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Old Concepts, New Risks: Trends in Medical Education Support Compliance

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Panel*

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*The views and ideas expressed during the presentation are from each panelist's own perspective and should not be attributed to their employer.

OIG Guidance: Education Grants

- In 2003, OIG's Compliance Program Guidance for Pharmaceutical Manufacturers ("CPG") recognized that:
  - "grants or support for educational activities **sponsored and organized by medical professional organizations** raise little risk of fraud or abuse, provided that": (1) "the grant or support is not restricted or conditioned with respect to content or faculty"; and (2) grant funding is not being used 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" (emphasis added)
- OIG noted that:
  - Manufacturer grants to third-parties could implicate the AKS if the funding "is conditioned, in whole or in part, on the purchase of product … even if the educational or research purpose is legitimate."
  - Manufacturers with "any influence over the substance of an educational program or the presenter" can present "risk that the educational program may be used for inappropriate marketing purposes."

OIG Guidance: Education Grants (cont'd)

- To reduce the risk that a Manufacturer's educational grant "is used improperly to induce or reward product purchases or to market product inappropriately" OIG recommended the following:
  - Grants managed by a medical function (e.g., Medical Affairs) that is "separate … from sales and marketing"
  - Medical functions should establish "objective criteria for making grants"
  - Manufacturers "should have no control over the speaker or content of the educational presentation";
  - "Compliance with such procedures should be documented and regularly monitored"

CME and the Anti-Kickback Statute

- In June 2022, OIG Advisory Opinion 22-14 analyzed a proposed arrangement from an ophthalmology practice (Requestor) to subsidize continuing education (CE) for local optometrists
  - Requestor located in a state where optometrists need 30 CE hours every two years for licensure
  - OIG : “CE programs are a mainstay for physicians and other licensed practitioners to update their technical knowledge and skills and to learn about new or modified diagnostic and treatment options”
- Requestor proposed offering two annual CE programs:
  - 6 CE hours, $6-$9K cost, ~$20 food; Requestor’s own ophthalmologist, optometrists serve as faculty
  - 2 CE hours, $500-$1,500 cost, $15-20 food; faculty assumed to be Requestor’s own employees
  - Programs (1) only offered to local optometrists w/in 20 miles of Requestor, but open to all optometrists in area, and (2) not limited to optometrists who refer to Requestor or who prescribe Manufacturer products
- Faculty would be paid honorarium, expenses at fair market value
- Four (4) proposed arrangements (varied based on registration fee charged, manufacturer support)
  - OIG approved only one; others OIG reasoned were not low risk of fraud and abuse

OIG Analysis: 22-14 (cont'd)

- "CE programs that are educational in nature, … may constitute **a vehicle to provide remuneration to referral sources** in violation of the Federal anti-kickback statute in **some circumstances**" (emphasis added)
- Usually CE program "organizers … **are independent entities not directly involved in the provision of patient care** (e.g., a professional organization)" (emphasis added)
- The Requestor is a "**direct referral source for sponsoring medical device and pharmaceutical companies**" and by providing grants to the Requestor, the Manufacturers would "**pay expenses the Requestor otherwise would incur**," including any excess funds the Requestor may use to donate to a local charity (emphasis added)

Compliance Considerations

- How should manufacturers address grants with facts similar as 22-14?
- Can manufacturers provide grants to CE providers owned or controlled by direct referral sources (e.g., HCPs)?
  - What type of customer (e.g., HCP office, GPO, pharmacy, hospital)?
  - What if the CE provider is only part-owned by HCPs?
  - What kind of diligence should a manufacturer perform to assess these risks?
  - Conflict of interest (COI) controls?
  - Can an HCP owners of the CE provider serve as a speaker/faculty?
- Can manufacturers provide grants to a CE provider working with a non-accredited provider that is HCP-owned?
- Can CE programs be targeted to small geographic territories?
- What are some risk factors to consider when assessing grant requests?

FDA 1997 Guidance: Independence Factors

- In determining whether an activity is "independent of the substantive influence of a company," FDA examines "whether and to what extent a manufacturer is in a position to influence the presentation of information related to its products or otherwise transform an ostensibly independent program into a promotional vehicle"
- FDA Guidance outlines 12 "independence" factors, including:
  - Manufacturer's control, influence of content, presenters, moderators
  - Disclosure to audience of conflicts, funding
  - Overall relationship between manufacturer and education provider (both Medical and Commercial work)
  - Involvement, influence of sales/marketing teams
  - Nature of program (e.g., opportunity for discussion; co-existing promotional activities)

Old Concepts, New Risks

- Can a manufacturer support a CE program:
  - For rare or orphan diseases?
  - When the manufacturer is the only company with an FDA-approved treatment?
  - When the manufacturer is studying a new indication of an FDA-approved product?
  - **Note:** What about a non-accredited program based on these factors?
- Can Medical Affairs engage in external meetings (e.g., symposia) that are not accredited?
  - If it's disease state or scientific only? Can treatments be discussed (on or off-label)?
  - Moderator? Author? Faculty?
  - Provide a grant? Or is it a sponsorship? What if the manufacturer is the sole sponsor?
- Any additional considerations for medical device companies?
- How can CE providers engage with learners via social media? What are the risks?
- What are some of the risks associated with global medical education?