

MANAGING CONFLICTS OF
INTEREST IN HEALTHCARE
Health Care Compliance Institute
March 2020

James G. Sheehan, Chief
Charities Bureau
Office of Attorney General Tish James
James.Sheehan@AG.NY.gov
and
Roy Snell
Strategic Adviser HCCA/SCCE
Roy.Snell@corporatecompliance.org

1

NEW YORK ATTORNEY GENERAL
TISH JAMES



2

Conflicts of Interest

- “Conflict of interest affects virtually every aspect of medicine, including research, teaching, and clinical care.” JAMA editorial 2018
- “a conflict of interest arises whenever activities or relationships compromise the loyalty or independent judgment of an individual who is obligated to serve a party or perform certain roles.”
- “Conflicts of interest can influence action, but they are not acts and do not constitute a breach of duty” Marc A. Rodwin Professor of Law, Suffolk University Law School (2017)
- Two kinds of conflict of interest:
 - 1) conflicts between an individual’s obligations and their financial or other self-interest;
 - 2) conflicts resulting from an individual’s divided loyalties, dual roles or conflicting duties, sometimes referred to as conflicts of commitments (Peters, 2012).

3

Should We Care About Conflicts of Interest?

- Organizational systems and processes-governance expectations
- Physician duty to patients and independent judgment
- Unconscious bias/ reciprocity
- Media (public and social) Reputation for Integrity/Transparency
- Compliance culture/ consistency
- Legal requirements

4

How to Address Conflicts of Interest?

- 1) ignore
- 2) tolerate and trust judgment
- 3) train, tolerate, trust judgment
- 4) permit but require internal disclosure
- 5) permit but require public disclosure
- 6) manage (systems, thresholds, reporting, review, decide)
- 7) test and discipline
- 8) prohibit

5

Memorial Sloan Kettering- Conflict of Interest Concerns

- Chief Medical Officer Dr. Jose Basalga failed to disclose millions of dollars in payments from drug and healthcare companies in published articles, resigns 9/13/18-NY Times Pro Publica
- “Dr. Basalga and MSK said that he had disclosed his industry relationships to the cancer center.”
- After internal investigation-NY Times reports statement by outside counsel investigator that plans to manage conflicts of interest “were not implemented because it was felt to be unnecessary or because there was a failure to realize that a management plan was needed.”
- Beginning in 2014, NY Times reported that senior executives were no longer required to vet financial relationships with a conflict of interest advisory committee because the hospital felt the committee should not be asked to make decisions about executives to whom they reported.
- 2016 Schedule O “**The Compliance Officer and staff are responsible for administering the conflict of interest program. . .**”
- 2017 Schedule O The Compliance Officer and staff are responsible for administering the conflict of interest program. . .”
- April 2018-Debra Berns has been named as MSK’s Senior Vice President and Chief Risk Officer
- April 2019-new MSK New and Enhanced Conflict of Interest Principles approved
- September 2019-new policies-attached-Conflict of Interest and Commitment (Eileen-sent to you 1/20 at 558 PM.)

6

The University of Maryland Medical System

- UMMS spent \$500,000 to purchase 100,000 copies of “Healthy Holly” (a book series self-published by Baltimore’s now ex-Mayor Catherine Pugh) to donate to Baltimore school children, while she was a trustee of UMMS, a private, not-for-profit health system with 11 hospitals and \$2 billion in annual revenues.
- UMMS’s 2015 IRS 990— yes on line 12 This Schedule O actually has a monitoring and enforcement policy: the **general counsel** “reviews the responses...” to determine whether a conflict exists and consults with the audit committee in appropriate cases. In addition, there is a requirement that in all invitations for bids, proposals, or solicitations for offers, the vendor, supplier, or contractor must disclose any “actual or potential transaction with any organization officer, director, or employee.”
- The Baltimore Sun reported on March 13, 2019 that a third of the UMMS’s board received payments from the system “through contracts with their businesses.”
- The CEO, COO, chief compliance officer, and general counsel “left” their positions in June, 2019 and UMMS announced a new conflict of interest policy on May 31, as required by a new Maryland state law passed after the Baltimore Sun stories. The policy lays out specific responsibilities for the new chief compliance officer.
- July 2019-new Corporation Conflicts of Interest Policy (attached)
- October 2019-UMMS advertising for new chief compliance officer

