



Much Ado About Arrangements: Compliance Perspectives on Conflicts of Interest in Physician Relationships

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Overview

- Why the Interest?
- Disclosure of Physician Relationships –Transparency is the Goal!
- State Controls and Pending Federal Legislation
- Industry Self-Commentary and Studies
- Federal Government Enforcement Tools
- Recent Settlements
- OIG Corporate Integrity Agreement Requirements
- Practical Tips For Compliance Programs





Why the Interest?

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- OIG has publicly announced an interest in examining physician arrangements
- OIG believes these arrangements can create conflicts of interest that may affect medical decision-making, increase costs, and improperly steer business
- Government has also noted anticompetitive effect and barriers to entry for new or smaller companies that cannot compete
- *“Kickbacks to physicians are incompatible with a properly functioning healthcare system. They corrupt physicians’ medical judgment and they cause overutilization and misallocation of vital health care resources.”*
 - Peter D. Keisler, Assistant Attorney General for DOJ’s Civil Division



Historical – Focus on CME

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- 1997: FDA Guidance on Industry-Supported Scientific and Educational Activities
- 2003: OIG Compliance Guidance for Pharmaceutical Manufacturers: recommendations to limit conflicts of interest:
 - Separate educational grant making functions from sales and marketing functions
 - Manufacturers should take steps to ensure that CME activities are not used to channel improper remuneration to physicians
- 2004: ACCME revises its Standards for Commercial Support
- 2005: US Senate Finance Committee inquiry; April 2007 Report discusses potential for off-label messages; September 2007 inquiry to device manufacturer and letters to CME providers



Virtually All Physicians Report Participation in Industry Arrangements!

- According to a study published in the New England Journal of Medicine:
 - 94% of physicians self-report some type of relationship with industry;
 - 83% report receiving food and beverages in the workplace;
 - 78% report being given drug samples;
 - 35% report reimbursement for meeting costs or CME;
 - 28% report payments for consulting, speaking, or enrolling patients in trials
- Campbell et al., *A National Survey of Physician-Industry Relationships* (April 26, 2007) 356 N. Engl. J. Med. 1742



Physician Conflicts of Interest – Proposed Federal Legislation

- September 2007 – U.S. Senators Charles Grassley and Herb Kohl introduce the Physician Payments Sunshine Act – designed to “shine a much needed light on a situation that contributes to the exorbitant cost of health care,” says co-sponsor Senator Charles Schumer
- Manufacturers of pharmaceuticals and devices with annual revenues in excess of \$100 million would be required to disclose the amount of money they give to a physician (including consulting fees, dinner, etc.)



Physician Conflicts of Interest – State Interest

- Medicaid particular focus for states, with NY OMIG leading way.
- In 2006, Massachusetts Medicaid Fraud Control Unit acknowledged some shift away from traditional interests in FCA or “common fraud” cases to kickback (as well as off-label marketing) enforcement.
- States are piggy-backing on federal enforcement priorities, with a particular focus on physician arrangements.
- DRA incentives for state FCA laws further spur state interest.
- Other jurisdictions have taken different tact – e.g., D.C. has debated legislation regulating/licensing pharmaceutical sales representatives.



Conflicts of Interest – Industry Standards

- AMA Code of Ethics on Gifts to Physicians from Industry
- PhrMA Code
- AdvaMed Code of Ethics
- NEMA Code



Conflicts of Interest – Government Standards

- OIG Work Plan
- OIG Compliance Program Guidances (particularly Pharmaceutical Manufacturer, DME, Hospital, and Physician Guidances)
- Recent Settlements and CIAs
- State Statutes and Regulations



Conflicts of Interest – Industry Comments

- Conflicts of interest occur when physicians have motives or are in situations for which reasonable observers could conclude that the moral requirements of the physician's roles are or will be compromised. In terms of industry influences, financial conflicts of interest occur when physicians are tempted to deviate or do deviate from their professional obligations for economic or other personal gain. The bias thus introduced violates both the best interests of patients and the standards of scientific integrity. Policing such conflicts clearly lies within the scope of professional responsibilities set forth in the *Physician Charter on Medical Professionalism*.

