

West Coast Compliance Program: Anti-Kickback Statute

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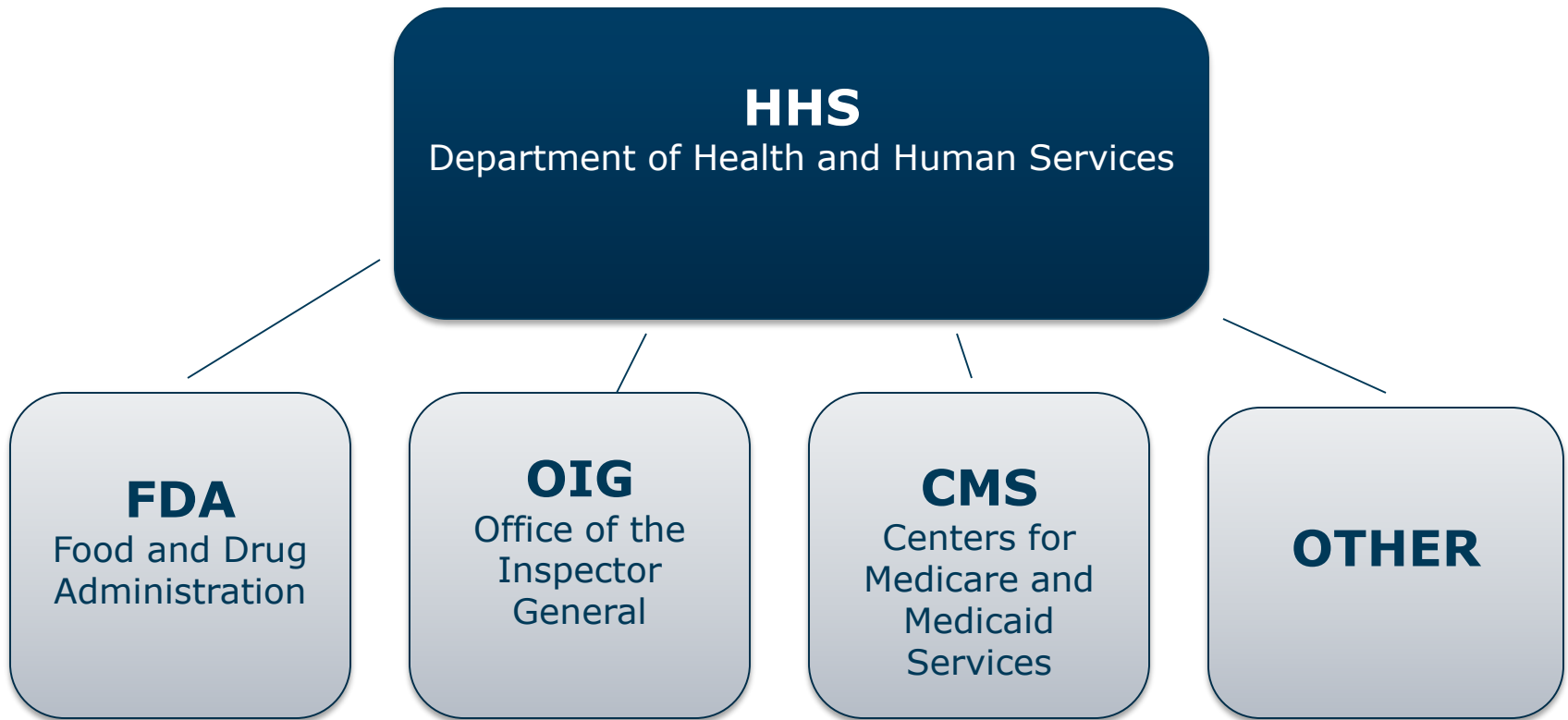
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Agenda

Important Health Care Concepts

- Anti-Kickback Statute
- False Claims Act

Regulatory Entities



The Regulatory Landscape for Manufacturers

- Extensive federal and state laws govern the pharmaceutical/biotech/device industries
- FDA is one of the primary, but not exclusive, regulators addressing:
 - Clinical trials
 - Manufacturing processes
 - Packaging and labeling
- OIG is the enforcement arm

The Regulatory Environment

- Costs of health care are increasing
- Role of government as payor is growing
- Distrust of the industry and concerns about safety are on the rise
- Political popularity of attacking manufacturers is increasing



Hillary Clinton ✓
@HillaryClinton

 Follow

Price gouging like this in the specialty drug market is outrageous.
Tomorrow I'll lay out a plan to take it on. -H

twitter.com/nytimes/status...