7

Psychiatry Conflict of Interest Headlines - Senator Grassley

- 2008-Joseph Biederman-Harvard, Mass. General (atypicals for children)(current Mass. General website visited 1/20/20: “Dr. Biederman’s work is supported by multiple federal and pharmaceutical industry grants.”)
- 2008-Alan Schatzberg, Stanford-\$4.8 million in stock options, reported as \$100,000+
- 2008-Charles Nemeroff, Emory (\$960,000 from GSK, reported \$35,000);resigned and went to University of Miami School Medicine; now (October 2018) at Dell Medical School, UT Austin
- Impetus for Sunshine law, new (2011) NIH regulations

8

Physician Payments Sunshine Act-2010

- Part of Obamacare
- 9/30/2014 –first Open Payment Program reporting (openpaymentsdata.cms.gov)
- 1/20/2020- currently reporting 2018 payments
- Dollars for Docs (projects.propublica.org)
 - HUP-\$26 million from 130 companies-primarily licensing/royalty
 - Total for all Pa. physicians and hospitals-\$97.6 million
 - 9 of 10 top Pa. physicians in Philadelphia
 - Many payments –royalties on devices
 - One Ca. ophthalmologist received \$20.7 million in “promotional speaking/other”

9

Continuing Education Conflicts of Interest

- Accreditation Council for Continuing Medical Education (“ACCME”) proposed revisions –Standards of Integrity and Independence in Accredited CE-1/7/2020 (formerly “Standards for Commercial Support”) (comments closed February 2020) (ACCME.org)
- Individual presenters required to disclose “all financial relationships,” to accredited Continuing Education provider, regardless of amount, with “ineligible entities” regardless of relevance to their presentation. Includes known financial relationships of spouse or partner.
- “All financial relationships with ineligible entities” for the prior 12 months.
- CE provider decides what disclosures are necessary to learners.

10

2011 Disclosure and Management of Federal Financial Conflict of Interest Regulations, as amended in 2016

- 42 CFR 50.603-apply to institutions that apply for or receive NIH funds
 - Investigator training once every four years
 - Institution responsible for soliciting and reviewing disclosures for each investigator who is planning to participate in or is participating in NIH research.
 - Institution must have designated official responsible for reviewing disclosures (can be committee)
 - Institution must post fcoi policy on publicly available website.
 - Institution must impose fcoi policy on subrecipients
 - Examples: Drexel University (Drexel.edu/research/compliance);Jefferson.edu (only accessible internally)

11

HHS/OIG Audit 03-19-03003 of NIH (9/2019)

- 2011 Financial Conflicts of Interest regulations
- HHS/OIG Audit
 - NIH has limited policies in place to require institutions to report all sources of research support, financial interests, and affiliations
 - 1875 institutions received NIH funding in FY 2018
 - 1013 did not have FCOI policies posted on their websites
 - Sample of 90 nonposted, 41 did not have policies
 - Recommendations: ensure posting; enhance NIH monitoring programs; implement procedures to assure that entities have policies

12

Philadelphia City Council 2019 Votes Down Ban on Pharma Industry Gifts, Dinners to Doctors – Feb 7, 2019

- Proposed prohibition on detail reps providing meals and gifts to physicians when they discuss “potentially addictive” prescription drugs.”
- “The idea that meals influence the prescribing behavior is not only insulting to physicians it’s insulting at its face. . . I have a lot more faith in physicians than that.” Chris Molineaux, Life Sciences Pennsylvania.
- “Decades of study have made it clear that meetings between doctors and sales reps lead to changes to the way physicians prescribe medications . . .” testimony of Dr. Patrick Brennan, CMO of University of Pennsylvania Health System

13

How Do Other People Handle Conflicts

- Strategic advantage:
- What is an allowable gift or meal by a supplier to any Walmart employee?
 - ___ \$50
 - ___ \$25
 - ___ \$0
- University of Pennsylvania Guidelines for Interaction with Industry
 - No gifts, meals, services, subsidies from drug or device firms
 - No medication samples from Industry representatives
 - Sample medication voucher program ok
 - Reimbursement for travel to present findings if company funds research.

14

What Rules Govern Conflicts of Interest?

- IRS private inurement Section 4958 of Internal Revenue Code-excise tax-excess benefit transactions to “disqualified persons”
- State Law and Policy: new York modelhttps://www.charitiesnys.com/pdfs/Charities_Conflict_of_Interest.pdf
- Duty of Loyalty-“Acts of self-dealing constitute a breach of fiduciary duty. . . (directors and officers) should avoid conflicts of interest . . .”
- (at 7-8) “board members and senior management have a duty to avoid potential or apparent conflicts of interest. . . An individual who has a conflict of interest should not be present in the room during any discussions that relate to the transaction.”
- Conflict of interest policy (in bylaws or otherwise) a good idea, not required by statute.
- Representations to IRS and state

15

What State Law Rules Govern Conflicts of Interest?