– Brennan et al., *Health Industry Practices that Create Conflicts of Interest: A Policy Proposal for Academic Medical Centers* (Jan. 25, 2006) 295 JAMA 429 [cited references omitted].



Conflicts of Interest – Industry Comments (cont'd)

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- Brennan, et al. propose that Academic Medical Centers more strongly control, or even prohibit, practices which have the potential to create a conflict of interest, including:

- Gifts to physicians
- Payments for conference and lecture attendance (including travel)
- Payments for consulting relationships
- CME contributions
- Grants for research projects
- Payments for ghostwriting

– Brennan et al., *Health Industry Practices that Create Conflicts of Interest: A Policy Proposal for Academic Medical Centers* (Jan. 25, 2006) 295 JAMA 429 [cited references omitted].



Industry Standards – Institutions Adopting Policies Limiting Contacts with Physicians

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- Boston University School of Medicine
- Boston Medical Center
- University of Michigan Health System
- University of Pennsylvania
- Yale University School of Medicine
- Geisinger Health System (Pennsylvania)
- Stanford University School of Medicine
- Affinity Health System (Wisconsin)
- Kaiser Permanente
- HealthPartners (Minnesota)
- University of California at San Francisco (UCSF)



Federal Government Enforcement Tools

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- Anti-Kickback Statute
 - Deferred Prosecution Agreements
- Stark Law
- Civil False Claims Act Settlements
- Corporate Integrity Agreements
- Exclusion from Program Participation
- Civil Monetary Penalties Law



Enforcement Tools – Anti-Kickback Statute

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- AKS is a **criminal** prohibition against payments (in any form, whether the payments are direct or indirect) made purposefully to induce or reward the referral or generation of Federal health care program business
- AKS addresses not only the offer or payment of anything of value for patient referrals, but also the offer or payment of anything of value in return for purchasing, leasing, ordering, or arranging for or recommending the purchase, lease, or ordering of any item or service reimbursable in whole or in part by a Federal health care program
- AKS extends equally to the solicitation or acceptance of remuneration for referrals or the generation of other business payable by a Federal health care program



Criminal Prosecutions Against Physicians?

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- January 2008 – E.D. Arkansas – U.S. Attorney’s Office announces the guilty plea of Dr. Patrick Chan, a neurosurgeon, to soliciting and receiving kickbacks from a sales representative for several medical companies that supplied surgical equipment and devices that Chan utilized
- Settlement agreement in related qui tam law suit for \$1.5 million



Civil Settlements with Physicians

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- May 2007 – W.D. Kentucky – U.S. Attorney’s Office announces \$210,561 settlement of Dr. Ricky S. Collis for accepting kickbacks to refer beneficiaries for back braces
- Collis entered five-year Integrity Agreement





Deferred Prosecution Agreements

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- Deferred prosecution agreements usually involve a complaint or indictment filed with the court, along with a simultaneous agreement deferring prosecution of the charges for a fixed period of time, after which the charges are dismissed if the company has complied with the conditions of the agreement
- Avoids imposition of mandatory exclusion



Enforcement Tools – Stark Law

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- The Stark Law prohibits entities from submitting – and Medicare from paying – any claim for a “designated health service” (DHS) if the referral of the DHS comes from a physician with whom the hospital has a prohibited financial relationship
 - Intent is not required to find a violation (but is required for the related CMP)
- Limited applicability when the focus is vendor relationships with physicians – but compare the themes!



