

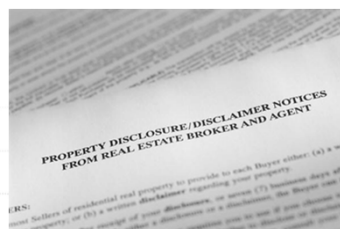
The Top 10 Conflicts of Interest Developments Healthcare Professionals Need to Know About

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March 31, 2014 – San Diego, California



Disclaimer

- The materials and views expressed in this presentation are the views of the presenter and not necessarily the views of the North Shore-LIJ Health System

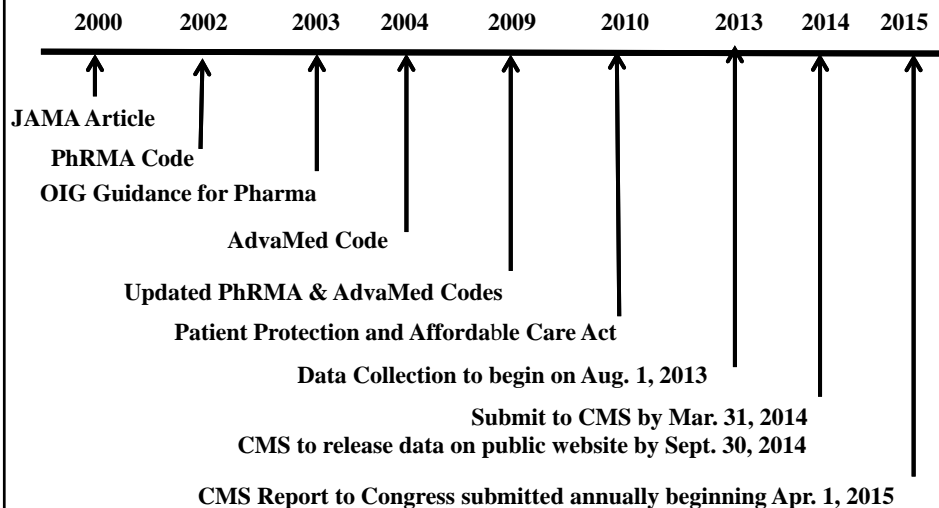


Goals of the Presentation

- Summary of new laws and industry guidance on COI and gifts
- Practical tips to avoid Stark and Anti-kickback issues
- Guidance on auditing and monitoring your COI and Gift Policy
- Answer your questions



Brief Timeline of Industry COI Developments



Pharmaceuticals

Glaxo will stop paying doctors to promote its products

Partly in response to new physician payment disclosure rules, U.K.-based GlaxoSmithKline said it will stop paying physicians for promoting its products at speaking engagements and for attending medical conferences. But for now, other large drugmakers say they will keep paying doctors to give



Dr. Daniel Carlat
Director
Pew Charitable Trusts

“We’re seeing that companies are generally curbing the more aggressive marketing tactics that they considered business as usual in the past.”

directly with doctors and other healthcare professionals who prescribe medications.

“We’re seeing that companies are generally curbing the more aggressive marketing tactics that they considered business as usual in the past,” said Dr. Daniel Carlat, director of the Pew Charitable Trusts’ prescription project. “The Sunshine Act is a critical part of the story because the fees paid to docs to market drugs are embarrassing to everyone involved.”

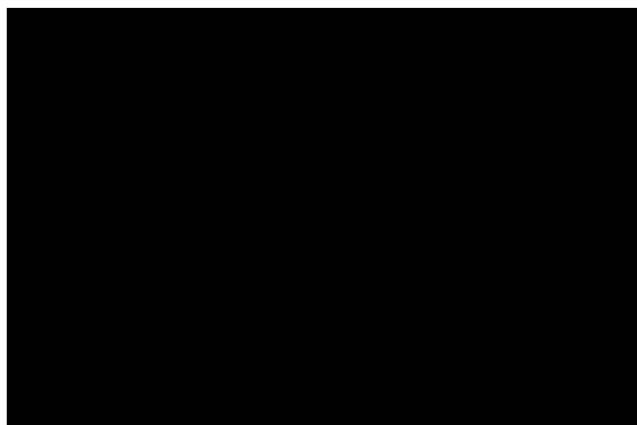
But Eli Lilly & Co., Pfizer, Bristol-Myers Squibb and Shire told Bloomberg News that they won’t stop paying doctors to talk with other physicians about their products.

