

# **Government, Industry and Health Profession Compliance Guidance: Welcome to the Era of Ethics and Transparency**

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# The Perfect Storm for Reform

- Industry, Hospitals and Physicians Under DOJ Scrutiny for Financial Arrangements
- Congressional interest
- Consumer/Patient interest
- Public Health agency interest
- Media interest: NYT, WSJ, NEMJ
- Medical Professional interest
- Transparency Initiatives
- International Anti-Corruption Initiatives



# Discussion Agenda

- Government Guidance: OIG CIAs and DOJ DPAs. Policy by Enforcement.
- Industry Codes of Ethics and Transparency Efforts.
- Medical Society Codes of Ethics and Disclosure Initiatives.
- Government Mandated Transparency.
- Hospital Conflicts and Access Policies.

# U.S. Sentencing Guidelines

- Chapt. 8 Organizational Guidelines. Alive and Well As Force in Compliance.  
[WWW.USSC.GOV/ORGUIDE](http://WWW.USSC.GOV/ORGUIDE)
- Recent USSG Updates to Corporate Compliance Guidance.
- Emphasis on industry standards and misconduct, not just illegality, to assess effective corporate compliance.

# U.S.S.G. 2010 Updates

- Board Reporting Relationship with Compliance Officer.
- Compliance Officer and Program non-involvement in criminal or wrongful activity.
- Corporate actions following the detection of criminal conduct.
- Corporate obligations to Court in criminal sentencing.

# Corporate Compliance and Firewalls

- “Firewall” is an important and developing concept. Separation of business functions that may be in conflict and create legal risk.
- Biggest contribution to bad evidence-sales division emails.
- Separate sales initiatives from Education, Research and Clinical Initiatives.
- Firewall concept is necessary in compliance too. Recent DOJ criminal and civil prosecutions of compliance officers underscore structural lack of independence and integrity.
- U.S. v. Caputo and U.S. v. Sulzbach.
- U.S.S.G. April 2010 amendments to organizational guidelines.

# Government Guidance

- **OIG Compliance Program Guidance (CPG) for Pharmaceutical Manufacturers.**
- **Other OIG Guidance: OIG Workplan; Advisory Opinions; Fraud Alerts & Bulletins.**
- **Enforcement Lessons: DPAs; Settlements; and CIAs.**

# Industry and Professional Codes

- AMA Code of Medical Ethics Opinion 8.061 (1990) – Gifts to Physicians from Industry.
- PhRMA Code – 2002; revised 2008.
- AdvaMed Code – 2003, revised 2008.
- AAOS-2007 Standards of Professionalism and 2010 Disclosure Program.
- Council of Medical Societies-2010 Code for Interactions with Companies.
- Hospital Conflicts of Interest Policies: Pittsburgh, Cleveland Clinic, Mass Memorial, Sloane-Kettering.



# OIG CPG

- Pharma CPG “Areas of Concern.”
  - Integrity of pricing data (AWP, AMP, Medicaid Best Price).
  - Kickbacks to customers (hospitals), prescribers (physicians), middlemen (GPOs, PBMs); sales force commissions.
  - PDMA Samples.
- Not exhaustive, e.g., no mention of off-label.

# Risk Areas

## ■ Pricing issues

- Mainly pharmaceutical (AWP, AMP, Medicaid Best Price).
- Discount issues.
- Payments to GPOs, PBMs.

## ■ Physician Relationships

- Consulting & product development.
- Gifts.
- Sampling.
- Education.

## ■ Other promotion and marketing

- Sales force issues.
- CME.

# **INTEGRITY OF PRICING DATA**

# Integrity of Pricing Data

- The government always feels it is overpaying.
- The government always suspects companies are disguising/not reporting discounts.
  - AWP cases (repackaging, grants).
  - Marketing the spread.
  - Nominal pricing.
  - Arrangements with PBMs.
  - Not as big an issue for device manufacturers, since no AWP/Medicaid rebate exposure.
- Government guidance on discounts and AKS is confusing (volume discounts; market share discounts; bundled products; free goods).
- Revised AdvaMed Code provides very specific policies on reimbursement support and related activities.

# OIG Formulary/PBM Issues

- Any remuneration from a manufacturer directly or indirectly to a person in a position to influence formulary decisions related to the manufacturer's products is suspect and should be scrutinized.
  - *Revised PhRMA code requires that formulary committee members used as speakers disclose relationship to formulary committee extending 2 years after termination.*
- Manufacturers are should review their contacts with sponsors of formularies to ensure that price negotiations do not influence decisions on clinical safety or efficacy.
- Any rebates or other payments made by a manufacturer to a PBM based on the PBM customers' purchase has the potential to implicate the anti-kickback statute.