7:56 AM - 21 Sep 2015

↩ ↻ 2,357 ❤ 2,758

“The pharmaceutical industry has become a health hazard for the American people. The time is long overdue for Congress to listen to the needs of the American people and not the enormously-profitable pharmaceutical industry.”

- Bernie Sanders

Government Enforcement Overview

- Primary goal: Ensure that financially-motivated decisions do not trump good medical judgment or appropriate health policy
- Main enforcement strategy is “follow the money”
- OIG’s primary enforcement tools:
 - Federal Anti-Kickback Statute
 - False Claims Act

FEDERAL ANTI-KICKBACK STATUTE

Selling a Product

- Differentiation
- We choose certain products over others because they are:
 - Cheaper
 - Stronger
 - Longer-lasting
 - More effective
 - Have better customer service
 - A better value for price

Sales 101

Refer a friend. Get rewarded.

DISH Customers



Spread the news about DISH and get up to \$500 a year. It's easy!

- 1** Give your friends and family Referral Gift Cards to use when signing up for DISH.
- 2** Get **\$50 off your bill** when your friend signs up.
(\$5/mo for 10 months)
- 3** Receive **5 FREE Pay-Per-View movie certificates** for your first referral.

Request Gift Cards!

Federal Anti-Kickback Statute (“AKS”)

- Prohibits
 - Any person from
 - Knowingly and willfully
 - Soliciting, offering, paying, or receiving
 - Any remuneration
 - In return for making referrals or otherwise generating business
 - For which payment *may* be made under Federal or state health care programs

Persons to Whom AKS Applies

- “Whoever”
 - Gives
 - **Receives**
 - Offers
 - **Solicits**
- Both sides of the transaction and anyone in between, *e.g.*,
 - Physicians
 - Sales people
 - Hospitals

Prohibited Activities

- Do not have to make or receive payment to violate the AKS
- Broad scope of expressly prohibited activities
 - In other words:
 - Paying a kickback is illegal
 - Accepting a kickback is illegal
 - Offering to pay a kickback is illegal
 - Soliciting a kickback is illegal
- The mere offer or request of a bribe is prohibited by the statute

Remuneration

- Remuneration is defined broadly to include *anything of value*
 - E.g.,
 - cash
 - gifts or free services
 - salaries, business opportunities, or loan guarantees
 - payment for unnecessary services
 - Remuneration can be direct or indirect
 - No amount is too small to trigger the law

OIG's View of the AKS

- Practices that may be common or longstanding in other businesses may be illegal when soliciting federal health care program business
- Remuneration from a manufacturer that is expressly or impliedly related to a sale could implicate the AKS
- Selective offers (*i.e.*, offers made to some but not all) may increase risk if the selection criteria relate to how much Medicare or Medicaid business can be generated

-OIG Compliance Program Guidance for
Pharmaceutical Manufacturers (May 5, 2003)

Purpose of AKS

- Prevent money from influencing or skewing healthcare decisions
- Prevent overutilization of products
- Catch these schemes before they even happen: Not necessary that the transaction actually happen

AKS Safe Harbors

- Because of the broad sweep of AKS, the government created safe harbors

- These safe harbors only provide protection if you **comply with ALL of the requirements of the safe harbor**

- Many safe harbors are purposely defined in a manner that makes it difficult to ever comply fully with their requirements
 - *e.g.*, personal services safe harbor
- What happens when a safe harbor cannot be fully complied with?