U.S. Rep. Elijah Cummings (D-Md.) urged other drug companies to follow Glaxo’s lead. “For companies that choose not to stop these practices, they should be aware that Congress will scrutinize their actions very closely through the ACA’s new reporting requirements,” he said.

The Sunshine Act is not the only impetus for changing pharmaceutical industry marketing practices.

talks about their products. cal industry marketing practices.

Conflicts of Interest Training Example



2014 Top 10 List: #10 Physician Payment Sunshine Provisions (PPACA Section 6002)



- Final regulations finally released on Feb. 1, 2013! (Official FR date Feb. 8, 2013)
- Manufacturers to report any payments to physicians/teaching hospitals above \$10 unless an exception applies
- Broad definition of payment
- Manufacturers plus GPOs must report any ownership/investment interests by a physician and his/her immediate family
- <http://www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/index.html>

Who Paid for Your Doctor's Bagel?

ObamaCare's 'Sunshine Act' will benefit only accountants, bureaucrats and lawyers.

By THOMAS P. STOSSEL

Embedded in ObamaCare is a toxic rule called the Physician Payments Sunshine Act. The Act requires all companies that manufacture medical products purchased by the government to disclose on a public website anything they give physicians valued above \$10. Last month, the Centers for Medicare and Medicaid Services (CMS) issued draft guidelines.

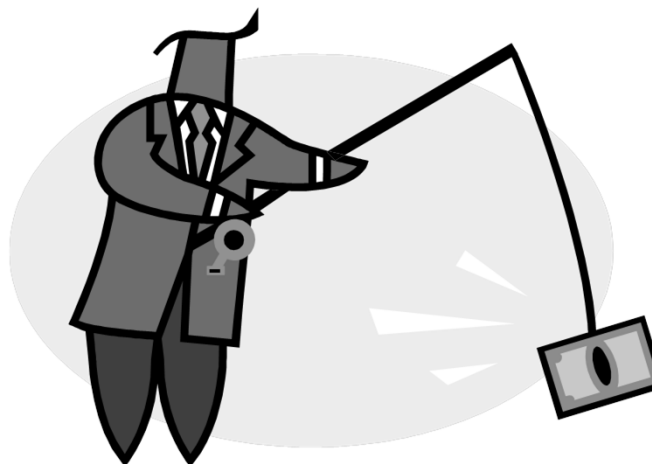
CMS justifies this legislation by citing "conflicts of interests that may influence research, education and clinical decision-making in ways that compromise clinical integrity and patient care, and may lead to increased health care costs."

This reasoning inverts reality. Medical care is incomparably better today than when I received my M.D. degree in 1967—due primarily to the availability of products developed by industry in unencumbered collaboration with physicians, and to industry's commitment to teach physicians how to use them.

Thanks to this collaboration, longevity has increased by a decade, and in my specialty, hematology, treatments for anemia, blood-clotting disorders and malignancies of the blood have improved spectacularly.

<http://online.wsj.com/article/SB10001424052970204468004577166840760748000.html>

What Will be the Real Impact of the Physician Sunshine Provisions?

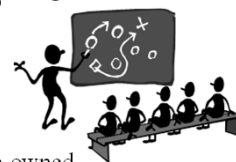


2014 Top 10 List: #9 Physician-Owned Distributorships (PODs)

- “These business ventures raise substantial concerns that a physician’s [ROI] from the venture may influence the physician’s choice of device.” – OIG Feb. 2008
- “Senators Request Probe of Surgeons” – WSJ June 9, 2011
- PODs – Senate Finance Committee, June 2011
- “In Small California Hospitals, The Marketing of Back Surgery – WSJ Feb. 9, 2012
- OIG national study on spine implant PODs survey (2012/2013)
- March 26, 2013 OIG Special Fraud Alert: Physician-Owned Entities
- October 2013 OIG Report – Spinal Devices Supplied by Physician-Owned Distributors: Overview of Prevalence and Use



Sample Procurement Screening Form Questions



- Does your company or any of its subsidiaries use any physician-owned distributorships? Yes No If yes, describe:

- Is your company publicly-traded? Yes No

If Yes, please disregard the following:

- Do any of X's employees (full or part-time) including physicians have any ownership interests or receive any other compensation from the company itself or any distributorship(s) used by the company to serve X or any of its facilities? Yes No