# CPG PBM Solution

- The GPO safe harbor, 42 C.F.R. § 1001.952(j), and the managed care safe harbor, 42 C.F.R. § 1001.952(m), (t) and (u).
- Avoid the provision of funding for purchasers or PBMs support activities (particularly those with physicians and patients) where the manufacturer's dollar replaces the dollar of the sponsor.
- Relevant questions are:
  - Is the funding tied to specific drugs?
  - If so, are the categories especially competitive?
  - Is the formulary sponsor funding similar activities for other drug categories?
  - Has funding of PBM activities increased as rebates are passed back to PBM customers?

# SAMPLING

# Drug Sampling

- OIG CPG – drug sampling must comply with PDMA.
- PhRMA Code – same.
- AdvaMed – yes, including demos.
- Hospital and AMC Policies increasingly restrict sampling.
- Transparency laws may impact sample reporting.
- DOJ Conference Room Discussions.



# Demonstration Products

- Revised AdvaMed Code adds new section on the provision of evaluation and demonstration products.
  - Evaluation products are for use on patients.
  - Demonstration products are mock ups or single use products for MD or patient education, awareness or training.
- Evaluation products must be reasonable in number or length of loan for evaluation purposes.

# **PAYMENTS FOR PHYSICIAN SERVICES**

# Payments to Physicians

- Physicians are the gatekeepers and decision makers for the health care industry and the Medicare trust fund.
- Any payments or gratuities by entities in position to benefit from physician decision making are suspect.
- Primary focus of CPG, the industry codes, professional codes, and recent enforcement activity.
- The underlying issue is the potential conflict of interest created by these financial arrangements.

# The OIG Approach – Anti-Kickback Statute

- Identify remunerative arrangements with persons who refer, purchase, prescribe, or otherwise influence such decisions.
- Assume one purpose to induce referral or purchase.
- Evaluate the risk.
  - Potential to skew clinical decisions.
  - Potential to increase federal program costs.
  - Potential to increase utilization.
  - Potential to affect patient safety or quality of care.

# The OIG Solution

- Try to fit in the personal services safe harbor.
  - In writing.
  - Identified services.
  - Fixed fair market value payment.
- Absolutely no quid pro quo or tying.

# The PhRMA Code Approach

- Manufacturers may offer and pay reasonable compensation to consultants (not defined—but, assumed to include medical professionals) who provide services to manufacturers.
- Token consulting arrangements or advisory arrangements used to compensate healthcare professionals for their time or travel, lodging or other out-of-pocket expenses.

# The AdvaMed Approach

- Original Code focused on bona fide personal service agreement. Revised Code more detailed.
  - In writing & detail the services. For research, a written protocol.
  - Need for services documented in advance.
  - Consultant selection based on needed expertise & not controlled or unduly influenced by sales staff.
  - Compensation is FMV and not reflect the value or volume of business.
  - May reimburse for documented and reasonable expenses.
  - Meetings should be in setting appropriate to subject matter.
  - Can provide modest meals and refreshment but no entertainment or recreation.
  - Special provisions on royalties.

# AAOS Standards of Professionalism

- Industry and Surgeon Collaborations must be lawful and consistent with medical ethics.
- Disclosure of compensated relationships.
- Fair market value and commercial reasonableness.
- Enforcement standards.



# The DOJ “The Hammer” Approach

- DOJ September 2007 Deferred Prosecution Agreement and Settlement.
- Newark, NJ U.S. Attorney’s Office settles with five (5) orthopedic device manufacturers: Biomet, DePuy, Smith & Nephew, Stryker and Zimmer.
- Monitor approach.
- Micro-suspension of business operations.



# DPA - The Needs Assessment

- Establish a budget for the total payments intended to be made to physicians for which no Consulting Services are provided (e.g., honoraria, fellowships, gifts, charitable contributions);
- Establish detailed protocols or procedures for authorizing any Consulting Agreement;
- Quantify the services needed within each discrete service category (e.g., operating room training, speaking engagements), and provide written support for the needs;
- Detail the nature of the needed services, the range of hours or other quantitative measure needed to complete the services, the number of Consultants needed, and the maximum fair market value compensation to be paid for each consulting service;
- Identify the qualifications and expertise required to perform the services;

# DPA - Product Development

- The Company shall pay a Consultant (no more than the Hourly Rate) on a product development team for the actual time spent providing Services.
- Royalty Payments
  - In addition to Hourly Rate payments, the Company may pay each product development team member royalties on any product the team may develop.
  - Aggregate royalties paid per project to all Consultants must not exceed fair market value expressed as a certain percentage of all domestic and international product sales of the product or products that are the subject of the product development agreement.
  - Royalty payments and Hourly Rate payments shall be the only compensation a Consultant may receive for participation on a product design team; that is, the Company shall not make any flat rate payments or minimum guaranteed payments in lieu of or in addition to Hourly Rate payments and royalty payments.
  - Company may pay royalties to a Consultant only for Intellectual Property received by the Company for products that have actually been sold.