AKS Safe Harbor: The Discount Safe Harbor

- The discount harbor contains specific and distinct requirements for “**buyers**,” “**sellers**,” and “**offerors**.”
 - A pharma or device manufacturer would generally be required to comply with the standards applicable to “sellers.”
- Where a discount is known at the time of sale, in order to comply with the discount safe harbor, a seller must:
 - Fully and accurately **report such discount** on the invoice submitted to the buyer,
 - **Inform the buyer** of its obligation to report the discount
 - **Provide information** about the discount **upon request** by the government, and
 - **Refrain** from doing anything that would **impede** the buyer from meeting its obligations.

AKS Safe Harbor:

Personal Services Safe Harbor

- “Remuneration” does not include any payment made by a principal to an agent as compensation for the agent’s services (*i.e.*, payment to an HCP) if:
 - The written agreement is signed by both parties.
 - The agreement specifies aggregate payment and such payment is set in **advance**.
 - Compensation is **reasonable, fair market value** and determined through **arm’s length negotiations**.
 - The term of the agreement is for at least one year.
 - The agreement sets out the exact services required to be performed.
 - Compensation is determined in a manner that does not take into account the volume or value of referrals.
 - The arrangement serves a commercially reasonable business purpose.

Examples of Non-Compliant Activity

- **Travel:** all expense-paid trips to medical conferences (Sereno, 2005 settlement for \$740 million)
- **Speaker Fees:** payments to high prescribing physicians for speaking at events (Jazz Pharmaceutical, 2007 settlement for \$20 million)
- **Consulting Agreements:** payments to HCPs to attend conferences and listen to off-label presentations (Cell Therapeutics Inc., 2007 settlement for \$10.5 million)
- **Samples:** free samples to influence HCPs to prescribe drugs (Pfizer, 2009 settlement for \$2.3 billion)
- **Gifts:** entertainment, TVs, or nominally priced drugs (TAP Pharmaceutical, 2001 settlement for \$875 million)

Penalties

- Felony
 - Up to 5 years in prison + up to \$250,000 fine for each violation for individuals, \$500,000 for corporations
 - Mandatory exclusion
- Violation may also trigger civil monetary penalties
 - Up to \$50,000 fine for each violation
 - Permissive exclusion
- Violation triggers False Claims Act liability (per health care reform amendment)
 - “In addition to the penalties provided for [under the AKS], a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim [under the FCA].”

You Be the Judge

MegaPharma, a leading pharmaceutical manufacturer, plans to roll out several new drugs next year. Once it receives approval from the FDA, it plans to market these drugs aggressively to physicians. MegaPharma's marketing director intends to have her "detailers" – representatives who visit doctor's offices to market pharmaceutical products and explain their benefits – offer large amounts of samples and give each doctor a souvenir iPod inscribed with the MegaPharma logo and the names of the new drugs. In addition, MegaPharma will offer a \$500 honorarium and free travel to 50 physician "opinion leaders" from around the country to attend an annual educational seminar it sponsors.

**What are some of the activities that
implicate the Federal Anti-Kickback Statute?**

Be the Judge Again

PharmCo is seeking to obtain FDA approval of a new indication for one of its existing products and is assembling a panel of physician experts to discuss the proposed indication. Paul, a PharmCo sales representative, thinks Dr. Brown would be an excellent candidate for the panel. During his next meeting with Dr. Brown, Paul asks Dr. Brown to participate in the recurring expert panel, offering a percentage of product sales as compensation for Dr. Brown's time and advisory services.

Should Dr. Brown be compensated in this manner? Does this implicate the Federal Anti-Kickback Statute?

