

# Conflicts of Interest in Health Care

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Aaron Narva  
CEO  
Conflixis



Judy Ringholz, RN, JD  
Founder & Principal  
Sage Compliance Advisors



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## Conflicts of interest can be found throughout the US Healthcare System.

**The Boston Globe**

Brigham President resigns from  
Moderna Board after Conflict of  
Interest Questions Raised  
July 2020

**PROPUBLICA**

Memorial Sloan Kettering  
Leaders Violated Conflict-of-  
Interest Rules Report Finds  
April 2019

**The New York Times**

What These Medical Journals  
Don't Reveal: Top Doctors' Ties to  
Industry  
December 2018

**CNBC**

Biogen to pay \$900 million to settle  
allegations it paid doctors kickbacks to  
prescribe drugs  
Sept. 2022



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## **Conflict of Interest – Definition**

A situation that might compromise an individual's judgment, decisions, and/or actions in the workplace because of their own or an immediate family member's personal interests or financial interests related to an outside activity.



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## **Actual Conflict of Interest**

An actual conflict of interest exists when there is a direct conflict between an individual's work-related duties and responsibilities and their personal/financial interests or those of an immediate family member influence and affect the performance of those duties.



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## Appearance of Conflict of Interest

An appearance of a conflict exists when an individual is involved in a particular matter involving outside parties (including individuals, corporate entities, etc.) and the circumstances are such that a reasonable person with knowledge of the relevant facts might question the individual's impartiality in the matter.



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## Conflict of Interest: Enforcement

### False Claims Act

Imposes liability on a person who (or entity that) “knowingly” presents a false claim for payment to the U.S. Government.

No specific intent to defraud required



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## Conflict of Interest: Enforcement

Potential Repercussions:

- Civil penalties and/or criminal enforcement
- Reputational Harm
- Corporate Integrity Agreement
- Licensure/Board issues
- Private liability
- Attorneys' fees and expenses



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## Conflict of Interest: Enforcement

### Anti-Kickback Statute

A criminal law that prohibits the knowing and willful payment of "remuneration" to induce or reward patient referrals or the generation of business involving any item or service payable by any Federal health care program



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## Conflict of Interest: Enforcement

### Stark Law

The Stark Law forbids physicians from directing patients to obtain "designated health services paid for by Federal healthcare programs from any entity in which the physician or their immediate family member has a financial interest, except in circumstances where an exception applies.



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## Compliance and Conflicts of Interest

Health care organizations need a robust COI policy. They also need to collect and manage conflicts disclosures.

