

A vertical sidebar on the left side of the slide, set against a dark blue background. It contains several white line-art icons: a stethoscope, a hand holding a pulse oximeter, a large medical syringe, a clipboard with a checklist, a computer monitor displaying a person's profile, and another clipboard with a checklist.

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Assoc. of Healthcare Internal Auditors

40th Annual Conference

The Vaccine for Your Healthcare Internal Audit Risks

September 27 – October 1, 2021

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Conflict of Interest

A Key Consideration in Physician Financial Arrangements

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About PYA

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- Operations optimization
- Risk assessments
- IT advisory
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- Fair market value and commercial reasonableness assessments
- Business valuations
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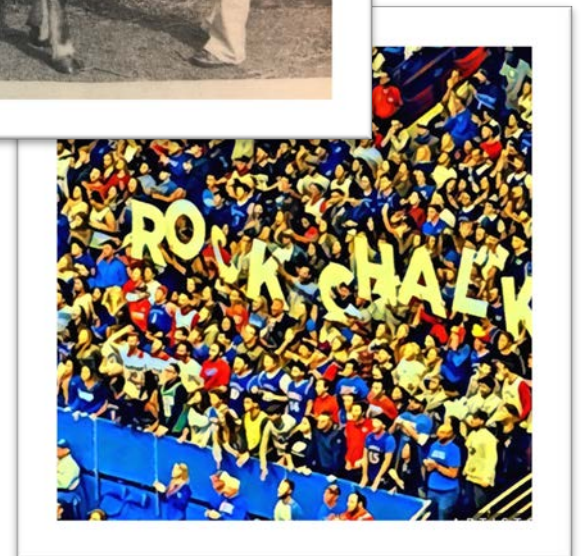
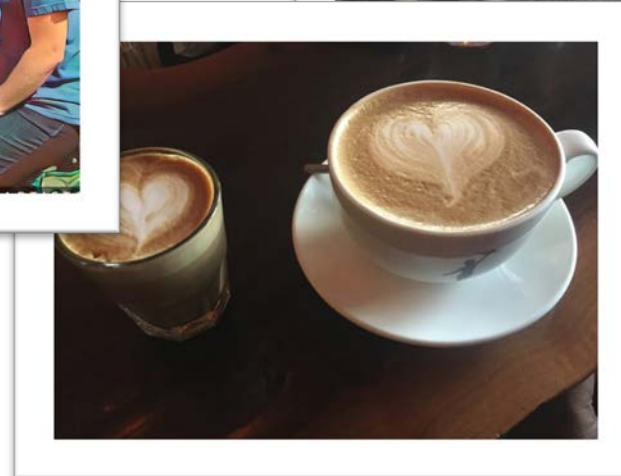
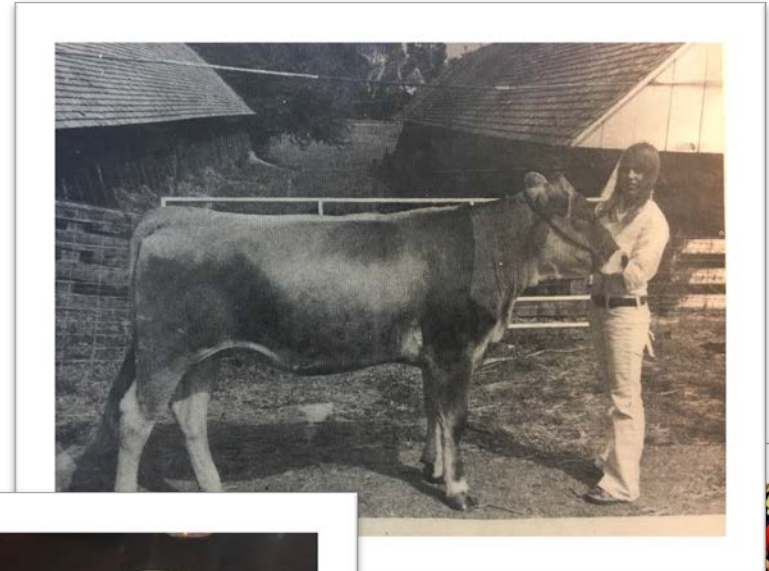
Introductions!

