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## Current Solutions in Shoulder and Elbow Surgery

What is in Store for Orthopaedic Surgeons? Healthcare  
Policy and DOJ Update.

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# 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.



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# Enforcement Landscape

- ❖ Kerlan Job Orthopaedic- Calif. 2009. \$3 million kickback settlement for Health South payments: stock options, loan forgiveness on equipment leases, high ownership rate in ASC with hospital.
- ❖ Wheaton Community Hospital and Dr. Gallagher- Minn. 2009. \$563,000 medically unnecessary inpatient admissions by doctor.
- ❖ Kyphoplasty- Nationwide. 2009. FCA settlements against hospitals for inpatient admissions by doctors. F/U Medtronic \$75 million settlement.
- ❖ South Texas Health System-Texas. 2009. \$27 million kickbacks to physicians for leases and medical directorships.
- ❖ Synthes Indictments re: spine procedures and unapproved products.

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# Health Reform Provisions

- ❖ Payment Changes and increased auditing.
- ❖ Lowers the government burden of proof for kickback violations, eliminating actual knowledge or intent.
- ❖ Increases personnel resources, prosecutors
- ❖ Increases funding for investigations \$100 million.
- ❖ Payment Sunshine Act-manufacturer reporting for payments or TOV to physicians over \$10.
- ❖ Restricts Physician owned hospitals.
- ❖ Implements 60 day deadline for repaying Medicare overpayments.

# Health Reform Provisions

- ❖ Requires reporting of physician ownership and investment in GPOs and manufacturers.
- ❖ Amends the False Claims Act to encourage more whistleblower suits, allowing suits for publicly available information.
- ❖ Enhanced exclusion authorities for obstructing HHS investigation by delay or refusal to allow access for audits.

# Key Surgeon Issues

- ❖ Industry Collaborations
- ❖ Industry Reps in the OR
- ❖ Off-Label Procedures-AAOS Policy Statement
- ❖ Conflicts of interest management.
- ❖ Professional Billings
- ❖ Reimbursement.
- ❖ Compliance Programs
- ❖ Ownership and Investment interests.

# 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”

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# Anti-Kickback Statute

## ❖ Public interest concerns:

- corruption of medical decision-making;
- increased risk of over-utilization;
- increased costs to federal health care programs;
- harm to patient freedom of choice; and/or
- unfair competition.

# CME CONCERNS

- CME perceived as vehicle for off-label promotion and undue industry influence.
- Conflicts of interest not managed well.
- 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.

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## Other Compliance Initiatives

- ❖ AAOS Standards of Professionalism, April 2007
- ❖ Hospital Conflict of Interest Policies.
- ❖ Physician Network Conflict of Interest Policies.
- ❖ AdvaMed Updated Code of Ethics

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# The Strategy

- Transparency and Disclosure
- Conflict of interest management
- Alliance on ethical standards
- Education on need for innovation, research, and training.

## Compliance Safeguards for Collaborations

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

# Contact Information

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