



**Legal Issues and Best Practices
in Nonprofit Governance**

**2009 Annual Meeting
Toronto, Canada
August 17, 2009**

All contents copyright 2009, American Society of Association Executives and The Center for Association Leadership, except noted selections which have been reprinted with permission of the copyright owner.

Connecting Great Ideas and Great People



**Ronald A. Henrichs, CAE
AAD Executive Director/CEO**

**Pamela Kaul
President, Association Strategies**

**Robert M. Portman, JD, MPP
Powers Pyles Sutter & Verville PC**

All contents copyright 2009, American Society of Association Executives and The Center for Association Leadership, except noted selections which have been reprinted with permission of the copyright owner.

Connecting Great Ideas and Great People

What We'll Cover Today

- Introduction
- Legal Background
- Discussion
 - Conflict of Interest
 - Transparency
 - Industry Relationships



Legal Background

- Common law fiduciary obligations re conflict of interest
- IRS Form 990 and other requirements re conflict of interest and transparency
- Legal developments re nonprofit-industry relationship (with focus on health care)



Fiduciary Obligations

- Duty of Care
- Duty of Loyalty
- Duty of Obedience




Fiduciary Obligations

- Duty of loyalty includes duty to avoid conflicts of interest that would bias an individual's ability to act in the best interest of the organization




Fiduciary Obligations

- Types of Conflicts
 - Financial
 - Business
 - Professional
 - Personal
- Conflicts may be actual, potential, apparent, or perceived conflicts--key is to avoid appearance of impropriety




Fiduciary Obligation

- Options for resolving conflicts:
 - Disclosure (minor conflicts)
 - Recusal (serious conflicts)
 - Resignation (serious, visible continuing, pervasive conflicts)
- Organization, not individual, makes final call on conflicts through fair procedures.
- When in doubt—avoid conflict
- Must have/enforce COI policy




Tax Issues: Good Governance

- IRS view of good governance practices
 - Within IRS purview to monitor governance practices of tax-exempt entities
 - Tool for ensuring compliance with IRC requirements for tax exempts
 - Clear statement of tax-exempt purpose
 - Engaged, informed, independent board
 - Proper use and safeguarding of assets
 - Transparency—record retention, whistleblower protection, accurate publicly available 990s
 - One size does not fit all; but need controls to ensure compliance




Tax Issues: New Form 990

- Redesigned form issued on Dec. 20, 2007
- First major redesign in 30 years
- New form used for 2008 tax year (filed in 2009)




Tax Issues: New Form 990

- **Governance Section**
 - 3 sections (Governing Body, Policies, Disclosures)
 - Not all questions required by IRC
 - Are decisions of governing body subject to approval by members?
 - Was a copy of the organization's Form 990 provided to its governing body before the form was filed? Describe process in Schedule O.
 - Written conflict of interest policy?
 - Whistleblower policy?
 - Document retention/destruction policy?
 - Compensation process? Plus more disclosure
 - How are foregoing policies made available to public?



Tax Issues: New Form 990

- **Governance Section**
 - **What if you answered "no" to one of the governance policy questions?**
 - IRS:
 - "The IRS will use the information reported in Part VI, along with other information reported on the form, to assess noncompliance and the risk of noncompliance with federal tax law for individual organizations and across the broader exempt sector."
 - In other words, proceed at your peril!



Tax Issues: Disclosure

- Required to make following documents with schedules and supporting documents available for public inspection upon request:
 - Form 1023 (tax exemption application)
 - IRS Determination Letter
 - Form 990 for three years (except Schedule B)
- May place reasonable restrictions on time, place, and manner of inspection
- May charge reasonable fees



Tax Issues: UBIT

- What is it?
 - Income from trade or business that is regularly carried on by exempt organization and that is not substantially related to tax exempt purpose
 - Advertising is classic example
- Exceptions
 - Royalties from affinity agreements/IP licenses
 - Make sure you split payment for services from royalties for use of name and logo
 - Mailing list rental
 - Dividends, interest, investment income
 - Rents from real property
 - Qualified Sponsorship Payments (except for return benefits)
 - Trade Show Exhibit Fees




Industry Relationships

- General
- Health Care



Industry Relationships

- General
 - Must disclose total grants on Form 990
 - Report value of return benefits as UBIT
 - Antitrust issues/policies
 - Membership
 - Exhibitor policies
 - Ethics codes
 - Standard setting



asae & the center
for association leadership

Industry Relationships


- Health Care Issue:
 - Conflicts of Interest between Physicians and Pharmaceutical and Device Manufacturers
 - Conflicts for Health Care Associations/Charities



asae & the center
for association leadership

Industry Relationships

- Health Care Issue:
 - Conflicts of Interest between Physicians and Pharmaceutical and Device Manufacturers
 - Physicians need to be educated by manufacturers on current pharmaceutical and device innovations and vice versa
 - Development of manufacturer-physician relationships leads to questionable activities:
 - lavish trips to posh resorts for "academic conferences"
 - other forms of entertainment/gifts
 - questionable consulting/research arrangements
 - payments for "switching" patients
 - improper sale of free drug samples



asae & the center
for association leadership


Industry Relationships

- Health Care
 - Conflicts of Interest between Medical Societies and Pharmaceutical and Device Manufacturers
 - Societies depend on industry support to help fund educational programs (CME and public education)
 - Industry support and physician-industry relationships threaten objectivity of CME and overall credibility
 - Disease-related and other health care charities face similar issues




OIG Compliance

- OIG Compliance Guidance for Pharmaceutical Manufacturers
 - Identifies industry-physician relationships that raise risk of anti-kickback or false claims violations
 - OIG will look at following factors:
 - nature of relationship
 - manner in which payment is determined
 - value of remuneration
 - impact on federal program costs/utilization
 - potential conflicts of interest




OIG Compliance

- OIG Compliance Guidance for Pharmaceutical Manufacturers
 - Re compliance with PhRMA Code:
 - Not given safe harbor status—but close
 - “provides useful and practical advice for reviewing and structuring these relationships.”
 - “will substantially reduce the risk of fraud and abuse and help demonstrate a good faith effort to comply with the applicable federal health care program requirements.”