Susan Thomas, beyond the suit...



Susan Thomas

MHSA, CHC, CIA, CRMC,
CPC, CCSFP, CHIAP
Senior Manager

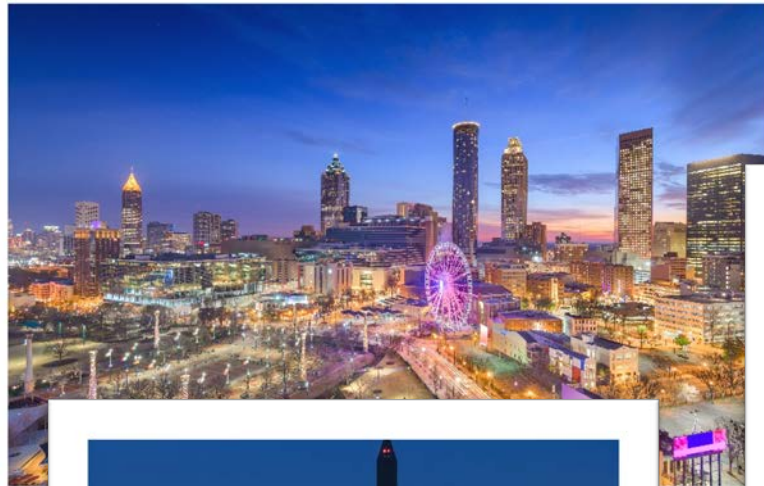




Introductions! Tynan Kugler, beyond the suit...



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Polling Question #1



Topics for Discussion

- Federal Regulations that Affect Physician Compensation Arrangements
- Physician Conflict of Interest (COI) Defined
- Sunshine Act and CMS Open Payments Database
- Speaker Programs
- Industry Position on Physician COIs
- Impact of Inaccurate COI Disclosures
- Tips and Tools for a Robust COI Process
- Bringing It All Together...
- Physician COI Case Studies



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A little humor...



*“We’re going to parachute in and do a surprise audit,
but I want to keep the whole thing low-key.”*



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Federal Regulations that Impact Physician Compensation Arrangements



The Stark Law: A Refresher

- In general, if a physician has a direct or indirect financial relationship with a designated health services (DHS) entity:
 - The physician may not make a referral to that entity for the furnishing of DHS for which payment otherwise may be made under Medicare; and
 - The entity may not bill Medicare, an individual, or another payor for the DHS performed pursuant to the prohibited referral:
 - DHS includes clinical lab, physical therapy, occupational and speech therapy, radiology and certain other imaging services, radiation therapy services and supplies, durable medical equipment, parenteral and enteral nutrients, drugs and supplies, prosthetics and orthotics, home health services, outpatient prescription drugs, and inpatient and outpatient services.
- ...Unless a specific exception applies
- Strict liability law



Key Stark Law Concepts

- From CMS' "eye":
 - Fair Market Value (FMV) = Did the calculation result in compensation that is fair market value for asset, item, service, or rental property?
 - Commercially Reasonable (CR) = Does the arrangement make sense as a means to accomplish the parties' goals?
 - Volume or Value Standard = How did the parties calculate the remuneration?



FMV Definition

- In general, the value in an arm's length transaction, consistent with the general market value of the subject transaction
- General market value means:
 - **Assets:** The price that an asset would bring on the date of acquisition of the asset as the result of bona fide bargaining between a well-informed buyer and seller that are not otherwise in a position to generate business for each other.
 - **Compensation:** The compensation that would be paid at the time the parties enter into the service arrangement as the result of bona fide bargaining between well-informed parties that are not otherwise in a position to generate business for each other.
 - **Rental of Equipment or Office Space:** The price that rental property would bring at the time the parties enter into the rental arrangement as the result of bona fide bargaining between a well-informed lessor and lessee that are not otherwise in a position to generate business for each other.



