

Session P 12 Hot Topics in the Medical Device Industry Sunday, April 26, 2009

Presenters

Tama Donaldson, Jackie Huber, Tom Schumacher and Andrew Van Haute

Agenda

Time	Session	Presenter
2:00-2:05	Introduction of Panel Program Overview and Agenda ■ Hand out / collect note cards with "what do you most hope to learn in this session" and "what is your concern in the medical device compliance world"?	Tom
2:05-2:50	Advanced Code of Ethics and Q&A (certification process) Topics to consider: ■ General Overview on Review/Process ■ Deep Dive on Sections ■ Highlight Changes ■ Major points from Q&A ■ Certification and Logo Process ■ Questions Question: What can the compliance community do to better inform the physicians and the provider community about these changes?	Andy / Tom (certification)
2:50-3:05	Pharma/Advanced Codes ■ Overview of New Pharma Code ■ Compare/Contrast with Advamed ■ Implementation/Training ■ How to Handle Differences/Combined Roles ■ Questions Question: How do you separate "hats" for employees that sell/market products in both areas or "combo" product?	Tama

Agenda (continued)

Time	Session	Presenter
3:05-3:30	CIADPA ■ Overview of the Standard Elements ■ Discussion Implementation ■ Challenges/Tips for the Responsible Compliance Officer ■ Questions Question: Does the CIA represent the most effective compliance program model organizations should voluntarily adopt, and if not, what elements should be changed?	Jackie
3:30-3:45	Break	
3:45-4:30	Federal/State Legal Update 1. Federal Physician Payment/Sunshine Act ■ Questions 2. Massachusetts Regulations ■ Questions 3. Other States ■ Questions Question: What should we do now to get "ready"?	Andy Andy/Tom/Jackie/ Tama Andy
4:30-4:45	Institutional Policies Sample of Policies Major Themes ■ Conflict of Interest Focus ■ Transparency ■ Access Limitations ■ Gift/Meal Bars ■ Questions	Tom (Overview) All (Discussion)
4:45-5:00	Open/Wrap Up	

Federal Legislation

- **Name:** Physician Payment Sunshine Act
- **What:** Tracking and reporting of payments and "transfers of value" between "manufacturer" of covered drug/device/ biologic or med. supply & physicians & physician practice/groups
 - Additional reporting for physician ownership interest in Mfr, or GPO
- **When:** Current Draft: tracking Jan. 1, 2010; first report due March 31, 2011.
- **How:** Industry to track info in specified fields
 - E.g. name, value, date, form, purpose —one of 15 fields
 - Annually aggregated payments in each category
 - Submit in annual "data dump" to HHS
 - HHS creates a publically searchable database
- **Penalties:** Fines for Mfr. Non-compliance

State Law: Massachusetts

- **Name:** The Pharmaceutical and Medical Device Mfr. Code of Conduct
- **What:**
 - Required: codes of conduct, training, policies, and submissions;
 - Bans on certain activities;
 - Restaurant meals. Meals for spouses or "guests"
 - Gifts
 - So-called "logo items" (pens, mugs, etc.)
 - Regulations on education/consulting
 - Requirement to meet "bone fide" consulting
 - Limits on CME support
 - Tracking and reporting of certain payments and "transfers of value" between pharma/med device mfr and "covered recipients"
- **When:** Effective July 1, 2009, first report due July 1, 2010.
- **How:** (reporting) Industry to track payments >\$50, report on "standardized reporting formate developed by the dept"
- **Penalties:** Fines for Mfr. Non-compliance

Institutional Trends

- **Restrictions**
 - Bans on gifts/ branded items, entertainment, meals
 - Broad definition of "gifts" (e.g. travel funding, meals, etc.)
 - Follows 2008 AAAMC recommendations
 - Access, esp. to clinical areas
 - E.g. by invitation, "check in", credentialed, etc.
- **Disclosures**
 - Consulting payments, others (part of COI policies)
- **Limits on educational support**
 - Particularly for education for fellows/residents
 - E.g. Unrestricted educational grants to dept/college
 - E.g., CME to a central office
- **Process issues**
 - Stakeholder input—has impact on patient care/physican practice been considered; has impact on education been considered (e.g. inservice value)
 - Education: Impacts on peer-to-peer education
 - Impacts on Technical education for highly complex/dynamic devices particularly fellows education
 - Access—Clinical value of device technical/clinical support

Examples

- http://www.partners.org/documents/CommissionPressRelease_PartnersHealthCare2009.pdf
- <http://www.hopkinsmedicine.org/Research/OPC/JHIndustryinteractionpolicyFINAL.pdf>
- <http://my.clevelandclinic.org/Documents/About/COI.pdf>
- http://www.cumc.columbia.edu/dept/ps/facultycouncil/docs/New_COI_Policy.pdf
- <http://somapps.med.upenn.edu/fapd/documents/ext00065.pdf>
- <http://www.coi.pitt.edu/IndustryRelationships/policy.htm>
- <http://www.ucop.edu/ucophome/coordrev/policy/PP031208Policy.pdf>
- http://www.vanderbilt.edu/compliance/html/conflict_of_interest_policy.pdf
- <http://med.stanford.edu/coi/siip/>
- http://www.mssm.edu/coi_policy/