PhRMA Code Updated 2009

- PhRMA published a revised code effective January 2009
- Major changes include prohibition on distribution of non-educational items to health care professionals
- Requires disclosure for providers on formulary boards
- Only in-office meals allowed




PhRMA Code

- PhRMA Code
 - Founded on the principle that information needs to flow in both directions between pharmaceutical companies and physicians
 - Goal is to preserve independent medical decision-making
 - Prohibits provision of subsidies, scholarships or any other support to a health care professional "in exchange for prescribing or continuing to prescribe products."



PhRMA Code

- Meals
 - Originally, meals permitted in connection with informational presentations; now only in connection with in-office meetings
- Third Party Educational or Professional Meetings
 - Must be legitimate, reasonable compensation, speakers must disclose that he/she is presenting on behalf of the company
 - Contributions go to the sponsor, not individuals, may use funds to subsidize fees or meals
- Consultants/Speaker Training Meetings
 - Must be legitimate, reasonable compensation and disclosure



AdvaMed Code Revisions

- AdvaMed revised code effective July 2009
- No entertainment for health care providers
- Website to list companies adopting the Code and require annual certifications of compliance
- Requires bona fide consulting arrangement for provision of royalties
- Encourage voluntary and ethical relationships



ACCME Standards for Commercial Support

- Provider of CME must exercise complete control over content of CME – commercial support cannot have any role in selection of content, objectives and presenters at a CME
- Individuals in positions of control over content must disclose relevant financial interests associated with commercial support from the past 12 months
- Provider cannot use commercial support for expenditures related to travel, lodging or personal expenses for a non-faculty participant but may use funds for bona fide employees or volunteers
- Specific product promotion material is prohibited in or during CME and promotional activities must be separate




FDA Off Label Use

- What is an "Off-Label Use"?
 - Use of an FDA approved drug or device legally marketed for other uses that goes beyond use(s) approved by agency
- Practice of Medicine Exception
 - Health care practitioners are permitted by professional license to put an approved drug or device to another use that they may feel is appropriate in diagnosing or treating a patient
- FDA regulation of physicians/medical societies via "aiding and abetting" theory




CME and Off-Label Promotion

- FDA Guidance
 - Permits industry to sponsor CME that includes discussion of off-label uses if independent and nonpromotional—i.e., no industry role in/influence over content, speakers, agenda, etc.
 - Societies/physicians at risk if they act as agent of industry in promotion of off-label uses
- ACCME Standards
 - No disclosure required prior to discussion of off-label use




Civil Litigation

- Don't forget Pedicle Screw litigation!!!



Physician Payments Sunshine Act of 2009, S. 301

- Introduced by Senators Grassley, Kohl and Klobuchar
 - Requires pharmaceutical and drug device manufacturers to submit transparency reports detailing gifts, compensation, entertainment, traveling fees and ownership or investment interests provided to physicians or physician groups. Excludes from the reporting requirements the provision of educational materials
 - Information will be accessible to the public via an online database
 - Would preempt state reporting requirements



State Sunshine Acts

- Massachusetts recently enacted legislation requiring pharmaceutical and medical device companies to disclose financial benefits and gifts to health care providers; plus other restrictions that go beyond PhRMA/AdvaMed Codes.
- Seven other states also have disclosure requirements



Discussion

- Conflict of Interest
- Transparency
- Industry Relationships



Discussion

- Conflict of Interest
 - AAD Case Study
 - Detailed COI policies
 - Online reporting for board and committee members, JAAD, CME speakers
 - Peer review program for CME speakers
 - Example: BOD discussion of new physician certification program




Discussion

- Conflict of Interest
 - Other Issues
 - Hiring CEO from board members
 - Industry sponsors/vendors serving board members




Discussion

- Transparency
 - AAD Practices
 - Form 990 and IRS determination letter available upon request
 - Disclosure of industry relationships?
 - Board review and approval of Form 990 and state returns



Discussion

- Transparency
 - Other Issues
 - CEO and executive staff compensation
 - Board review of contracts???
 - CEO performance appraisal
 - Board assessment
 - Using Form 990 to your strategic advantage



Discussion


- Industry Relationships
 - JAMA Article
 - AAD Practices
 - Written corporate sponsorship policy approved by BOD in advance
 - Written IRS compliant
 - Executive Committee sign off required on specific agreements and joint ventures



asae & the center
for association leadership

Discussion


- Industry Relationships
 - Effect of restrictive Federal/State laws on
 - Association relationships with industry
 - Decisions about where to hold meetings



asae & the center
for association leadership

Speaker Information

Ron Henrichs, CAE
Executive Director & CEO
American Academy of Dermatology
Phone: (847) 240-1028
E-mail: rhenrichs@aad.org
Websites: www.aad.org



asae & the center
for association leadership

Speaker Information

Pamela Kaul
President
Association Strategies, Inc.
Phone: (703) 683-0580
E-mail: pamela@assnstrategies.com
Website: www.assnstrategies.com



Speaker Information

Robert M. Portman, JD, MPP
Principal
Powers Pyles Sutter, & Verville PC
Phone: (202) 872-6756
E-mail: rob.portman@ppsv.com
Websites: www.ppsv.com