Applications of New FMV Definition

- “General market value” is not “market value”
- “A hospital may not value a physician’s services at a higher rate than a private equity investor or another physician practice...we recognize that reliance on similar transactions in the marketplace could simplify the process of determining FMV for purposes of the MD self-referral law, but adopting such a standard would allow parties to consider additional (or investment) value to certain types of entities, skewing the buyer-neutral fair market value.”¹
- Any CR methodology may be used to establish FMV

1. <https://www.federalregister.gov/d/2020-26140/p-416>



CR Definition

- Commercially reasonable means “... that the particular arrangement furthers a legitimate business purpose of the parties to the arrangement and is sensible, considering the characteristics of the parties, including their size, type, scope, and specialty. An arrangement may be commercially reasonable even if it does not result in profit for one or more of the parties.”²

2. <https://www.federalregister.gov/d/2020-26140/p-1154>



Applications of New CR Definition

- Determination of CR “is not one of valuation”
- Arrangements may appear to further legitimate business purposes but may not be CR
- What is “sensible”?
 - It is not good enough just to have a legitimate business purpose—execution/ongoing re-evaluation counts
 - Examples of legitimate business purposes
 - Addresses community need
 - Provides timely access to healthcare services
 - Fulfills licensure or regulatory obligations (e.g., Emergency Medical Treatment and Active Labor Act)
 - Provides charity care
 - Improves quality and health outcomes



Volume or Value Standard

- New “special rule” defining compensation methodologies that are considered to “take into account the volume or value of referrals or other business generated”³
- Addresses compensation paid to a physician or immediate family member (IFM) of a physician by a DHS entity, and from a physician (or IFM) to a DHS entity
- CMS developed a two-part test to determine whether an arrangement meets the volume or value standard
 - Does a mathematical physician compensation formula exist that includes DHS referrals or other business generated as a variable?
 - If the answer to Question #1 is “Yes,” then does a physician’s compensation increase or decrease based on a positive or negative correlation with the physician’s referrals or other business generated?

3. <https://www.federalregister.gov/d/2020-26140/p-260>



The Anti-Kickback (AKS) Statute: A Refresher

- Prohibits knowing and willful offer or receipt of remuneration intended to induce or arrange for referrals of business paid for by federal healthcare programs
- “One Purpose” test
 - Violation does not require actual knowledge of AKS or specific intent
 - Claim for items or services resulting from AKS violation constitutes a false claim under the False Claims Act
- Arrangements are not necessarily unlawful because they do not fit in a safe harbor – would be reviewed based on the totality of their facts and circumstances, including the intent of the parties



Polling Question #2



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Physician COI defined



COI Defined

- Conflict of interest describes a situation in which a person is or appears to be at risk of acting in a biased way because of personal interests.
- Physician (individual) COI may arise when there is conflict between the interest of the physician and those of his/her patients.
- Interactions between physicians and industry representatives, when not properly managed, may lead to the compromising of professional values or negative effects on the physician-patient relationship.



Physician-Industry Relationship

- A physician's goal is to provide good patient care.
- Pharmaceutical and medical device companies develop, produce and market drugs and products to treat various ailments or disorders. Their goal is to maximize product sales.
- Physicians are a main conduit for sales, which have made them an ideal target for marketing strategies.



Key Opinion Leaders (KOL)

- Trusted influencer with proven expertise
- Distinguish themselves in one or more ways
 - Spoken at a national conferences or events
 - Published their research in medical journals
 - Participated in a significant number of clinical trials
- Pharmaceutical, medical device and other companies often consult with KOLs to
 - Provide insight into a specific disease state
 - Inform clinical trial design
 - Participate in product development and improvement
 - Assist with “go-to-market” messaging



Common Vendor Interactions

- Promotional Items (pens, notepads, hand sanitizer, water bottle)
- Education on the safe and effective uses of products
- Arrangements for consulting fees for services
 - Peer-to-peer training
 - Medical advisory boards
 - Speaker's fees
- Royalty payments for services and inventions
- Charitable giving
- Questionable consulting agreements or clinical studies



Industry Guidelines

- American Medical Association (AMA)
- Association of American Medical College (AAMC)
- American College of Physicians (ACP)
- Accreditation Council for Continuing Medical Education (ACCME)
- Office of Inspector General (OIG) Department of Health and Human Services (HHS)
- Pharmaceutical Research and Manufacturers of America (PhRMA)
- American Medical Technology Association (AdvaMed)