### COI Program Best Practices



Policy



Train



Collect

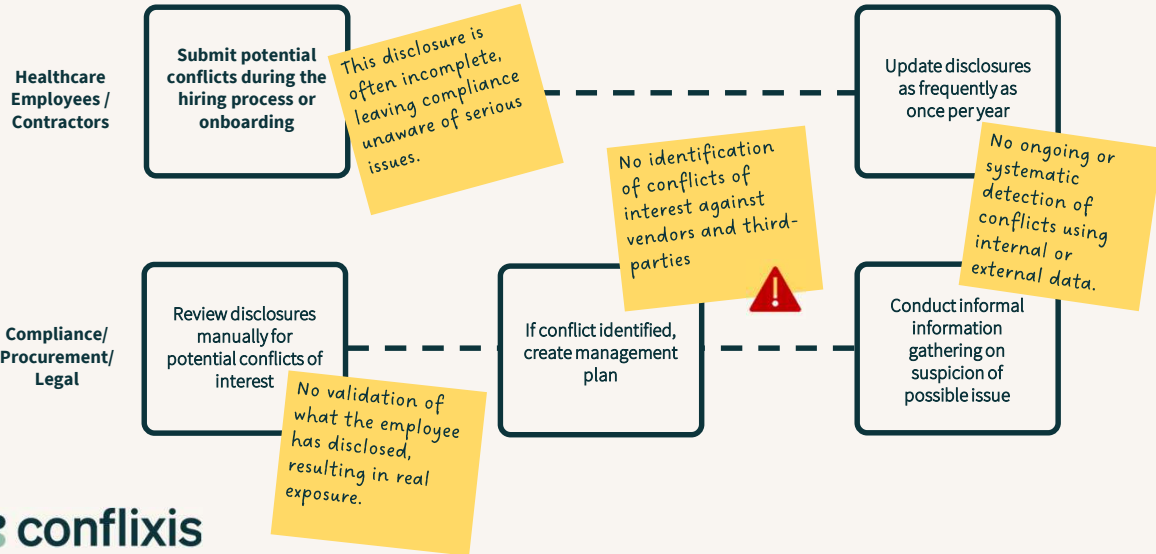


Identify



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## Most organizations have documented conflicts— but are unaware of them.



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## COI Focus Area – Research

HHS regulation 42 CFR Part 50 Subpart F, Promoting Objectivity in Research (FCOI regulation)

Establishes standards that provide a reasonable expectation that the design, conduct, or reporting of NIH-funded research will be free from bias resulting from any Investigator’s conflicting financial interest.

NIH requires recipient institutions and their investigators to fully comply with all FCOI requirements.

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## COI Focus Area – Research

In 2020, the University of Nevada Las Vegas entered into a settlement agreement with the HHS OIG. UNLV refunded \$1.07 million and paid a penalty of nearly \$400,000.

- Subaward payments made by UNLV “were unallowable [...] because they were made to entities with which the principal investigator had an undisclosed conflict of interest.”



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## COI Focus Area – Research

Studies show non-disclosure and under-disclosure of conflicts of interest by physicians are discovered often.

Examination of Potential Industry Conflicts of Interest and Disclosures by Contributors to Online Medical Resource Databases

Journal of the American Medical Association – July 2022

Conclusions: Contributors received \$78 million from pharmaceutical and medical device companies and these payments were often not disclosed.

A Cross-sectional Examination of COI Disclosures of Physician Authors Publishing in High-Impact US Medical Journals

British Medical Journal – April 11, 2022

Conclusions: High payment amounts, as well as high proportions of undisclosed financial compensation comprised potential COIs for two influential US medical journals.

Discrepancies in Self-reported Financial Conflicts of Interest Disclosures by Physicians

British Medical Journal – April 8, 2021

Conclusions: Physician self-reports of financial COI are highly discrepant with objective data sources reporting payments from industry.



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## COI Focus Area – Relationships with Industry

Relationships between providers and the pharmaceutical and medical device industries are very common and can present enforcement repercussions and reputational risks.

Disclosure of these relationships is often inaccurate, despite data being available via Open Payments.



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## HHS OIG released a special fraud alert related to industry speaker programs in 2020.



DEPARTMENT OF HEALTH AND HUMAN SERVICES  
**OFFICE OF INSPECTOR GENERAL**  
WASHINGTON, DC 20201



### Special Fraud Alert: Speaker Programs

November 16, 2020

#### I. Introduction

This Special Fraud Alert highlights the fraud and abuse risks associated with the offer, payment, solicitation, or receipt of remuneration relating to speaker programs by pharmaceutical and medical device companies. For purposes of this Special Fraud Alert, speaker programs are generally defined as company-sponsored events at which a



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## Health System Exposure to Industry Payments: A real example.

A review of Open Payments data for affiliated providers at  
A medium-sized hospital system (2018 – 2022)

- \$24 million in consulting payments to physicians
- \$15.1 million for travel, entertainment, food and beverage
- \$49 million for faculty, speaking and other related fees
- \$102,387 for “gifts” including unspecified \$14,000 gift
- \$47.4 million in ownership/investment interests
- \$8,700 – the most expensive single food payment for a single provider



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## Where Conflicts of Interest and Compliance Meet – Outside Interests

Relationships between employees, contractors and their non-industry  
business interests carry the same risks and are the hardest to detect.