Key Takeaway Concepts

- This law is counterintuitive. Common sense is not enough.
- Government believes decisions that **increase government healthcare program costs** are **inherently suspect**
- Government tends to **infer intent** from **structure, such as “secretive” arrangements**
 - Government expects “transparency”

Key Takeaway Concepts (cont'd)

- Activities that **threaten patient health** will be aggressively pursued
- Government's leverage gives it power to reject "legal" defenses
- Government tends to articulate policy or programmatic issues as enforcement matters

Key Takeaway Concepts (cont'd)

- Fraud and abuse risks interact with one another
 - AKS, off-label promotion, and price reporting issues are a common example
- Context is critical to evaluating and managing the risks

Examples of Non-Compliant Activities

- **Off-label promotion:**

- Promoting drugs for uses not approved by the FDA (GlaxoSmithKline LLC, 2012 settlement for \$3 billion)

- **Kickbacks:**

- Offering payments to physicians for prescribing the company's products (Amgen, 2013 settlement for \$762 million)

Examples of Non-Compliant Activities

- **Price Reporting:**

- Inflated pricing information causing Medicaid to overpay for drugs (McKesson, 2012 settlement for \$190 million)

- **False Statements:**

- Unsubstantiated claims about the efficacy of drugs (Boehringer Ingelheim Pharmaceuticals, Inc., 2012 settlement for \$95 million)

CONSEQUENCES OF NON- COMPLIANCE

Consequences of Non-Compliance

- Damage to company integrity and reputation
- Patient and provider confidence shaken
- Becoming a government target
- Corporate Integrity Agreements
- OIG Exclusion
- Challenges in recruiting and retaining employees

Enforcement Environment: Recent Settlements

Company	Alleged Illegal Conduct	Theories of Liability	Fine (total)	Date
Novartis	SP performance based discounts and adherence programs	FCA, AKS	\$390 million	Nov 2015
Warner Chilcott	Reimbursement support activities	FCA, AKS, criminal health care fraud	\$125 million	Oct 2015
Johnson & Johnson	Off-label promotion of Risperdal, Invega, and Natrecor; kickbacks to long-term care pharmacy and providers	FCA, criminal FDCA, AKS	\$2.2 billion	Nov 2013
Wyeth Pharmaceuticals (Pfizer)	Off-label promotion of Rapamune; kickbacks in connection with speaking, continuing education events, and grants for studies	FCA, criminal FDCA, AKS	\$491 million	Jul 2013
Ista Pharmaceuticals	Reimbursement support activities; off-label promotion of Xibrom; kickbacks in the form of free samples, and speaker fees, sponsorships	FCA, AKS, criminal conspiracy	\$33.5 million	May 2013
Sanofi-Aventis	Kickbacks through distribution of free Hyalgan	FCA, AKS	\$109 million	Dec 2012
Amgen	Off-label promotion of Aranesp, Enbrel, and Neulasta; kickbacks to induce purchase of these and other drugs	FCA, criminal FDCA, AKS	\$762 million	Dec 2012

Corporate Integrity Agreements

- CIA is a contract with the OIG
 - Negotiated with OIG as part of resolving claims or investigations brought by or on behalf of the federal government
- Requires ongoing compliance
- Imposes structural, programmatic, and reporting obligations

Corporate Integrity Agreements (cont'd)

- May prohibit company from providing compensation to sales force based on drug/device sale volume
- May impose restrictions on future promotion of products
- Company can be excluded from federal health care programs for material breach of CIA

OIG Exclusion

Depending on the nature of the underlying misconduct, OIG may be required or authorized to exclude a company or individual from participation in the Federal health care programs.

- Mandatory Exclusion – OIG must exclude for various reasons, including:
 - Conviction of program-related crimes
 - Felony conviction relating to health care fraud
- Permissive Exclusion – OIG may exclude an entity or individual for various reasons, including:
 - Fraud, kickbacks, submission of false claims, and other prohibited activities



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Hypothetical Situations

Selling to the “Hard-to-Reach” Physician

Jake, a sales representative for a pharmaceutical company that manufactures a leading AIDS drug, invites a physician out for a round of golf and lunch at a nearby country club. This physician, who mainly provides services to HIV/AIDS patients, is usually very busy and difficult to see in her office. Jake believes that the best way to reach the physician is by scheduling an out-of-office visit. The cost of the golf and the lunch combined are \$65.

WHAT DO YOU THINK: Is it ok for Jake to meet schedule this type of out-of-office visit?