Reality Check

- Prescribing practices of physicians may be influenced by both subtle and obvious marketing messages and gifts.
- Physicians may not recognize or admit to any changes in their practice of medicine due to these influences.
- Medical students and residents who report higher levels of pharmaceutical marketing interactions were more likely to prescribe brand name drugs and less likely to rely on evidence-based treatment options.⁴

4. Austad KE, Avorn J, Franklin JM, Campbell EG, Kesselheim AS. Association of Marketing Interactions With Medical Trainees' Knowledge About Evidence-Based Prescribing: Results From a National Survey. JAMA Intern Med. 2014;174(8):1283–1290. doi:10.1001/jamainternmed.2014.2202



Polling Question #3



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Sunshine Act and CMS Open Payments Database



Sunshine Act Background

- Financial relationships between physicians and medical product manufacturers are common:
 - Include everything from free meals, to consulting or speaker fees, to direct research funding
 - Can have many positive outcomes—particularly in the context of consulting and research funding—but can also create COIs



Sunshine Act Background

- The majority of physicians have had some form of financial interaction with manufacturers of drugs, devices, biologicals, and medical supplies
- There is a growing awareness among researchers and policy makers of the ways that physician-industry relationships can bias physician decision making, encourage inappropriate prescribing, and undermine the clinical independence and validity of research
- Over the past decade, many healthcare organizations and professional associations have implemented conflict-of-interest policies aimed at mitigating industry influence on health decision making
- There have been attempts to increase transparency around these financial relationships, in the hopes that disclosure would help to reduce their negative consequences without unnecessarily blocking constructive partnerships



Sunshine Act Reporting Process

Who must report payments?	<ul style="list-style-type: none">▪ All drug, biologic, and medical device manufacturers who manufacture one or more products that are covered for payment under Medicare, Medicaid, or CHIP▪ GPOs and physician-owned distributors of medical devices
What kind of providers must be reported on?	<ul style="list-style-type: none">▪ All licensed physicians – MDs, DOs, Dentists, Podiatrists, Optometrists, Chiropractors▪ Teaching hospitals that receive direct or indirect GME funding from Medicare
What must be reported?	<ul style="list-style-type: none">▪ General payments, in-kind items or services, consulting and speaker fees, gifts, honoraria, travel and entertainment expenses, meals, education, charitable contributions, and grants▪ Ownership or investment interests by physicians and immediate family members▪ Research payments for clinical investigations
What does not need to be reported?	<ul style="list-style-type: none">▪ A payment less than \$10, unless total payments exceed \$100 per year▪ Product samples, discounts and rebates, in-kind for charity care, educational materials for patients, loaned devices for research, warranty services share in publicly traded mutual funds
What is the timeline for reporting?	<ul style="list-style-type: none">▪ Manufacturers and GPOs must complete their reporting by the 90th day of the following calendar year— usually March 31
What are the consequences for failure to report?	<ul style="list-style-type: none">▪ Manufacturers and GPOs may be fined \$1000-\$10,000 per unreported payment up to an annual maximum of \$150,000▪ For deliberately failing to report, fines can be \$10,000-\$100,000 per payment up to a maximum penalty of \$1,000,000 per year



CMS Open Payments

- The database reports payments made to physicians by the drug and device manufacturers
- Given the potential for financial COIs relating to patient outcomes, analysis of data is valuable for provider organizations



Database Requirements

- CMS must publish the data online, available publicly
- Must be searchable and understandable
- Must be able to be aggregated and downloaded
- Must include any enforcement activities taken
- Will not include physician NPI numbers




Open Payments Database

- Available at:

<https://openpaymentsdata.cms.gov/>

OpenPaymentsData.CMS.gov

Home Search Tool Summary Data Data Explorer Download Data About Take Survey Sign in



Search Open Payments

The Open Payments Search Tool is used to search payments made by drug and medical device companies to physicians and teaching hospitals.