2014 Top 10 List: #8 Anti-Kickback Statute (PPACA Section 6402(f))

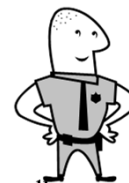
- **PPACA section 6402(f) eases the government's requirements to bring an AKS action**

- **PPACA changes:**

- "a person need not have actual knowledge of [the AKS] or specific intent to commit a violation of [the AKS]"
- "a claim that includes items or services resulting from a violation of [AKS] constitutes a false or fraudulent claim for purposes of [the False Claims Act]"



2014 Top 10 List: #8 Anti-Kickback Statute (PPACA Section 6402(f))



- **RehabCare Group Inc. (Rehabilitation Services) - \$30 million**
 - ❑ Allegedly paid a nursing home a one-time payment of ~ \$600K as well as a percentage of the profit from the ongoing therapy services performed pursuant to the contract
- **Victory Pharma Inc. (Pharmaceutical) - \$11.4 million**
 - ❑ Allegedly provided physicians tickets to sporting events, concerts, plays, along with paying for spa, golf and ski outings, dinners at expensive restaurants, other out of office events, and paid sales rep “preceptorships”
- **Sanofi-Aventis (Pharmaceutical) - \$109 million**
 - ❑ Allegedly provided free product kickbacks to physicians to market the “value add” of these units to physicians along with expensive dinners
- **GlaxoSmithKline (Pharmaceutical) - \$3 billion**
 - ❑ Among other issues, allegedly provided lavish vacations and “speaking fees” to doctors who agreed to promote the drugs to their colleagues
 - ❑ <http://www.justice.gov/opa/documents/gsk/us-complaint.pdf>
- **Dr. Steve Wasserman (Physician) - \$26.1 million**
 - ❑ Dermatologist in Florida allegedly accepted kickbacks from a pathology laboratory and billed Medicare for medically unnecessary services

2014 Top 10 List: #8 Anti-Kickback Statute (PPACA Section 6402(f))



- **C.R. Bard (Medical Products) - \$48.26 million**
 - ❑ Allegedly paid physicians kickbacks in the form of grants, guaranteed minimum rebates, conference fees, marketing assistance, and/or free medical equipment to use its brachytherapy seed therapy
- **Abbott Laboratories (Medical Device) - \$5.475 million**
 - ❑ Allegedly paid physicians for teaching assignments, speaking engagements, and conferences with the expectation to purchase vascular products
- **CareFusion (Medical Device) - \$40.1 million**
 - ❑ Allegedly paid one physician a \$11.6 million for recommending ChloroPrep products while he served as co-chair of the Safe Practices Committee of NQF
- **Other cases related to patient referrals and patient data (home care, lab)**
 - ❑ Goodwill Home Healthcare, a home health care agency in Illinois, allegedly participated in kickbacks in exchange for referral of Medicare patients
 - ❑ Biodiagnostic Laboratory Services in New Jersey allegedly offered bribes to physicians for referring patient blood specimens
 - ❑ Sacred Heart Hospital and four physicians in Chicago allegedly received bribes to induce patient referrals and increase the patient census
 - ❑ Pharmacist charged with paying more than \$50K in kickbacks to doctor for physician referrals

Government Guidance



- **OIG – A Roadmap for New Physicians, Avoiding Medicare and Medicaid Fraud and Abuse, Nov. 2010**
 - “Does the company really need my particular expertise or input?”
 - “Does the amount of money the company is offering seem fair, appropriate, and commercially reasonable for what it is asking me to do?”
 - “Is it possible the company is paying me for my loyalty so that I will prescribe its drugs or use its devices?”

2014 Top 10 List: #7 Increased Focus on Fair Market Value of Physician Compensation



- **Cooper Health System - \$12.6 million:** Allegedly paid outside physicians \$18K to serve on an advisory board and attend four meetings a year
- **HCA - \$16.5 Million:** Allegedly leased office space at a facility from diagnostic physicians at a rental rate in excess of fair market value
- **Intermountain Healthcare - \$25.5 million:** Voluntary disclosed. In addition to various technical violations, included a bonus structure that took into account the volume and value of referrals of physicians who referred patients to them
- **Adventist Health/White Memorial Medical Center - \$14.1 million:** Allegedly transferred assets to physicians who referred patients to the facility at less than fair market value and compensated physicians at above fair market value for teaching services at their family practice residency site
- **Tuomey Healthcare System - \$237 million:** Allegedly entered into part-time employment contracts with 19 physicians were for more than fair market value and were based on the volume of business generated by the physician
- **Health Management Associates:** Among other issues, allegedly paid physicians bonuses or awarded contracts to physician groups staffing HMA emergency rooms to induce physicians to admit patients unnecessarily, entered into sham medical directorship contracts, and sold physicians assets below fair market value