# DPA - Disclosure Requirements

- Consulting Agreements must require Consultants to disclose their financial engagement with the Company to their patients, as well as affiliated hospitals.
- If the Company has or does enter into a Consulting Agreement with an entity rather than an individual, the Company must post both the name of the entity and the individual providing Services.
- Payment information shall be updated to reflect the total Payments made to each Consultant within \$25,000 increments, and all other Payments made in other than dollar form.
- The Company must also disclose this information to the Consultant's affiliated hospitals.

# FELLOWSHIPS & GRANTS

# Research Grants

- AdvaMed Code (revised).
  - Clinical research should have written contracts and protocols.
  - Not awarded based on past or anticipated referrals.
  - Objective standards for reviewing and awarding grants.
  - Independent of sales force.
  - No unrestricted grants.

# DPA - Fellowships

- The Company may not fund any fellowships for fellows who work with any Consultant, with the exception of fellowship funding to legitimate medical education foundations or institutions so long as that funding is approved in advance by the Compliance Office and the Monitor.



# Pharma CIA Requirements – Grants & Research

- Funding of charitable grants or sponsorships complies with AKS and FDA requirements.
- Sponsorship or funding of research activities, including clinical trials, market research, or authorship of articles or other publications, by company, complies with AKS and FDA requirements.



# PHYSICIAN EDUCATION & TRAINING

# The PhRMA Code

- No payments to attendees unless for legitimate consulting or speaking services.
- Content must be educational or scientific.
- Modest meals can be provided for off-site company speaker program.
- No entertainment.
- No spouses.
- *Field sales staff can only provide meals to health care professionals and staff in the office or hospital and in connection with informational presentation or discussion.*

# The AdvaMed Code

- Revised Code delineates education from training.
  - Training is instruction on the safe and effective use of medical device.
  - Education is communications related to a particular device, such as intended use for specific ailments.
- Companies can pay for attendees travel and lodging for hands on training if an “objective reason” such as limited sites w/ equipment.
- Companies can provide modest meals and refreshments with training.
- No entertainment & no spouses.

# AMA Ethics Opinion 8.061

## Educational Meetings

- Meetings or conferences should be at appropriate location and primarily educational.
- Subsidies to conference sponsor ok to reduce registration fees.
- No payments for travel, lodging, expenses or lost opportunity of attending physicians.
- Ok for faculty honoraria and expenses.
- Scholarships for students, residents, fellows ok but selection by institution.

# THIRD PARTY CME

# Support For 3d Party CME

	PhRMA	AdvaMed
Payments to support programs	Permitted only to sponsors to defray costs of registration	Permitted if independent educational or scientific
Control of Content, Presenters	No	No
Payments to faculty	?	Yes, including travel, lodging, honoraria, meals, <i>but not if Company does business with the MD</i>
Payments to non-faculty	No , except students, residents	No, except students, fellows,
Meals	<i>No, but CME sponsor can with company \$\$</i>	Yes – modest meals and refreshments, subject to standards of CME sponsor

# Revised AdvaMed Code

- *New FAQ clarifies that it is appropriate for companies to sponsor a meeting for sales, promotional, or other business purpose that is scheduled at approximately the same time as a conference.*
- *Conducted at a separate location.*

# Revised PhRMA Code

- *Companies should separate CME grant-making from sales and marketing departments.*
- *Companies should develop objective criteria for making CME grant decisions.*
- *Companies should not provide any advice or guidance to sponsor regarding faculty or content of particular program.*



# Pharma CIAs and CME

- Funding or participating in any Educational or Informational Activity to insure that company funding and sponsorship complies with AKS and FDA requirements.
- Educational or Informational Activity shall mean any continuing medical education (CME), disease awareness, or other scientific, educational, or professional program, meeting, or event, including, but not limited to, sponsorship of booths or activities at medical conferences or symposia.
- Policies shall ensure that (i) disclosure of company financial support of the event and any financial relationship with faculty, speakers, or organizers; (ii) the event has an educational focus; (iii) the event is independent; (iv) the event is non-promotional in tone/nature; (v) the information is fair, balanced, accurate, and not misleading.