Search Physician, Teaching Hospital, or Company by Name

Or use the [Refined Search](#)

Open Payments data is from August 2013 to December 2019 – See About page

The Facts on Open Payments

Year: 2019

Icon	Value
	Total US Dollar Value 10.03 Billion
	Total Records Published 10.98 Million

[Explore the Facts on Open Payments Data](#)

Data Tools

[Search](#) [Advanced Search](#) [Data Explorer](#) [Download Data](#)



Polling Question #4



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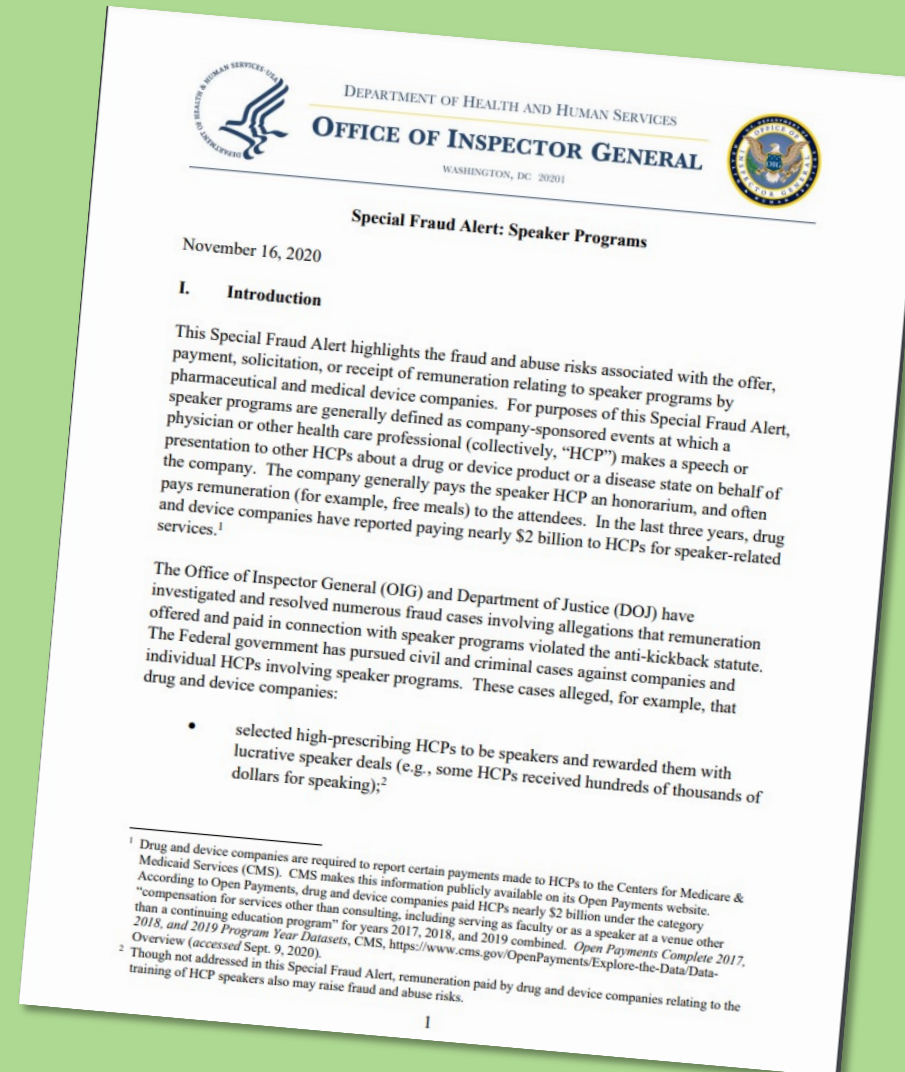
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Speaker Programs



Special Fraud Alert: Speaker Programs






Speaker Programs

- Remuneration opportunities under scrutiny include
 - Speaker compensation amounts
 - Speaker prescribing patterns
 - Number of times a speaker presents on behalf of a company
 - Audience selection and attendance
- Concern that participation may alter clinical decision-making instead of focusing on patient's best interest
- Knowing and willful offers or acceptance of remuneration without legitimate and supportable business interest may be subject to criminal, civil and administrative repercussions



Repercussions

- 2016
 - Salix Pharmaceuticals
- 2019
 - Insys Therapeutics
 - Avanir
- 2020
 - Novartis
- **2021** 

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Doctor loses license, pays \$100K fine in health care kickback scheme

LEAWOOD — A Leawood physician has surrendered his medical license after admitting that he told a drug company he would not sell one of its products unless he was hired for more speaking engagements.



