

American Academy of Orthopaedic Surgeons 2010 Annual Meeting

March 12, 2010

Developments in the Evolving Orthopaedic Surgeon - Industry Relationship

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My disclosure is in the Final Program Book and in the AAOS database.

I have no potential conflicts with this presentation.

Opportunities and Challenges

- ❖ Demand for industry compliance and ethical standards
- ❖ Demand for transparent relationships
- ❖ Increased regulatory oversight and enforcement globally
- ❖ Competition for physician and hospital business
- ❖ Management of conflict of interest



Enforcement

- ❖ Health Care industry remains target of ongoing focus.
 - Health reform provides for enhanced anti-fraud measures .
 - DOJ HEAT Task Force
- ❖ Stryker Biotech and top management indicted for alleged illegal compensation arrangements with HCPs. (Oct. 2009)
- ❖ AtriCure Inc. - \$3.8 million settlement of whistleblower case related to alleged fraudulent marketing practices. (Nov. 2009).
- ❖ Medtronic Kyphoplasty Qui Tam-hospital and physician liability for inpatient admission decisions. Hospital settlements.
- ❖ Off-label investigations involving cardiology, spine, neurology sectors.

Enforcement

- ❖ Stark Law violations involving hospital and physician arrangements: Wheaton-excessive physician compensation; Rush-technical lease non-compliance. (2010).
- ❖ Dr. Shakhar Desai-orthopedic surgeon in Florida. DePuy arrangement for operating room observation, training and consulting sessions. Work not performed over 13 month period but invoiced and payment received. Doctor paid \$70 to 120,000. Pled guilty to wire fraud, not kickback.
- ❖ St. Joseph Medical Center, Baltimore. Hospitals has advised 538 patients they have received unnecessary stents. Under investigation for relationship with cardiology practice and compensation and kickback issues. Senate Finance Committee interested in industry relationships.

Health Reform Provisions

❖ Physician Practice Issues:

- Ancillary services-patient disclosures
- Physician owned hospitals provider agreements.
- DME/Home Health certifications and physicians orders-face-to-face encounters.
- RAC and state audit contractors
- 60 day repayment obligations for overpayments

Statutes

- ❖ **ANTI-KICKBACK STATUTE**
- ❖ **STARK SELF-REFERRAL PROHIBITIONS**
- ❖ **RAC AND OTHER MEDICARE/MEDICAID AUDITS**
- ❖ **FALSE CLAIMS ACT AND QUI TAM PROVISIONS**
- ❖ **FOOD, DRUG AND COSMETIC ACT**
- ❖ **HIPAA COMPLIANCE-STATE ENFORCEMENT**
- ❖ **FOREIGN CORRUPT PRACTICES ACT**

Anti-Kickback Statute



- ❖ Prohibits recommending or arranging activities for purpose of inducing federal health care program business.
- ❖ The law may be violated if “anything of value” is offered, given, or received where one purpose of the offer or solicitation is to influence the reason or judgment. This is the “ONE PURPOSE TEST”.

CME Concerns

- CME perceived as vehicle for off-label promotion and undue industry influence.
- Conflicts of interest not managed well. Disclosure.
- April 2007 Senate Finance Report details abuses and lack of independence.
- ACCME 2008 and 2007 amendments to Commercial Standards of Support attempt to diminish commercial influence.
- Use of product champions and indirect influence of content are danger zones.

False Claims Act

- ❖ FCA prohibits anyone from knowingly presenting, or causing to be presented, a false or fraudulent claim to the Government.
- ❖ Primary government civil enforcement statute.
 - Whistleblower provisions
 - Civil Penalties - \$5,500-\$11,000 per claim, treble damages
- ❖ 2009 Amendments vastly expands FCA liability.
 - New definition of “claim” – Expands who may be subject to FCA.
 - Extends liability to those that do business with federal grantees
 - New definition of “obligation” – Now covers regulatory violations –Stark compliance

Stark Law Compliance

Impact all physician compensations, investment and ownership arrangements for compliance assessment purposes. Complex area requiring legal review.

- ❖ Apply to hospital relationships: leases, compensation, joint ventures, ancillary services.
- ❖ Substantial monetary liability for technical violations.
- ❖ Strict liability. Payment ban for non-compliance.
- ❖ False Claims Act liability from whistleblower suits.

Other Compliance Initiatives

- ❖ AAOS Off-Label Use Position Statement-affirms FDA requirements and appropriateness of physician directed determinations.
- ❖ AAOS Disclosure Policy
- ❖ Hospital Conflict of Interest Policies, Technology Committees, Ban on Industry Compensation.
- ❖ Research integrity issues.

Safe and Effective Practice Management

- ❖ Invest resources in compliance guidance and structure.
- ❖ Conflict of interest management.
- ❖ Codes of Ethics awareness
- ❖ Arrangements assessment.
- ❖ Billing and coding review.
- ❖ Interactions with industry.
- ❖ Hospital relationships and arrangements.

Compliance Safeguards for Collaborations

- ❖ Needs Assessment will be expected by government to document bona fide activity and payments.
- ❖ Documentation of work, limits on compensation.
- ❖ Sales Force Firewall for all non-product activities. More complexity but greater protection.
- ❖ Re-structure product development teams and compensation.
- ❖ No entertainment or gifts. Business only interactions.

Contact Information

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