Enforcement Tools – Civil False Claims Act

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- Qui Tam (Whistleblower Provisions)
- FCA makes it illegal for any person to submit – *or cause to be submitted* – a false or fraudulent claim to the government
- Penalties include:
 - A civil monetary penalty of \$5,500 to \$11,000 per claim
 - Three times the amount of damages sustained by the government
 - The costs of a civil action
 - Relator’s legal fees are paid by the defendant



Enforcement Tools – Corporate Integrity Agreements

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- Often negotiated as part of an FCA settlement
- Terms are designed to protect the federal health care programs prospectively, in exchange for OIG’s permissive exclusion release
- Typically 5-year agreement to implement compliance program with OIG oversight
- Requirement to retain outside “independent review organization” to perform compliance reviews most significant of CIA provisions



Enforcement Tools – Exclusion

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- Exclusion extends to participation in all Federal health care programs (and collaterally to all Federal procurement and nonprocurement activities)
- Four mandatory exclusion bases arising from criminal convictions (note discussion above re: DPAs)
- Most significant of permissive bases permits exclusion for “fraud, kickbacks, and other prohibited activities”

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Enforcement Tools – Civil Monetary Penalties Law

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- Alternative/Supplement to Civil Action, bases include:
 - False or Fraudulent Claims (same elements and intent standard as FCA)
 - Kickbacks/Stark Violations
- Cases Initiated by OIG
- OIG Has to Prove Underlying Facts
- Six-Year Statute of Limitations
- DOJ Authorization
- ALJ Proceeding

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Enforcement Tools – Civil Monetary Penalties Law (cont'd)

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- For improper claim, CMP of up to \$10,000 for each item or service improperly claimed
- Assessment of up to 3 times the amount claimed (not “damages”)
- For AKS CMP, penalty of up to \$50,000 for each act plus assessment of up to 3 times the amount of the remuneration
- For Stark CMP, penalty of up to \$15,000 for each service improperly claimed plus assessment of up to 3 times the amount improperly claimed



Recent Settlements

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- Lincare
- Medtronic
- University Hospitals Health Systems
- Advanced Neuromodulation Systems
- Orthopedic Device Settlements
 - Stryker
 - Depuy (Johnson & Johnson)
 - Zimmer Holdings, Inc.
 - Biomet
 - Smith & Nephew



Lincare

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- May 2006
- \$10 million CMPL settlement
- Five-year corporate integrity agreement
- Allegations: Lincare remuneration to referral sources, including:
 - (1) Sporting and entertainment event tickets;
 - (2) Gift certificates;
 - (3) Rounds of golf, golf equipment;
 - (4) Fishing trips;
 - (5) Meals;
 - (6) Advertising expenses;
 - (7) Office equipment;
 - (8) Medical equipment; and
 - (9) Consulting agreements



Lincare (cont'd)

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- In a related settlement, two South Florida pulmonologists also settled with OIG as a result of their relationships with Lincare
- CMPL monetary payments of \$65,066 and \$57,030
- Three-year Integrity Agreements
- Allegations: Lincare provided Miami Dolphins tickets and meals in exchange for patient referrals





Medtronic

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- July 2006 Settlement of \$40 million to resolve civil allegations that one division paid kickbacks to doctors to induce them to use certain company products, in violation of the AKS and FCA
- Resulted from a qui tam filing
- Five-year corporate integrity agreement

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University Hospitals Health Systems

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- August 2006
- \$14 million False Claims Act monetary settlement
- Five-year corporate integrity agreement
- Allegations: UHHS paid illegal remuneration to physicians, including:
 - Practice support in excess of FMV,
 - Directorship agreements that did not require any duties to be performed, and
 - Salary payments to physicians' employees
- First CIA to include "focus arrangements" provisions

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Advanced Neuromodulation Systems

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- July 2007
- \$2,950,000 monetary settlement under CMPL
- Three-year corporate integrity agreement
- Allegations: ANS paid illegal remuneration to referral sources, including:
 - Educational grants and fellowships,
 - Conferences held at resort locations,
 - Free dinners and gifts,
 - Expenses paid to physicians under consulting agreements

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Orthopedic Device Settlements

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- September 2007 – 5 companies making 95% of hip and knee implants were alleged to have used sham consulting agreements and other tactics to induce use of their products
- Agreements were alleged to violate AKS (consulting arrangements requiring little or no actual physician work)
- 4 entered into DPAs (5th entered into a non-prosecution agreement with similar terms)
- 4 paid a combined \$311 million (5th did not enter into a civil settlement)