“Suspect Characteristics”

- Little or no substantive information is actually presented
- Alcohol is available or a meal exceeding modest value is provided to attendees (free alcohol heightens concern)
- Program held at location not conducive to exchange of educational information
- Large number of programs sponsored on same or substantially same product
- Significant period of time with no new medical or scientific information



“Suspect Characteristics” (cont’d)

- Attendees include individuals who don’t have legitimate business reason to attend the program or have no use for the information
- Company’s sales and marketing units influence the selection of speakers based on past or expected revenue that speakers or attendees have or will generate
- Company pays speaker more than FMV for speaking service or pays compensation that takes into account the volume or value of past or potential future business generated



Polling Question #5



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Industry Position on Physician COIs



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When a doctor's ability to act in the best interests of a person or group could be affected by relationships with other people, groups, or businesses, then a COI exists. Even when doctors think they are acting without bias, their judgments and actions may still be influenced by COI.

JAMA Network. Conflict of Interest in Medicine. 5/2/2017



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Conflict of interest does not mean that physicians are biased or that they have inflicted harm. It simply means that there is a risk of bias, which can occur through subconscious forces.

Intensive Care Medicine. Conflicts of Interest and the Patient-Doctor Covenant. 7/6/2018

Nine out of 10 medical professional bodies think patients have a right to know if their doctor had financial or other links with pharmaceutical or medical device companies.

The BMJ Briefing: Why do we need a mandatory register of doctors' interests? 5/20/2021



Recommended Best Practices

- Meals and Educational Gifts
 - The category of “practice related gifts” is eliminated.
 - Items that do not advance disease or treatment education should not be offered to physicians.
- CME and Other Educational Events
 - **Funding:**
 - Vendor funding should go to conference sponsor
 - Meeting sponsor should fully disclose financial support from vendor
 - **Content:**
 - Program should be unbiased assessment of therapeutic options
 - No vendor control over program content



Recommended Best Practices

- Consultant Agreements
 - Establish objective criteria for selection of physician consultants or advisors
 - Maintain records about how the company used/considered consultant's work product
 - Payment for services provided are FMV
- Writing Articles
 - **Transparency:** Physicians should disclose any related financial interests
 - **No Ghost Writing:** Physicians should not allow articles to be published under their own name if the article has been written in whole or in part by vendor employees



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Polling Question #6



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Impact of Inaccurate COI Disclosures



Physician Preference

- Per the OIG “[P]hysician-industry interactions can provide tangible benefits to patients and the advancement of medical science. These interactions can also create COIs that, if not managed effectively, can pose significant challenges to medical professionalism and undermine the integrity of the Nation’s health care system.”⁵
- OIG concluded that gifts and offers of value to physicians appear to affect physicians’ prescribing decisions and some practices may indeed be illegal, violating the AKS⁶
- These reports set the stage for the Sunshine Act.⁷

5. OIG Senate Special Committee on Aging Hearing: 2/27/2008

6. OIG, Promotion of Prescription Drugs through Payment and Gifts (OEI-01-90-00480) (Aug. 1991), available at <http://oig.hhs.gov/oei/atod.html>.

7. Section 6002 of the Patient Protection and Affordable Care Act Health-related Portions of the Health Care and Education Reconciliation Act of 2010



Trust and Reputation

- Financial incentives can influence the judgment of well-motivated, well-meaning physicians
- Be aware of payments that may improperly influence medical decision making
 - Payments can be for legitimate services but be wary of situations where companies derive little value for these services beyond increased sales
 - For some interactions (e.g., consulting arrangements) make sure work is actually being performed



Hypotheticals

- Orthopedic surgeon
 - Data reported on Open Payments showed that the physician had received significant royalty payments from a company who sells implant devices
 - Annual Conflict of Interest Disclosure Form does not include these payments
 - Physician influences the Products Committee regarding which implant devices to stock for ortho procedures
 - Review of surgical cases for the surgeon reveals use of device in significant number of patient procedures
 - Review of medical necessity is warranted to ensure patient care was not compromised due to financial influence



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Tips and Tools for a Robust COI Process



Questions

- Does the vendor interaction have the potential to:
 - Interfere, skew, influence, undermine:
 - Medical decision-making?
 - Clinical integrity of a formulary process?
 - Increase costs to the federal health care programs, beneficiaries, or enrollees?
 - Promote increased and/or inappropriate utilization?
 - Raise patient safety or quality of care concerns?



