved and uninsured populations. The purposes to which the Requester expects to put the donated sums -- social service programs,

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3 OIG Advisory Opinion 01-02, Page 4, March 27, 2001
4 OIG Advisory Opinion 01-02, Page 5, March 27, 2001
scholarships, and holiday gift giving to low-income families -- clearly further that mission.\(^5\)

Second, the participation of the Requester’s vendors is incidental to a broad community solicitation and broad participation by non-vendors. The Golf Committee’s members and tournament sponsors and participants are drawn from a broad pool of civic leaders and business sources, many of whom have little or no nexus to the health care industry or to the Requester’s business with the Federal health care programs. The tournament’s promotional materials are widely disseminated and emphasize the community service provided by the Requester and the tournament’s charitable goals.\(^6\)

Third, the Requester has certified that it does not take tournament participation or sponsorship into account when awarding or renewing contracts or purchasing items or services. Overall, the Proposed Arrangement provides significant community benefits without presenting a significant risk of abuse of Federal health care programs.\(^7\)

While the above safeguards are not onerous, they will not fit every fundraising situation, especially those that are geared toward larger, capital campaigns. Additionally, OIG Advisory Opinions are only applicable to the requestor. The concepts can be used, however, when designing controls for fundraising solicitation campaigns.

2. **Compliance Guidance for Pharmaceutical Manufacturers**

The 2003 Compliance Guidance to Pharmaceutical Companies, contains substantial discussion on educational grants to health care providers, that reveals the Federal concerns about grants to providers and safeguards that can be used to address these concerns. The following quotations are extracted from the Guidance:

*Educational Grants.* Pharmaceutical manufacturers sometimes provide grant funding for a wide range of educational activities. 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

\(^{5}\) OIG Advisory Opinion 01-02, Page 5, March 27, 2001  
\(^{6}\) OIG Advisory Opinion 01-02, Page 5, March 27, 2001  
\(^{7}\) OIG Advisory Opinion 01-02, Page 5, March 27, 2001
the educational program may be used for inappropriate marketing purposes.  

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 ensure 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.

**Educational and Research Funding.** In some cases, manufacturers contract with physicians to provide research services on a fee-for-service basis. These contracts should be structured to fit in the personal services safe harbor whenever possible. Payments for research services should be fair market value for legitimate, reasonable, and necessary services. Research contracts that originate through the sales or marketing functions—or that are offered to physicians in connection with sales contacts—are particularly suspect. Indicia of questionable research include, for example, research initiated or directed by marketers or sales agents; research that is not transmitted to, or reviewed by, a manufacturer’s science component; research that is unnecessarily duplicative or is not needed by the manufacturer for any purpose other than the generation of business; and post-marketing research used as a pretense to promote product. Prudent manufacturers will develop contracting procedures that clearly separate the awarding of research contracts from marketing or promotion of their products.

In addition, pharmaceutical manufacturers also provide other funding for a wide range of physician educational and research activities. Manufacturers should review educational and research grants to physicians similarly to educational and research grants to purchasers (described above). As with grants to purchasers, the OIG recognizes that many grant-funded activities are legitimate and beneficial. When evaluating educational or research grants provided by manufacturers to physicians, manufacturers should determine if the funding is based, in any

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8 68 FR 23735  
9 68 FR 23735  
10 68 FR 23738
way, expressly or implicitly, on the physician’s referral of the manufacturer’s product. If so, the funding plainly implicates the anti-kickback statute. In addition, the manufacturer should determine whether the funding is for *bona fide* educational or research purposes. Absent unusual circumstances, grants or support for educational activities sponsored and organized by medical professional organizations raise little risk of fraud or abuse, provided that the grant or support is not restricted or conditioned with respect to content or faculty.  

Pharmaceutical manufacturers often provide funding to other sponsors of continuing medical education (CME) programs. Manufacturers should take steps to ensure that neither they, nor their representatives, are using these activities to channel improper remuneration to physicians or others in a position to generate business for the manufacturer or to influence or control the content of the program. In addition, manufacturers and sponsors of educational programs should be mindful of the relevant rules and regulations of the Food and Drug Administration. Codes of conduct promulgated by the CME industry may provide a useful starting point for manufacturers when reviewing their CME arrangements.  

C. Industry Guidance  

Two industry associations, the Pharmaceutical Research and Manufacturer Association, and the Advanced Medical Technology Association developed a voluntary Code of Ethics for their members. These Codes include guidance on educational grants and similar charitable giving.  

1. **PHRMA Code of Ethics.** The following quotations are extracted from the PHRMA Guidance.  

**THIRD-PARTY EDUCATIONAL OR PROFESSIONAL MEETINGS**  

a. Continuing medical education (CME) or other third-party scientific and educational conferences or professional meetings can contribute to the improvement of patient care and therefore, financial support from companies is permissible. Since the giving of any subsidy directly to a healthcare professional by a company may be viewed as an inappropriate cash gift, any financial support should be given to the conference’s sponsor which, in turn, can use the money to reduce the overall conference registration fee for all attendees. In addition, when companies underwrite medical conferences or meetings other than their own, responsibility for and control over the selection of content, faculty, educational methods,
materials, and venue belongs to the organizers of the conferences or meetings in accordance with their guidelines.

b. Financial support should not be offered for the costs of travel, lodging, or other personal expenses of non-faculty healthcare professionals attending CME or other third-party scientific or educational conferences or professional meetings, either directly to the individuals attending the conference or indirectly to the conference’s sponsor (except as set out in section 6 below). Similarly, funding should not be offered to compensate for the time spent by healthcare professionals attending the conference or meeting.