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Lessons Learned from Recent Settlements

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- Enforcement focus on arrangements that include travel, entertainment, consulting agreements, and practice support
- Multiple arrangements with single physician will be evaluated in the aggregate – coordination key to an effective compliance program!
- OIG particularly interested in arrangements with device companies
- DOJ and OIG particularly interested in arrangements they believe may intersect with off-label or other marketing activities
- Both competitors and physicians have been source of qui tam complaints and other allegations



Compliance Programs

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- Develop contracting database to store contract information, specifically parties, type, dates, remuneration amount, and FMV methodology
- Develop reporting to track remuneration to and from all parties
- Establish formal written review and prior approval process and mechanism to maintain documentation that process was followed
- Ensure no payments are made without documentation of services provided by developing standards and formalized procedure for documentation



Compliance Programs (cont'd)

- Incorporate language into new contracts to include certification by both parties that agreement does not violate AKS
- Establish mechanism to track and report on remuneration by amount and party
- Develop mechanism to identify existing and future vendors which can be flagged as potential health care referral sources
- Evaluate current procedure for creating vendors in A/P system to avoid duplication of individuals/entities, misspelling and misclassification of vendors
 - *Special thanks to Bill Huron, Sorin Group*



CIA Arrangements Provisions

- Training Related to Arrangements
- Policies and Procedures Related to Arrangements
- Arrangements Databases
- Physician Relationships or Arrangements Reviews
- Reportable Events



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Arrangements Databases

- OIG began incorporating into CIAs in 2002 (McLeod Regional Medical Center)
- Beginning in 2004, OIG's new CIAs omitted Arrangements databases entirely or omitted providing the databases to OIG (except on request)
- Best practice? Incorporate centralization of approvals and tracking, but it is not necessary to follow CIA provisions exactly

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Focus Arrangements

- First introduced in CIA with University Hospitals Health System in 2006
- Differentiates obligations with respect to “focus arrangements” and other types of arrangements. More stringent CIA requirements may apply only to “focus arrangements” (e.g., database, review, procedures)
- At least three other OIG CIAs also contain “focus arrangements” provisions:
 - Tenet and UHHS: with actual (as opposed to actual or potential) referral sources
 - Medco: with pharmaceutical manufacturers, PBM clients, and broker/agents
 - Rural/Metro: focus on arrangements in state designated by OIG (1st year of CIA) or company (remaining years) each year



Contractual Versus Noncontractual Arrangements

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- Originated with Lincare CIA in May 2006
- Used in a number of settlements with device or DME companies (ANS, Biomet, DePuy, Medtronic, Smith & Nephew, Zimmer)
- Import is that some obligations only applicable to certain types of arrangements: e.g., in Lincare CIA, differences affect:
 - Elements tracked in databases
 - Requirement for signed, written agreement (Contractual)
 - Requirement for a certification that Arrangement does not violate AKS (Contractual)
 - Review/audit (Noncontractual)
- Charitable contributions and grants have been grouped differently in the various CIAs



Specific Types of Arrangements

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- Support for Third Party Educational Conferences (CME)
- Vendor-Sponsored Product Training and Education
- Physician Participation in Sales and Promotional Meetings
- Physician Consulting and Royalty Arrangements
- Travel, Gifts, Entertainment, Recreation, Meals
- Charitable Donations
- Research Grants



OIG Advisory Opinions

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- Guidance primarily on Anti-Kickback Statute, but also CMPL and OIG exclusion authorities
- 42 U.S.C. § 1320a-7d; 42 CFR Part 1008
- FAQs on OIG website
- Specific factual situations
- No FMV issues
- Actual or proposed own arrangement – No hypotheticals. No questions on competitor's arrangements
- Legally binding only on OIG and requestor



Disclosing Physician Relationships

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- OIG Provider Self Disclosure Protocol and 2006 Open Letter
- U.S. Attorney's Office/DOJ and False Claims Act incentives
- FI/Carrier/Contractor not appropriate venue for these types of allegations
- Decision to disclose is factually and jurisdictionally specific





Questions & Answers



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