Common Types of Outside Interests:

- Physician Owned Distributorships (PODs)
- Investments in health care business ventures
- Consulting arrangements
- Ownership of other medical businesses
- Ownership of hospital/clinic vendors and suppliers



Notice:  
POD Ownership  
information will  
become publicly  
available in June  
2024.



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## Compliance Program Expectations - COI

Most organizations have documented conflicts, but they are unaware of them.

Regarding Conflict of Interest Disclosures - Develop a process for:

- Distribution and collection of disclosure forms
- Reviewing disclosures
- Managing potential or actual conflicts
- Monitoring compliance with submitting disclosures, as well as implementing and following corrective action plans



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## Compliance Program Expectations - COI

Combine data sets to identify risk.

Employee Contractor  
Disclosure  
Statements

+

Public Records/  
Open Payments/  
Corporate Records

+

Vendor/ Supplier/  
Third Party Data

- Material undisclosed relationships
- = • Material relationships between employees/contractors and vendors
- Identify potential COI before onboarding



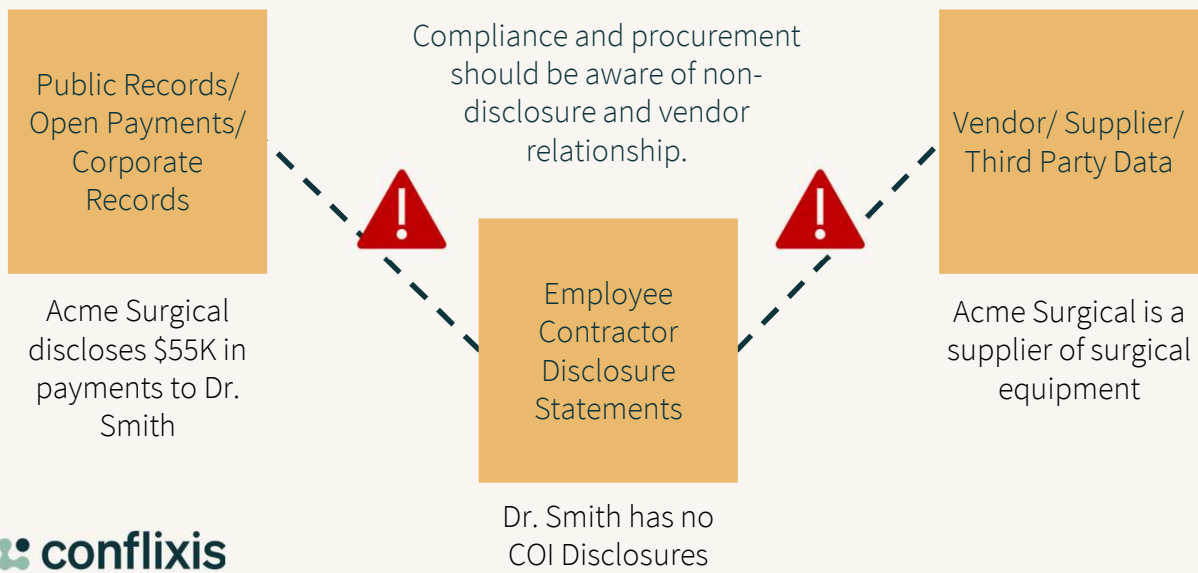
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## Compliance Program Expectations - COI



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## Compliance Program Expectations - COI



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## Compliance Program Expectations - COI

Law enforcement, payers, whistleblowers and others are using data to identify outliers and unusual patterns in healthcare data.

Technology plays a critical role in healthcare fraud investigation, compliance and enforcement. Vast data sets generated by the healthcare industry guide agency decisions at all stages of enforcement.



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## Compliance Program Evaluation

- Prosecutors will evaluate compliance programs at two points in time: when the offense occurred and when the charging decision was made.
- DOJ will also consider how the company has incentivized or sanctioned employee and director behavior—including through compensation plans.
- More broadly, is the compliance program “well designed, adequately resourced, empowered to function effectively, and working in practice”?
- The results of this evaluation could be a factor in determining whether to impose an independent compliance monitor.



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**Thank You!**

Questions?