Hypothetical #3:

There's No Such Thing as Free Meds

Susie is a nurse practitioner in an office that provides care to older adults, many of whom have hypertension and osteoarthritis of the knee.

Susie recently met with a sales representative from a pharmaceutical company who regularly visits this practice to discuss the company's latest product line.

During their last visit, Susie informed the sales representatives of the financial constraints many of her patients face.

Wanting to help those who could not afford the drugs, the sales rep provided Susie with a large amount of samples of various medications for hypertension and osteoarthritis so they could be distributed to needy patients.

WHAT DO YOU THINK: Is it okay to provide samples? Aren't you grateful to receive samples from your doctor?

Hypothetical #4:

Relationship Building – No Gifts

Christina, a pharmaceutical sales representative, has a strong working relationship with ABC Physician Group. Christina has been calling on ABC Physician Group for years and has good relationships with the physicians, mid-level practitioners and front office staff. As the holiday season approaches, Christina decides that she will provide the office with a large gift basket as a gesture of her appreciation.

Should Christina provide ABC Physician Group with a holiday gift basket?
Does this implicate the Federal Anti-Kickback Statute?

Hypothetical #5:

What Is An Educational Item?

Brian, a sales representative for a pharmaceutical company, is meeting with a physician. Their discussion turns to how the physician is making his office “paperless” and is using tablets instead of paper. Brian would like to assist the physician in his efforts and understands that he can provide “educational items” to physicians. Accordingly, Jake thinks that he may be able to provide the physician with iPads, so long as they are loaded with an app that provides the physician with access to the most recent academic studies involving his company’s pharmaceutical products.

Is the iPad an educational item?

Hypothetical #6:

Retaining Physician Consultants

PharmCo is seeking to obtain FDA approval of a new indication for one of its existing products and is assembling a panel of physician experts to discuss the proposed indication. Paul, a PharmCo sales representative, thinks Dr. Brown would be an excellent candidate for the panel. During his next meeting with Dr. Brown, Paul asks Dr. Brown to participate in the recurring expert panel, offering a percentage of product sales as compensation for Dr. Brown's time and advisory services.

Should Dr. Brown be compensated in this manner? Does this implicate the Federal Anti-Kickback Statute?

Hypothetical #7:

Speaker Programs

Mark, a device company's sales representative, has met Dr. Sorenson on several occasions and has found him to be intelligent, articulate, and a strong supporter of the company's products. The company does not have any speaker programs currently scheduled, and company leadership has not identified a need for speakers at the moment. Nevertheless, assuming that the company might want speakers down the line, Mark executes a consulting agreement with Dr. Sorenson, using a generic description of the services to be provided to allow for flexibility in the future.

Should Mark have retained Dr. Sorenson as a consultant? Is the type of description provided in the consulting agreement appropriate? Does this implicate the Federal Anti-Kickback Statute?

Hypothetical #8 (cont'd from Hypo#7): Speaker Training Sessions

Months later, MegaPharma's leadership team decides to roll out a series of speaker programs focused on one of the company's therapeutic areas of interest. Several of the selected physician speakers fall within Mark's call area, so Mark is tasked with coordinating the logistics for the speaker training session. Mark, wanting to provide high-quality service to the physicians, chooses the Ritz Carlton as the training venue. Since many of the physicians will be traveling for the training, he also makes dinner reservations at the nicest restaurants in the city as a gesture of hospitality.

Are the selected venues and dinners appropriate for the training program? Do such selections implicate the Anti-Kickback Statute?

Penalties for FCA

Severe Consequences of FCA Liability

- Treble damages
- Civil penalties of \$5,500-\$11,000 *per claim*
- Exclusion: individual or corporate
- Civil monetary penalties
 - Up to \$50,000 fine for each violation
 - Permissive exclusion
- Criminal penalties
 - Up to 5 years imprisonment and a \$250,000 fine for an individual, or a \$500,000 corporate fine
 - Criminal liability is imposed under separate statutory provisions that criminalize general false claims to the Government as well as false health care claims