Under the Microscope:
Mitigating Risk through Robust Conflict of Interest Processes for Health Systems

WE ARE AN INDEPENDENT MEMBER OF HLB —
THE GLOBAL ADVISORY AND ACCOUNTING NETWORK

Monitoring the conflicts of interest disclosure process in a health system with hundreds or even thousands of providers can be challenging for compliance or internal audit professionals. Combine that onerous task with the increase in outside interests with pharmaceutical or medical device manufacturers whom physicians encounter as they conduct vital research, and you have a perfect storm. Recent government enforcement efforts in conflict of interest related to physician decision-making heighten the importance of developing and maintaining a robust conflict of interest disclosure process.

Conflicting Definitions

Merriam-Webster defines a conflict of interest (COI) as "a conflict between the private interests and the official or professional responsibilities of a person in a position of trust." Others define conflicts distinctly separate from conflicting interests: "Conflicts of interest can influence action, but they are not acts and do not constitute a breach of trust. Furthermore, conflicts of interest are distinct from conflicting interests. Multiple interests often pull people in different directions. But unless such conflicting interests compromise an individual or party's obligations, no conflict of interest exists."[1] Herein lies the question: Can you have a conflict absent an action? Regardless of how one might interpret the existence of a conflict, the mere appearance of a conflict can have consequences from the lack of trust regarding a decision, an action, or an outcome. Reports of conflicts based on appearances can undermine public trust; therefore, apparent conflicts should be evaluated and managed with the same vigor as actual conflicts of interest.

1 *Conflict of Interest in the Pharmaceutical Sector: A Guide for Public Management* Marc A. Rodwin Suffolk University Law School, marcrodwin@gmail.com.

Physician Decision-Making: The Risk of Bias

Physician collaboration in industry research is a vital element in the advancement of medical technologies and pharmacological science and offers important opportunities to advance medical knowledge and corresponding clinical outcomes. This paper explores how medical institutions can mitigate the risk of bias in physician decision-making when conflict opportunities are present, thus also deflecting the risk of organizational and reputational harm. Future papers will explore conflict of interest related to in-depth clinical research and fair market value issues.

Government Enforcement – Anti-Kickback Statute

Recent government enforcement actions within the healthcare space have shed light on the consequences of failing to monitor transactions involving interested parties. For example, pharmaceutical company, Biogen Inc., recently paid a $900 million settlement to resolve allegations related to improper physician payments. In the *qui tam* settlement, the relator alleged that Biogen violated the Anti-Kickback Statute by offering and paying remuneration in the form of speakers' honoraria, training fees, consulting fees, and meals to physicians who spoke at or attended Biogen's speaker programs in exchange for prescribing Biogen's drugs.

In a similar settlement, the U.S. Department of Justice (DOJ) announced a $12.95 million settlement with Biotronik Inc., a medical device manufacturer, to resolve allegations that the company violated the False Claims Act. Whistleblowers who were former independent sales representatives alleged that Biotronik paid kickbacks to physicians in violation of the Anti-Kickback Statute in the form of lavish meals with no legitimate business purpose and provided international business class airfare and honoraria in exchange for making brief appearances at international conferences.

"Paying kickbacks to doctors to influence their selection of medical devices undermines the integrity of federal healthcare programs," said Principal Deputy Assistant Attorney General Brian M. Boynton, head of DOJ's Civil Division. "When medical devices are used in surgical procedures, patients deserve to know that their device was selected based on quality of care considerations and not on improper payments from manufacturers."

The Era of Greater Transparency

These settlements are examples of several recent enforcement actions within the healthcare industry and reflect the catalyst behind the Physician Payments Sunshine Act (PPSA), also known as Section 6002 of the Affordable Care Act (ACT) of 2010. The PPSA requires drug and medical device manufacturers to disclose to the Centers for Medicare and Medicaid Services (CMS) payments made to physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, anesthesiologist assistants, and certified nurse-midwives. Additionally, any physician ownership or investment interests in drug or medical device companies must also be disclosed. These payments and disclosures soon became publicly available. In 2014, CMS created a publicly available and searchable database registry (Open Payments) at https://openpaymentsdata.cms.gov/.

In addition, on November 16, 2020, the Office of Inspector General (OIG) published "Special Fraud Alert: Speaker Programs,"[2] which "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." On January 1, 2023, California became the first state to require physicians to disclose the availability of the Open Payments registry to their patients (California Assembly Bill 1278) and to post an Open Payments database notice in an area that is likely to be seen by all individuals who enter the office in each location where the licensee practices. We anticipate that other states will follow suit as public awareness of these disclosures gains momentum.

While the amount of available data has substantially increased because of the implementation of the PPSA and subsequently the Open Payments registry, the awareness of perceived and actual conflicts in the medical profession has existed for decades, particularly in the clinical research arena. In 2008, the OIG published *How Grantees Manage Conflicts of Interest in National Institutes of Health (NIH) Supported Research Studies*[3]. Also in 2008, the pharmaceutical industry's PhRMA *Code on Interactions with Healthcare Professionals* was revised to specifically address the various scenarios and contracting provisions with providers to avoid conflicts of interest. Federal agencies such as the NIH, as required under HHS regulation 42 CFR Part 50 Subpart F, Promoting Objectivity in Research (Financial Conflict of Interest (FCOI) regulation), must establish standards and related controls to ensure that NIH-funded research will be free from bias resulting from any investigator's conflicting financial interest. Federal regulations, state laws, and hospital policies require that faculty members submit financial disclosure forms at the time a research study proposal is submitted for funding. When a financial interest and possible COI are disclosed, the case is reviewed by an independent committee.