- Example-Pennsylvania: 15 P.S.A. 5728-Interested Officers or Directors; quorum
 - Contract or transaction not void or voidable **solely** because conflicted director present in the room, or the conflicted director vote is counted, if:
 - Material facts as to the relationship or interest and as to the transaction are disclosed or are known to the board of directors, if approved by majority of disinterested directors; or
 - Material facts as to the relationship or interest and as to the transaction are disclosed or are known to the members entitled to vote, and the contract or transaction is specifically approved in good faith by vote of the members; or
 - The contract or transaction is fair to as to the corporation as of the time it was approved

16

What Rules Govern Conflicts of Interest

- IRS 990 Reporting Rules for 501©(3) entities-Section VI, Question 12 and Schedule O
- Stark Law
- Pharmacy and Therapeutics Committee Conflicts of Interest policy
- International Committee of Medical Journal Editors (ICMJE)
- National Institute of Health Conflict of Interest regulations 42 CFR Part 50, Subpart F. (related to grants)

17

The New York Cookbook NPCL 715(f) Requirements

- Not-for-Profit Corporation Law (“NPCL” 715(f))
- Written policy adopted by board
- Applies to directors, officers, and key persons
- The Policy must require that each officer, director and key employee submit to the Secretary of the Corporation prior to initial election to the board, and annually thereafter, a written statement identifying possible conflicts of interest.
- Disclosure of conflicts is required; the requirement of disclosure to the Secretary can be satisfied by disclosure to the Secretary’s designee as custodian (e.g., the compliance officer), if set forth in the conflict of interest policy.
- The Secretary must provide a copy of the completed statements to the chair of the audit committee or the chair of the board.
- Oversight based on IRS 990 submission

18

Financial Conflicts of Interest and the IRS 990

- IRS Governance Check Sheet 2009 (Form 14114) for use by Revenue Agents-look for-
- Written policy
- Written annual disclosures of conflicts
- Record of Recusals
- Have actual or potential conflicts been disclosed
- Whether the written policy has been followed

19

Form 990 Review-by Counsel or Compliance Officer?

- Part VI, Section B, of the Governance, Management, and Disclosure Section of the 990:
- “Did the organization have a written conflict of interest policy (12a). If no, go to line 13.”
- If yes on 12a go to line 12b: “Were officers, directors, or trustees, and key employees required to disclose annually interests that could give rise to conflicts?”
- If yes on line 12b, go to line 12c: “Did the organization regularly and consistently monitor and enforce compliance with the policy?” “
- If yes, describe in Schedule O how this is done.”

20

IRS 990 Instructions (2019)
Part VI: Governance, Management, and Disclosure

- Line 12a. Answer "Yes," if as of the end of the organization's tax year the organization had a written conflict of interest policy.
- "A conflict of interest arises when a person in a position of authority over an organization, such as an officer, director, manager, or key employee can benefit financially from a decision he or she could make in such capacity, including indirect benefits such as to family members or businesses with which the person is closely associated. For this purpose, a conflict of interest does not include questions involving a person's competing or respective duties to the organization and to another organization . . ." (at 24)

21

IRS 990 Instructions (2019) If "Yes" on Part VI line
12c, "describe in Schedule O how this is done."

- Line 12c. " , describe on Schedule O (Form 990 or 990-EZ) the organization's practices for monitoring proposed or ongoing transactions for conflicts of interest and dealing with potential or actual conflicts, whether discovered before or after the transaction has occurred."

22

IRS 990 Instructions (2019) If "Yes" on Line 12c, “Describe in Schedule O How this is Done.”

- The description should include:
 - an explanation of which persons are covered under the policy;
 - the level at which determinations of whether a conflict exists are made;
 - the level at which actual conflicts are reviewed;
 - Also explain any restrictions imposed on persons with a conflict, such as prohibiting them from participating in the governing body's deliberations and decisions in the transaction

23

Form 990 Review-Language from Filed 990s

- “The organization has a conflict of interest (COI) policy that addresses the consideration of potential conflicts of interest by the board of directors, committee members, key employees, and their relatives. As per the policy, such persons must make disclosure of any potential conflicts of interest and must abstain from voting on any action in which they have an interest. On an annual basis, all members are required to sign an annual conflict of interest form...” Hacienda HealthCare 990 Schedule O for 2016.
- Statement does not represent that the organization “regularly and consistently monitors and enforces compliance with the policy...” nor does it represent how monitoring and enforcement are done.