2014 Top 10 List: #6 Increased Focus on Technical Requirements of Stark Related to Gifts

- Non-Monetary Compensation Exception
 - \$385 limit applies to calendar year
 - Limited exception if hospital inadvertently exceeds annual limit
 - Government assumes hospitals track non-monetary compensation
 - Memorial Hospital (Ohio) voluntary disclosure
 - <http://www.cms.gov/PhysicianSelfReferral/DPS/list.asp#TopOfPage>

- Medical Staff Incidental Benefits Exception
 - Less than \$32 per occurrence
 - Item or service is provided to all members of the medical staff in the same specialty without regard to volume or value of referrals



2014 Top 10 List: #5 Co-Marketing Arrangements



- Co-Marketing Arrangements
 - Vendor/healthcare provider product/service advertisements
 - Vendor patient general education brochures
 - Community patient education events
 - Vendor training agreements
 - Preceptorships

2014 Top 10 List: #4 - Other Common Hospital/Physician Issues

- Educational Grant Activities
- Speakers' Bureaus
- Vendor FDA Related Training
- SEC Registration Disclosure Forms
- Royalty Agreements
- Establishing 501(c) (3) Foundations
- Insider Trading



2014 Top 10 List: #3 – Research

- **HHS Final Rule Financial Conflict of Interest Rules for Researchers**
 - More stringent Investigator disclosure requirements
 - SFI disclosure threshold lowered generally from \$10K to \$5K
 - Public disclosure requirements
 - Training requirements
- **Three New York Based Researchers Conspiracy to Receive Bribes from Chinese Company and Government Supported Research Institute**



2014 Top 10 List: #2 Changes to Beneficiary Inducement CMP



- 2002 OIG Special Advisory Bulletin, Offering Gifts and Other Inducements to Beneficiaries
- PPACA Section 6402 – Adds four new exceptions to allow “charitable and other innocuous” programs
 - Access to Care
 - Coupons, Rebates and Rewards Programs
 - Financial Need
 - Waiver of Co-pays for Covered Part D Generic Drugs
- Patient recruiter inducement cases

2014 Top 10 List: #1 IRS Form 990



- **IRS Form 990**
 - Increases transparency and disclosure of non-profit hospitals’ operations
 - Highlights conflicts of interest and insider dealings
 - Among other topics, requires reporting board members’ and key employees’ family and business relationships

IRS Form 990 – Transparency

Form 990 (2008)

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Part VI Governance, Management, and Disclosure (Sections A, B, and C request information about policies not required by the Internal Revenue Code.)

Section A Governing Body and Management

Section B. Policies

	Yes	No
12a Does the organization have a written conflict of interest policy? If "No", go to line 13	Yes	No
b Are officers, directors or trustees, and key employees required to disclose annually interests that could give rise to conflicts?	Yes	No
c Does the organization regularly and consistently monitor and enforce compliance with the policy? If "Yes," describe in Schedule O how this is done	Yes	No
13 Does the organization have a written whistleblower policy?	Yes	No
14 Does the organization have a written document retention and destruction policy?	Yes	No
15 Did the process for determining compensation of the following persons include a review and approval by independent persons, comparability data, and contemporaneous substantiation of the deliberation and decision		
a The organization's CEO, Executive Director, or top management official?	Yes	No
b Other officers or key employees of the organization?	Yes	No
Describe the process in Schedule O		

Engage Clinical Leadership



Data is King! – Medical Journal Articles

<http://www.amsascorecard.org/>

Educate on the Law and Internal Policy

COI Enforcement Settlements

Recruit Champions from Unbelievers

Don't Forget to Educate the Vendors!

COI Policy Educational Tools

- Employee Gift Brochure
- Vendor Gift Brochure
- Employee COI Brochure
- Frequently Asked Questions Document
- Cartoons
- Outside Activity Approval Form
- Sample Gift Return Letter



Awareness: Vendor Relations

Champ on Interactions with Vendors

Hi guys, I'm Sal Esrep from PharmaCorp. I'd like to tell you about Nitenite, our new sleep aid. Can I offer you a "lunch and learn" next week?