c. Financial support for meals or receptions may be provided to the CME sponsors who in turn can provide meals or receptions for all attendees. A company also may provide meals or receptions directly at such events if it complies with the sponsoring organization’s guidelines. In either of the above situations, the meals or receptions should be modest and be conducive to discussion among faculty and attendees, and the amount of time at the meals or receptions should be clearly subordinate to the amount of time spent at the educational activities of the meeting.

d. A conference or meeting shall mean any activity, held at an appropriate location, where (a) the gathering is primarily dedicated, in both time and effort, to promoting objective scientific and educational activities and discourse (one or more educational presentations(s) should be the highlight of the gathering), and (b) the main incentive for bringing attendees together is to further their knowledge on the topic(s) being presented.

6. SCHOLARSHIPS AND EDUCATIONAL FUNDS

Financial assistance for scholarships or other educational funds to permit medical students, residents, fellows, and other healthcare professionals in training to attend carefully selected educational conferences may be offered so long as the selection of individuals who will receive the funds is made by the academic or training institution. “Carefully selected educational conferences” are generally defined as the major educational, scientific, or policy-making meetings of national, regional, or specialty medical associations.

8. INDEPENDENCE OF DECISION MAKING

No grants, scholarships, subsidies, support, consulting contracts, or educational or practice related items should be provided or offered to a healthcare professional in exchange for prescribing products or for a commitment to continue prescribing products. Nothing should be offered
or provided in a manner or on conditions that would interfere with the independence of a healthcare professional’s prescribing practices.

2. **AdvaMed Code of Ethics.** The following quotations are extracted from the AdvaMed code of Ethics.

**II. Member-Sponsored Product Training and Education**

Members have a responsibility to make product education and training available to Health Care Professionals. In fact, the U.S. Food and Drug Administration mandates training and education to facilitate the safe and effective use of certain medical technology. Such programs often occur at centralized locations (necessitating out-of-town travel for some participants), and may extend more than one day. With regard to Member programs focused on the education and training in the safe and effective use of Member products:

- Programs and events should be conducted in clinical, educational, conference, or other settings, including hotel or other commercially available meeting facilities conducive to the effective transmission of knowledge.

- Programs requiring “hands on” training in medical procedures should be held at training facilities, medical institutions, laboratories, or other appropriate facilities. The training staff should have the proper qualifications and expertise to conduct such training.

- Members may provide Health Care Professional attendees with hospitality only in the form of modest meals and receptions in connection with these programs. Any such meals and receptions should be modest in value and subordinate in time and focus to the educational or training purpose of the meeting.

- Members may pay for reasonable travel and modest lodging costs incurred by attending Health Care Professionals.

- It is not appropriate for Members to pay for the meals, hospitality, travel, or other expenses for guests of Health Care Professionals or for any other person who does not have a *bona fide* professional interest in the information being shared at the meeting.
III. Supporting Third Party Educational Conferences

*Bona fide* independent, educational, scientific, or 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; conferences sponsored by accredited continuing medical education providers; and grand rounds. Members may support these conferences in various ways:

*Educational Grants.* Members may provide a grant either directly to the conference sponsor to reduce conference costs, or 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. Members may provide educational 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 Health Care Professionals who are in training.

Such grants should be paid only to organizations with a genuine educational purpose or function, and may be used only to reimburse the legitimate expenses for *bona fide* educational activities. Such grants also should be consistent with relevant guidelines established by professional societies or organizations. The conference sponsor should be responsible for and control the selection of program content, faculty, educational methods, and materials.

*Modest Meals and Hospitality.* Members may provide funding to the conference sponsor to support the conference’s meals and hospitality. Also, Members themselves may provide meals and receptions for all Health Care Professional attendees, but only if it is provided in a manner that is also consistent with the sponsor’s guidelines. Any meals, receptions, and hospitality should be modest in value and should be subordinate in time and focus to the purpose of the conference.
Faculty Expenses. Members may make grants to conference sponsors for reasonable honoraria, travel, lodging, and meals for Health Care Professionals who are bona fide conference faculty members.

Advertisements and Demonstration. Members may purchase advertisements and lease booth space for company displays at conferences.

VIII. Grants and Other Charitable Donations

Members may make donations for a charitable purpose, such as supporting genuine independent medical research for the advancement of medical science or education, indigent care, patient education, public education, or the sponsorship of events where proceeds are intended for charitable purposes. Donations should be made only to charitable organizations or, in rare instances, to individuals engaged in genuine charitable missions for the support of that mission. It is not appropriate for Members to make such donations for the purpose of unlawfully inducing Health Care Professionals to purchase, lease, recommend, use, or arrange for the purchase, lease or prescription of Members’ products. All donations should be appropriately documented. Examples of appropriate charitable grants and related considerations are:

Advancement of Medical Education. Members may make grants to support the genuine medical education of medical students, residents, and fellows participating in fellowship programs, which are charitable or have an academic affiliation or, where consistent with the preamble to this section, other medical personnel. (For additional considerations regarding educational grants, see Section III, Supporting Third Party Educational Conferences.)

Support of Research with Scientific Merit. Members may make research grants to support genuine medical research. The purpose of the grant must be clearly documented. (For guidance as to the limitations that apply when a Member contracts with a Health Care Professional to provide research on behalf of a Member, see Section V, Arrangements with Consultants.)

Public Education. Members may make grants for the purpose of supporting education of patients or the public about important health care topics.