# **GIFTS & OTHER PHYSICIAN INTERACTIONS**

# Gifts

	PhRMA	AdvaMed
<b>Cash or cash equivalents</b>	<b>No</b>	<b>No</b>
<b>Logo Reminder Items</b>	<b>No- only physician or patient educational items</b>	<b>No, only if physician education items or for benefit of patients</b>
<b>Gifts of \$100 or more</b>	<b>No</b>	<b>Yes, if text or anatomical model</b>
<b>Gifts under \$100</b>	<b>Yes, if benefit patient, practice, or educational</b>	<b>Yes, if benefit patient, practice, or educational</b>

# AMA Ethics Opinion 8.061--GIFTS

- No cash.
- Gifts should benefit patients.
- Gifts should not have substantial value.
- Textbooks ok and meals if they serve educational value.
- Reminder items of nominal value ok as long as related to physician's work (e.g., pens and note pads).

# Hospital Conflict of Interest Standards

- Ban all gifts, meals and entertainment.
- Require disclosure of compensated relationships with medical staff.
- Ban or regulate vendor access to health care professionals, including nursing staff.
- Regulate or ban certain research support.

# Entertainment and Recreation

- Just say no.
- Revised PhRMA and AdvaMed both specifically prohibit companies from providing or paying for any entertainment or recreational activity for a non-employee health care professional.
- Very big change from prior codes.

# Meals

- AdvaMed – revised code states it is not appropriate to provide a meal simply as part of development of good will or a business relationship.
  - Interaction must be for exchange of scientific, educational, or business information.

# Sales, Promotional & Business Meetings

## ■ AdvaMed

- Meetings w/ health care professionals (HCPs) for sales and promotional purposes are appropriate.
- Any payment for travel or expenses for HCP to attend only when necessary (equipment not portable) & only to persons with bona fide reason to attend.
- Modest meals.



# **SALES FORCE ISSUES**

# Pharma CIA and Sales Force

- Selling, marketing, and promoting products in compliance with all applicable federal health care program requirements, including AKS disseminating information about products in compliance with FDA requirements, including procedures for response to requests for information about off label use.
- Compensation (including salaries and bonuses) that are designed to ensure the financial incentives do not inappropriately motivate sales and marketing personnel to engage in improper promotion, sales, and marketing.
- Employee discipline for violation of company policies and procedures including federal health care program and FDA requirements.

# Revised PhRMA Code

- Adds new section on training and conduct of sales force.
- Requires training sales force on all applicable laws, regulations, and industry codes.
- Periodic assessment of sales force to ensure compliance.

# OFF LABEL MARKETING

# DOJ Enforcement

- Off-label allegations predominate current health care fraud investigations and involve pharma and device sales practices. Pharma and big dollar settlements.
- Tension between FDA promotion regulations and practice of medicine exception.
- DOJ and OIG resolutions focus on corporate sales, marketing and clinical activity.
- Impose transparency requirements.

# AAOS Off-Label Position

- Orthopaedic surgeon community.
- 2009 position statement and FAQ on off-label use from surgeon perspective.
- Addresses FDA standard for knowledge and regulation and disclosure of conflict of interest.
- Re-affirms appropriateness of practice of medicine exception if standards are met.

# Current Enforcement Related to Promotion

- DOJ and State AG False Claims Act Suits.
- 200 off-label cases qui tams under seal with promotion allegations.
- Criminal investigations. Synthes. Stryker.
- FDA Enforcement Agenda.
- State AG Consumer Interest. NY. Texas.
- Congressional, Media and Patient Interest.
- 510(k) Theories.

# Pharma Settlements Relating to Promotion

- AtriCure-device-marketing practices for ablation devices. \$3.8 million. Civil FCA.
- Biovail-pharma-phase IV clinical outcomes study.
- Pfizer-pharma-10 qui tams suits. \$2.3 billion. Criminal and Civil. Precedent for Promotion.
- Lilly-pharma-marketing practices for Zyprexa. \$1.4 billion. Criminal and Civil.
- AstraZeneca – marketing practices. \$520 million.
- OmniCare – marketing practices in nursing homes. \$98 million.



# Key Compliance Provisions Relating to Promotion

- Disclosures Related to HCP Interactions.
- Directed Promotion Policies.
- Broad Concept of Promotion.
- Field Force Monitoring and Review Efforts.
- Independent Survey Entities on Detailing.
- Third Party Education
- IRO for Promotion and Product Functions.
- Arrangements and Transactions Reviews.
- Management Certifications.