Guidelines for Appropriate Vendor Interaction

- Proper basis for vendor interaction with Providers must be for at least one of the following:
 - Benefit to patients
 - Enhance medicine
 - Inform about products
 - Provide scientific/educational information
 - Support legitimate medical research



General Policies: Conflict of Interest

- Does the organization have a Conflict of Interest (COI) policy and procedure?
 - Is there a code of conduct which outlines permitted/not permitted activities?
- Is the COI policy applicable to all employees, board members, and physicians, including medical staff?
- Does the COI policy address relationships with vendors, including:
 - Consulting arrangements
 - Speaker Fees
 - Travel
 - Meals
 - Entertainment
- Is there a vendor relationship policy for physician practices, and has this policy been communicated to such vendors?



General Policies: CMS Open Payment Registry

- Does the organization have a procedure for reviewing the CMS Open Payment Registry and does it include the following?
 - Frequency of review (upon hire, upon contract initiation, upon credentialing, etc.)
 - Dollar threshold for review (e.g., \$5,000; \$10,000; etc.)
 - Research and resolution of any reportable events
 - Analysis of potential conflicts, such as serving in a medical decision-making capacity related to the drug or device manufacturer
 - Monitoring of OIG/DOJ enforcement activities related to
 - drug or device manufacturers and relationships with current employees/contractors/medical staff
 - Reporting of analysis to management and governance



Open Payments Registry Checklist

www.pyapc.com/insights/cms-open-payment-registry-review-checklist/

CMS Open Payment Registry Review Checklist

	Yes	No
General		
Does the organization have a Conflict of Interest (COI) policy and procedure? Is there a code of conduct which outlines permitted/not permitted activities?	<input type="checkbox"/>	<input type="checkbox"/>
Is the COI policy applicable to all employees and physicians, including medical staff? Does the COI policy address relationships with vendors, including consulting arrangements, honorarium, travel, meals, and entertainment?	<input type="checkbox"/>	<input type="checkbox"/>
Does the organization have a procedure for reviewing the CMS Open Payment Registry and does it include the following?	<input type="checkbox"/>	<input type="checkbox"/>
- Frequency of review (upon hire, upon contract initiation, upon credentialing, etc.)	<input type="checkbox"/>	<input type="checkbox"/>
- Dollar threshold for review (e.g., \$5,000, \$10,000, etc.)	<input type="checkbox"/>	<input type="checkbox"/>
- Research and resolution of any reportable events	<input type="checkbox"/>	<input type="checkbox"/>
- Analysis of potential conflicts, such as serving in a decision-making capacity related to the drug or device manufacturer	<input type="checkbox"/>	<input type="checkbox"/>
- Monitoring of OIG/DOJ enforcement activities related to drug or device manufacturers and relationships with current employees/contractors/medical staff	<input type="checkbox"/>	<input type="checkbox"/>
- Reporting of analysis to management and governance	<input type="checkbox"/>	<input type="checkbox"/>
Is there a person/department responsible for auditing COIs?	<input type="checkbox"/>	<input type="checkbox"/>
Is there a vendor relationship policy for physician practices, and has this policy been communicated to such vendors?	<input type="checkbox"/>	<input type="checkbox"/>
CMS Open Payment Registry		
Have the COI forms been reviewed and compared to the CMS Open Payment Registry?	<input type="checkbox"/>	<input type="checkbox"/>
Are there reportable events under the policy?	<input type="checkbox"/>	<input type="checkbox"/>
Are any physicians in a decision-making capacity, whereby they may influence purchasing decisions for pharmaceuticals or medical devices? This includes medical directors, product selection committee, drug formulary committee, etc.	<input type="checkbox"/>	<input type="checkbox"/>
Is there a person/department responsible for auditing COIs?	<input type="checkbox"/>	<input type="checkbox"/>
Is the proportion of time spent speaking, traveling, etc., appropriate?	<input type="checkbox"/>	<input type="checkbox"/>
Full-time employees?	<input type="checkbox"/>	<input type="checkbox"/>
Part-time employees?	<input type="checkbox"/>	<input type="checkbox"/>
Are these activities provided for in existing employment agreements?	<input type="checkbox"/>	<input type="checkbox"/>
Should any of the consulting fees/honoraria have been paid to the health system?	<input type="checkbox"/>	<input type="checkbox"/>
Is there a written contractual agreement between the physician and the vendor?	<input type="checkbox"/>	<input type="checkbox"/>
Is this agreement kept on file?	<input type="checkbox"/>	<input type="checkbox"/>
Are the fees reasonable?	<input type="checkbox"/>	<input type="checkbox"/>
Has an inventory of physician relationships with vendors (per the Open Payment Registry) been compared with the vendor listing to determine if any physicians, either on medical staff or employed, have existing arrangements with vendors utilized by the health system?	<input type="checkbox"/>	<input type="checkbox"/>

