

# The Compliance Environment and Grant Process: Oversight and Response in the Pharmaceutical Industry



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## Healthcare provider - pharmaceutical industry interactions are under intense scrutiny and comment

- Office of Inspector General (OIG)
- State Attorneys General
- PhRMA
- Congress
- Others (e.g., AMA, ACCME)

# OIG Final Guidance (2003)

In April 2003, OIG issued a “Compliance Program Guidance for Pharmaceutical Manufacturers.”

- Reflected intention of federal government to examine industry practice
- Addressed both patently illegal practices as well as “gray areas” of physician-industry interaction including consultancies, gifts and grants
- Grants and other payments made to healthcare providers not covered by a recognized safe harbor carried “significant potential for abuse” under the anti-kickback and related fraud and abuse statutes

## OIG Final Guidance (cont'd.)

- Research and educational services must reflect bona fide activities of scientific and medical substance, not thinly-veiled marketing activities
- Safe harbor concepts (e.g., written agreements outlining services to be rendered, payments reflecting “fair market value”) to be utilized

# OIG Final Guidance (cont'd.)

- Regarding grants and to reduce, if not eliminate, the risk that such payments are inducing or rewarding prescribing activity
  - urged separation of grant-making function from marketing and sales
  - suggested that CME programs sponsored and organized by independent and recognized medical associations raise “little risk of fraud and abuse, provided that the grant or support is not restricted or conditional with respect to content or faculty”

# PhRMA Code on Interactions with Healthcare Professionals (“PhRMA Code”)

- Originally created in 2002 as a voluntary marketing code by the Pharmaceutical Research and Manufacturers of America
- Code was effectively designated a minimum standard for industry relationships with healthcare professionals (“HCPs”) under the OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 2003 (<http://www.oig.hhs.gov/authorities/docs/03/050503FRC PGPharmac.pdf>)
- Compliance with the Code is now mandatory under the laws of two states (and is the basis for Massachusetts and DC’s codes)

# PhRMA Code (cont'd.)

- Original Code (2002) represented a significant shift in marketing practices
- New Code is carefully constructed as targeted guidance in response to specific criticisms
- New Code is effective January 2009



# PhRMA Code (cont'd.)

## Implementing the New Code: § 4, Support for CME

- 2002 Code: Permits financial support to underwrite costs of CME, third party educational conferences and professional meetings, provided that sponsors control selection of content, faculty, methods, materials and venue
  - Section 3(c) states: a company may provide meals or receptions directly at such events
- 2009 Code: Company should not provide meals or receptions directly at CME events, though a CME provider may use company support to provide meals for all participants at a CME event

# PhRMA Code (cont'd.)

## New Code provisions:

- Support for CME is intended to educate on a full range of treatment options, not to promote a particular medicine
- Should separate CME grant function from sales and marketing
- Should follow ACCME or other accrediting entity standards
- Should not provide advice to a CME provider regarding content or speakers, *even if asked by the provider*

# PhRMA Code (cont'd.)

## Implementing the New Code: § 13, Independence and Decision Making

- Unchanged from Current Code
- No grants, scholarships, subsidies, support, consulting contracts or educational or practice related items should be offered to an HCP in exchange for 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

# PhRMA Code (cont'd.)

## The Code and State Law Regulation

- When are companies required to comply with the revised PhRMA Code, effective “January 2009”?
  - Nevada statute: “Adoption of the most recent version of the Code ... satisfies the requirements....”
  - California statute: “A pharmaceutical company shall make conforming changes to its Comprehensive Compliance Program within six months of any update or revisions to the...Code....”
  - DC Safe RX: “Detailers are required to comply with the PhRMA Code, as amended or republished....”

# PhRMA Code (cont'd.)

## The New Massachusetts Law: Mass. Gen. Laws Ch. 111N, § 1-7

- DPH must promulgate a standard marketing code of conduct for pharmaceutical or medical device manufacturers to be no less restrictive than “the most recent update” of the PhRMA Code
- Requirements are similar to PhRMA Code requirements
- The future marketing code will specifically allow for the following activities:
  - Distribution of scientific peer reviewed journals and advertising therein
  - Samples provided for patient use
  - Fee for service compensation for in connection with a genuine research project or clinical trial
  - Payment for technical training on use of a medical device if the expense is part of the vendor’s purchase contract for the device
- The law requires reporting any “economic benefit” greater than \$50

# PhRMA Code (cont'd.)

## DC Safe RX: DC Law 17-131, 55 DC Reg. 9317

- In addition to DC reporting law
- Final rules issued October 1, 2008
  - Clarification promised in an FAQ to come
- “Pharmaceutical Detailing” is:
  - The practice by a representative of a pharmaceutical manufacturer or labeler of communicating in person with a licensed health professional, or an employee or representative of a licensed health professional, located in the District of Columbia, for the purpose of selling, providing information about, or in any way promoting a pharmaceutical product
- Detailers must be licensed effective April 1, 2009
- Detailers must comply with the DC Code of Ethics, which includes the PhRMA Code and other requirements

# American Medical Association (“AMA”) and Accreditation Counsel for Continuing Medical Education (“ACCME”)

Reflecting criticism of inappropriate industry influence, the AMA and ACCME have debated the industry relationship and influence on medical education

- AMA
  - Internal debate ongoing
  - AMA CEJA report (“Industry Support for Professional Education in Medicine”) scheduled for release at 2009 Annual Meeting in June
  - Preliminary intelligence indicates CEJA does not support eliminating commercial support
  - Opponents include medical schools, associations, hospitals and state medical societies
  - AMA CEJA and CME committees will solicit comments

# The ACCME Standards for Commercial Support

## Standard 1: Independence

- 1.1 A CME provider must ensure that the following decisions were made free of the control of a commercial interest. (See [www.accme.org](http://www.accme.org) for a definition of a “commercial interest” and some exemptions.)
  - (a) Identification of CME needs;
  - (b) Determination of educational objectives;
  - (c) Selection and presentation of content;
  - (d) Selection of all persons and organizations that will be in a position to control the content of the CME;
  - (e) Selection of educational methods;
  - (f) Evaluation of the activity.
- 1.2 A commercial interest cannot take the role of non-accredited partner in a joint sponsorship relationship.



# The ACCME Standards for Commercial Support (cont'd.)

ACCME considering further restrictions regarding “commercial support”:

- Should those who write promotional materials be excluded from having any role in writing CME content?
- Should those who teach in promotional activities\* be excluded from teaching in independent CME activities?
- Comment period closed 9/12/2008

\* Company sponsored speaker's bureaus

# Where are we now and where are we heading?

- “Transparency” is the new mantra
  - OIG
  - Congress (“Sunshine Act”)
- Pressure from within industry will impact compliance in the grant process
  - CIAs/federal and state settlements (Lilly, Merck)
  - PhRMA Code (e.g., compensation cap)
- Focus on Off-Label Promotion
  - Impact on research grants, Investigator Initiated Trials, CME funding

# Contract Information

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# Questions?