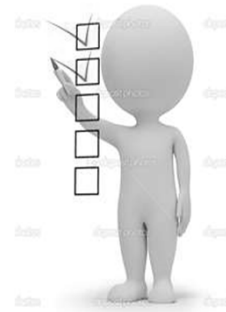
Well, it's an interesting new treatment. And I would never let something like lunch cloud my clinical decisions... so, sure, schedule it with my staff.

Make sure he leaves some samples. I could use a good night's sleep.



COI Monitoring Mechanisms

- Conflicts of interest questionnaires
- Certifications related to code of conduct and related policies and procedures
- Scope of individuals who complete an annual disclosure
- Procurement monitoring controls
- Compliance helpline and survey benchmarking
- Audits
- DRA mailing
- Contractual representations



Monitoring Control: Annual Conflicts of Interest Disclosure Form

Describe the service (e.g., consulting, speaking engagement, research, malpractice work).

List the total compensation, gift and/or meal (e.g., \$2,000.00).

Date(s) of service (e.g., 1/1/2011-12/31/2011).

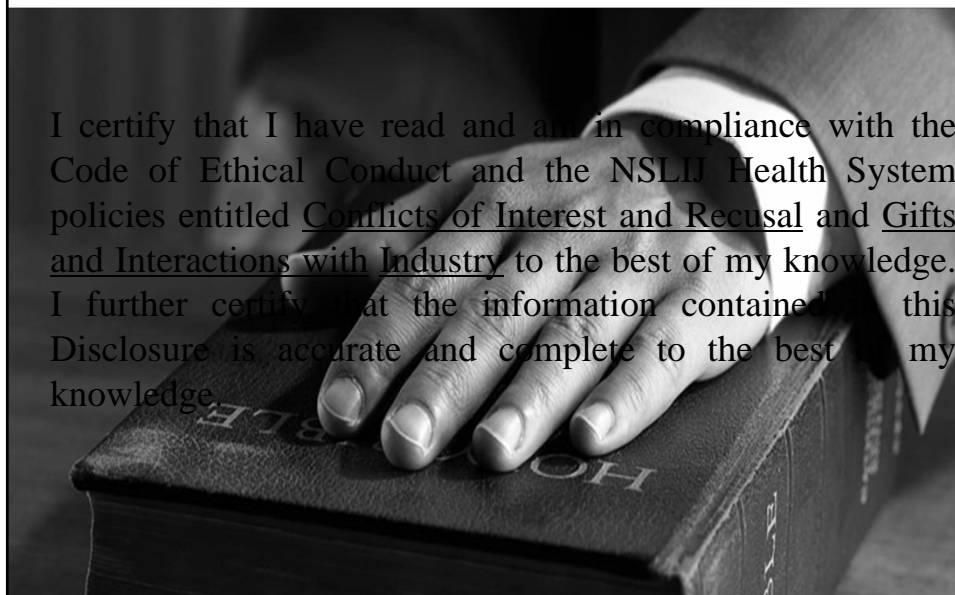
Does it conform with policy 800.04 entitled "Gifts and Interactions with Industry"? For a copy of this document, please refer to Document Library.

Yes

No

Monitoring Control: Annual Conflicts of Attestation Statement

I certify that I have read and am in compliance with the Code of Ethical Conduct and the NSLIJ Health System policies entitled Conflicts of Interest and Recusal and Gifts and Interactions with Industry to the best of my knowledge. I further certify that the information contained in this Disclosure is accurate and complete to the best of my knowledge.

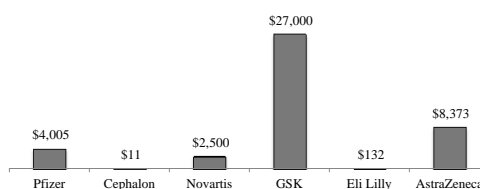


Sample Tearsheet



Joe Smith, MD
Internal Medicine, Radiology
Affiliations:
X Hospital
X Hospital

Industry Payments, by Company (2011)



9
unique industry
relationship disclosures

6
unique companies with
relationships

\$42,021
in total payments

Company	Bona Fide Serv.	Education	Meals	Speaker	Travel
Pfizer	\$3,798		\$207		
Cephalon			\$11		
Novartis	\$2,500				
GSK				\$27,000	
Eli Lilly			\$132		
AstraZeneca	\$1,150		\$73	\$7,150	

Questions



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