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Speaker Programs

	Yes	No
Is the information available through other means that do not involve remuneration (e.g. various online resources, medical journals)?	<input type="checkbox"/>	<input type="checkbox"/>
Is the event held in a location that is not conducive to learning (e.g. entertainment or sports venue)?	<input type="checkbox"/>	<input type="checkbox"/>
Has there been little to no new developments related to the pharmaceutical or medical device?	<input type="checkbox"/>	<input type="checkbox"/>
How was the provider selected to attend the speaker program (e.g. high prescriber, ordering physician for device)?	<input type="checkbox"/>	<input type="checkbox"/>
Has the organization assessed whether the remuneration is above Fair Market Value?	<input type="checkbox"/>	<input type="checkbox"/>
Is the information relevant to the selected audience?	<input type="checkbox"/>	<input type="checkbox"/>

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Polling Question #7



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Bringing It All Together . . .

How to consider potential conflicts in Physician Financial Arrangements



In a Nutshell...

- Review applicable federal, state, and organizational guidelines, policies and procedures relative to COIs
- Review industry guidelines specific to COIs
- Review existing COI policy and/or develop one if not already in place
- Identify all applicable areas for potential COI
- Evaluate process for identifying physicians or other providers who may have COIs
- Evaluate process for employee disclosure of all potential COIs (e.g., financial interests, other participation)
- Review and identify vendors who may interact with physicians or other providers



In a Nutshell...

- Implement effective strategies to minimize development of COI such as:
 - Assign independent personnel to monitor an employee's research activities.
 - Require review and approval of research projects of other endeavors that may be subject to a potential conflict.
 - Conduct annual review of Open Payments database.
 - Conduct annual internal review to identify potential issues.
 - Identify and review all individuals that may be subject to potential COIs.
 - Cross check individuals with purchasing department activities.
 - Compare to internal policies and conduct additional analyses as necessary (e.g., FMV, CR).
 - Define and audit compliance with process for addressing COI to include required modification of conflicted services or activity or divestiture or withdrawal from conflicted activity.



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Physician COI Case Studies



Physician COI Case Studies

1. ED Physician plead guilty to soliciting and receiving kickbacks from a sales representative for several medical companies that supplied surgical equipment and devices that the physician utilized
2. A biotechnology testing company settled allegations that it provided meals and happy hours for physicians and their employees to induce the ordering of their tests.
3. A physician assistant settled allegations that it solicited and accepted meals, gift cards, gifts, and compensation from speaking engagements, advisory boards, and consulting services from a pharmaceutical company in exchange for prescribing the company's drugs.
4. A medical device manufacturer settled allegations that it provided physicians, medical practices, and hospitals with free advertising assistance, practice development, practice support, and purported educational grants to induce the purchase and use of its products in medical procedures.



Polling Question #8



Thank you!



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