24

Arizona Republic 2/19/19

- Hacienda Board members who oversee the Phoenix care facility where an incapacitated patient was raped have a long record of self-dealing and nepotism.
- Hacienda HealthCare board members and their relatives benefited financially from their positions.
- Some board members do business directly with Hacienda, and some board members have business dealings with each other. Some of their children were hired at Hacienda.
- Hacienda's board chairman Tom Pomeroy brokered health insurance for roughly 800 Hacienda employees through his private company for decades, reaping lucrative commissions (4-7%) on the contracts.

25

Conflicts of Interest-Strategic Issues

- Funding for innovation and research/Joint projects with industry
- Compensation, equity interests for major researchers
- How many reporters? Who reports?
- Big Data management and analysis costs and opportunities
- Privacy, disclosure concerns-who receives, reviews information
- Give or get board memberships
- Size of boards
- Public Reporting-Sunshine Law, academic publications, IRBs, patient disclosures

26

Operational Challenges for Major Academic Medical Centers on Conflicts of Interest

- Written policy, state law requirements
- Need to address full range of conflict of interest issues and reporting for board members, officers, employees, physicians with privileges
- Reviewing, reporting process on Schedule O of annual IRS 990 (hint: counsel need to review conflict language before submission)
- Whose job should it be (counsel, compliance, audit committee, compliance committee, secretary) (Hint: not a process general counsel should be responsible for)
- Consequences of failure to respond/report
- Systems for capturing conflict reporting
- Record of Recusals-minutes and other decision documents

27

Vital Capabilities of a Conflict of Interest (COI) Technology Solution

Disclosure Submission	Disclosure Review	Case Management
<ul style="list-style-type: none"> <input type="checkbox"/> Smart Forms with branching logic that adapt in real-time to specific responses. <input type="checkbox"/> Applicable data should be pre-filled and carry over from previous submission. <input type="checkbox"/> Single Sign-On (SSO) support that provides easy access. 	<ul style="list-style-type: none"> <input type="checkbox"/> Ability to set organizational thresholds in order to identify conflicts in real-time. <input type="checkbox"/> Automatic reminders with escalations to supervisors. <input type="checkbox"/> CMS Open Payments integration to validate disclosures. 	<ul style="list-style-type: none"> <input type="checkbox"/> Management plan development and tracking with 360° signoffs <input type="checkbox"/> One audit-ready repository to collect and store all documents, notes, and communications. <input type="checkbox"/> Mitigation process that is capable of routing tasks according to conflict type.

28

Capabilities of a Conflict of Interest (COI) Technology Solutions

Operational Scalability *Enterprise scalability.*

- Targeted campaigns for flexible and precise interaction within your organization.
- Auto-provisioning of users supported through direct integration of HR System.
- Automated review process for disclosures detected to have no potential conflicts.

Best Practices

- Pre-packaged templates and workflows that can be modified for your business.
- Pre-production / beta test environment to vet communications and processes prior to changes or full development.
- Self-administration capability to allow modification on your own time and cost schedule.

29

Providers of Conflict of Interest Solutions

Osprey / Steele

OSPREY
Compliance Software
powered by Steele

Navex

NAVEX
GLOBAL

SAI Global

 SAI GLOBAL

Health Stream

 HealthStream

Huron

 HURON

30

30

For Further Reading: JAMA THEME ARTICLE 2017 JAMA. 2017;317(17)

- 23 separate articles covering:
- Academia/Academic medical centers
- Medical education
- Medical practice and research
- Industry payments to physicians and industry funding of and collaboration with researchers
- Guideline panels
- Professional associations
- Disclosures to patients
- Roles of journals and authors

31

For Further Reading

- **2019 Instructions for Form 990 Return of Organization Exempt From Income Tax (irs.gov)**
- **Conflicts of Interest Policies Under the Not-for-Profit Corporation Law New York Attorney General (attached)**
- **New York Charities Bureau (www.charitiesnys.com)**
- **https://www.irs.gov/pub/irs-tege/governance_check_sheet.pdf**
- **Sample conflict of interest policies (Montana)**

32

Thank You For Your Attention!

- Jim Sheehan (James.Sheehan@ag.ny.gov)
- Roy Snell (Roy.Snell@corporatecompliance.org)