# TRANSPARENCY

# U.S. Transparency Requirements- Global Impact

- Federal and State Legislation Focused on specific industry sectors: drugs, device, biologics and medical supply.
- Health reform create new obligations PBMs, GPOs, Nursing homes and hospitals related to financial conflict of interest.
- Government Investigations: DPAs and OIG CIAs. Government mandated sunshine terms as condition of resolving criminal and civil fraud allegations.
- Industry Voluntary Disclosure Practices. Global trend in disclosure.
- Hospital, Health Systems and Medical Societies Voluntary Disclosure Efforts. 2010 AAOS Disclosure Program.
- Initiatives have world wide impact.
- FCPA Enforcement.

# Transparency Challenges

- Transparency and Conflict of Interest Management is not limited to health industry. Major corporate responsibility initiative.
- Environment, Labor, Financial, Corporate Governance-areas of transparency. 2003 S&P European Transparency and Disclosure.
- Corporate challenges to integrate and systemize transparency as corporate value and mandated legal requirement. Role of technology and audit will change to implement and monitor multiple expectations and requirements.

# U.S. Sunshine Provisions

- March 31, 2013 any manufacturer that provides a payment or other transfer of value to a covered recipient (or to an entity or individual at the request of or designated on behalf of a covered recipient) shall submit to the Secretary [of HHS], in such electronic format as the Secretary shall require, information regarding any payments or transfers of value for the preceding calendar year.
- Covered recipient is a physician or teaching hospital.
- No later than October 1, 2011, HHS will establish procedures for applicable manufacturers and applicable group purchasing organizations to submit required information and to make such information available to the public.

# U.S. Sunshine Provisions-Core Reportable Activities

- Consulting fees
- Compensation for services other than consulting
- Honoraria
- Gift
- Entertainment
- Food
- Travel
- Education
- Research
- Charitable contribution
- Royalty or license
- Current or prospective ownership or investment interest
- Compensation for serving as a faculty or as a speaker for a CME program
- Grant
- **Any other payment or transfer of value. List is not exclusive.**



# U.S. Sunshine Provisions-Reporting Exclusions

- An **applicable manufacturer** shall not be required to submit information with respect to the following:
- A transfer of anything the value of which is less than \$10, unless the aggregate amount to a **covered recipient** during a calendar year exceeds \$100. For calendar years after 2012, the dollar amounts shall be increased by the same percentage increase in the consumer price index.
- Product samples that are not intended to be sold and are intended for patient use.
- Educational materials that directly benefit patients or are intended for patient use.
- The loan of a **covered device** for a short-term trial period, not to exceed 90 days, to permit evaluation of the **covered device** by the **covered recipient**.
- Items or services provided under a contractual warranty, including the replacement of a **covered device**, where the terms of the warranty are set forth in the purchase or lease agreement for the covered device.
- A transfer of anything of value to a **covered recipient** when the **covered recipient** is a patient and not acting in the professional capacity of a **covered recipient**.

# U.S. Sunshine Provisions-Reporting Exclusions

- Discounts (including rebates).
- In-kind items used for the provision of charity care.
- A dividend or other profit distribution from, or ownership or investment interest in, a publicly traded security and mutual fund.
- In the case of an **applicable manufacturer** who offers a self-insured plan, payments for the provision of health care to employees under the plan.
- In the case of a **covered recipient** who is a licensed non-medical professional, a transfer of anything of value to the **covered recipient** if the transfer is payment solely for the non-medical professional services of such licensed non-medical professional.
- In the case of a **covered recipient** who is a physician, a transfer of anything of value to the **covered recipient** if the transfer is payment solely for the services of the **covered recipient** with respect to a civil or criminal action or an administrative proceeding.



# State Transparency

- California
- District of Columbia
- Maine
- Massachusetts Marketing Law
- Minnesota
- New Hampshire
- Nevada
- Vermont
- West Virginia

# Hospital and Medical Profession

- AAOS Disclosure Program.
- Hospital Reporting Requirements under health reform.
- Hospital institutional policies.

# APPLYING THE LESSONS

# Compliance Touchstones

- Do the proposed terms or business practices violate *company or institutional conflict of interest* policies?
- Do the proposed terms or practices implicate medical conflict of interest policies and regulations?
- Do the proposed terms or practices impact patient rights in privacy, informed consent or other substantive areas?
- Is it possible to implement practical and appropriate precautions to diminish or eliminate conflict of interest through disclosure policies or other means?
- Is disclosure of the activity and related payments legally required?

# Compliance Touchstones

- Does arrangement meet industry standards of conduct and medical ethics standards? These standards, on paper, are more stringent in some areas than government guidance. JAMA Feb. 2006.
- Do not forget other federal agencies. Are NIH, FDA, OHRP regulations impacted by conduct or arrangement?

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