2 https://oig.hhs.gov/documents/special-fraud-alerts/865/SpecialFraudAlertSpeakerPrograms.pdf

3 https://oig.hhs.gov/oei/reports/oei-03-07-00700.pdf

Awareness is Key

While conflicts of interest can occur in a variety of settings and circumstances, three common areas include medical device product selection, drug formulary selection, and clinical research. For the first two areas, medical facilities should determine whether the individuals serving on product or drug selection committees have received any payments from drug or device manufacturers or have substantial investment interests in such companies. As noted previously, an outside interest or investment may not actually result in a conflict unless or until it influences an action that results in personal benefit. Disclosures of outside/financial interests and potential conflicts should be monitored closely and any conflicts declared as part of a standing selection committee meeting. Before a physician enters employment or a contractual relationship, however, compliance professionals should review the Open Payments registry to determine whether the physician has received any payments, and if so, these payments should be documented and clarified with the physician. This process should be implemented as part of the facility's credentialing policies and procedures.

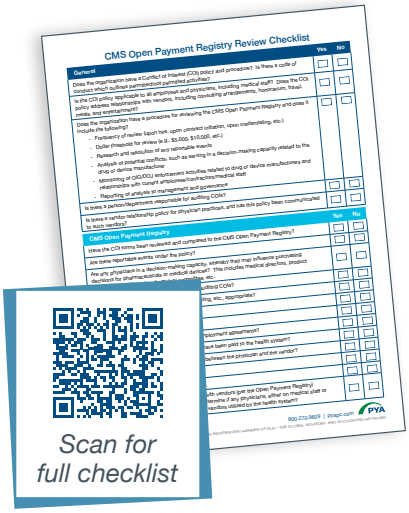
Physicians serving as principal investigators (PIs) in clinical research studies have additional layers of disclosure requirements given the nature of third parties involved in clinical research. These additional parties, combined with the PI's role as a researcher and their inherent interest in the successful completion of a research trial, elevates the importance of COI monitoring. In our experience, most organizations have uniform policies for the declaration of outside/financial interests, but they vary considerably in their methods of managing a potential conflict of interest, which is problematic for mitigating risk.

Managing a Potential Conflict

What happens when an outside business relationship is disclosed as part of the conflict of interest reporting process? As illustrated earlier, an outside business relationship alone does not always result in a conflict of interest. To identify COI, an internal vetting process should include a conflict of interest committee tasked with the analysis of the business relationship in the context of the physician's decision-making abilities. For example, a physician could personally benefit from a patient filling a drug prescription the physician prescribed. That transaction becomes a conflict only when/if the decision to prescribe the drug was *influenced* by the physician's investment or relationship with the drug manufacturer.

But how do we really know the catalyst behind the decision to prescribe a drug? As in every patient/physician clinical relationship, the physician's decision comes down to the physician's medical judgment, tempered by an organization's existing auditing and monitoring processes. Most healthcare organizations have existing conflict of interest policies requiring the disclosure of outside business interests, including the types of relationships addressed in the Open Payments registry. These policies generally require disclosures at the time of contract, time of employment, or upon joining a hospital's medical staff. The completeness and adequacy of the disclosures, however, vary. Before the Open Payments registry existed, organizations had to rely upon the reporting individual's statements, with little to no outside verification. Now, the Open Payments registry allows for the independent verification of disclosures that have been historically lacking.

Additionally, with the prevalence of conflict of interest reporting software now available, organizations can more easily capture, analyze, and monitor disclosures. Data from these types of software can be compared with findings from robust business analytics, such as PYA's Business Insights, to assess the completeness of reported disclosures.



Conflict of Interest Process Checklist

Upon completion of an inventory of disclosures of outside financial interests, an adequately documented discernment process to evaluate the disclosures could then take the shape of the process flow illustrated in the following PYA checklist:

STEP 1	Update your COI distribution listing to include the additional providers CMS added to the Open Payments registry in 2022.
STEP 2	Update your COI questionnaire to reference the Open Payments registry (via link), which lists the various transactions that should be reported/explained by the provider.
STEP 3	Inventory and compare disclosed conflicts (i.e., compare individual provider disclosures to reported transactions found on the CMS Open Payments registry).
STEP 4	Discuss the nature of disclosures, including any disclosure gaps, with the provider, and document responses.
STEP 5	Discuss results with the COI committee and document the decision process. Create a report to be presented to the board/designated board subcommittee for review and approval.
STEP 6	Create a monitoring mechanism for each specific disclosure above the organization's risk tolerance (the average within the industry is $5,000 to $10,000 per provider), which may include analyses to prevent overuse of procedures involving medical devices or analyses of drugs purchased off the facility's formulary.
STEP 7	Review and revise existing COI policies and procedures, and train staff (e.g., credentialing and physician contracting) and providers.
STEP 8	Create a schedule for updating the facility's drug formulary and product selection committees. Include a declaration of conflicts of interest as a standing agenda item for each committee meeting.

For assistance with compliance best practices, risk assessments, and internal auditing and monitoring, please contact:

Shannon Sumner
Principal
ssumner@pyapc.com
(800) 270-9629

Tynan Kugler
Principal
tkugler@pyapc.com
(800) 270-9629

© 2023 PYA, P.C.