

Are Your Physicians Following Your Conflicts of Interest Policies?



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Goal for Today

Empower you and your thinking with strategies, data, and confidence to identify potential conflicts of interest (COI) with medical staff members and ideas for mitigation to support a culture of ethics and compliance at your organization.

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Background

Conflicts of Interest

Situations or activities in which financial, non-financial, or other personal considerations may compromise, or have the appearance of compromising, a medical staff member's professional judgment in patient care, teaching, training, research, administration, management and other professional activities.

Physician Sunshine Act (Section 6002 of the Affordable Care Act (ACA) of 2010)

Requires manufacturers of medical products to disclose to the Centers for Medicare and Medicaid Services (CMS) any payments or other transfers of value made to physicians or teaching hospitals.

First data was posted publicly on the CMS Open Payments website on September 30, 2014.

<https://www.cms.gov/openpayments/>

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Why Is Managing COIs Important?

Protection of patients and your organization

- Ensure ethical clinical decision making
- Guarding against fraud and abuse
- Research integrity
- Utilization management
- Reputation

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In the News

New York Times article September 7, 2018: **Top Cancer Researcher Fails to Disclose Corporate Financial Ties in Major Research Journals**

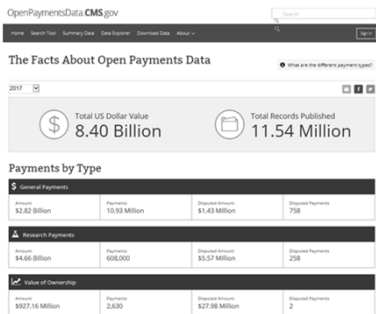
<https://www.nytimes.com/2018/09/08/health/jose-baselga-cancer-memorial-sloan-kettering.html?nl=top-stories&nid=65235909ries&ref=cta>

- Dr. José Baselga is the chief medical officer at Memorial Sloan Kettering Cancer Center in New York.
- Received \$3.5 million from 2013-2017 according to CMS Open Payments website.
- Dr. Baselga did not always disclose relationships such as paid board memberships, ownership interests, consulting and speaking arrangements to journals and professional societies.

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CMS Open Payments



CMS Open Payments

Payments by Entity

Entity Type	Number of Entities	General Payments	Research Payments	Value of Ownership or Investment Interest
Total Physicians	Receiving Payments 628,000	Amount \$2.07 Billion	Amount \$79.13 Million*	Amount \$927.16 Million
Total Teaching Hospitals	Receiving Payments 1,158	Amount \$751.21 Million	Amount \$1.04 Billion	Amount N/A**
Total Companies	Making Payments 1,525	Amount \$2.82 Billion	Amount \$4.66 Billion	Amount \$927.16 Million

Use the Search Tool to conduct your own specific search

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Gifts Keep On Giving

Drug and device companies have paid doctors and hospitals more than \$33.4 billion dollars since 2013, according to the Centers for Medicare and Medicaid Services (CMS).

August 2016 JAMA Internal Medicine study **Pharmaceutical Industry-Sponsored Meals and Physician Prescribing Patterns for Medicare Beneficiaries**

"Receipt of industry-sponsored meals was associated with an increased rate of prescribing the brand-name medication that was being promoted. The findings represent an association, not a cause-and-effect relationship."

<https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2528290>

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Set Boundaries

- Set clear guardrails in policy and procedure
 - Gifts
 - Meals
 - Consulting
 - Intellectual property
 - Speaking
 - Training
 - Paid travel and attendance at meetings
 - Advisory boards
 - Samples
 - Writing
 - Research
- Determine when \$ comes back to the organization and when it can be kept by the physician - keep fair market value (FMV) in mind
- Create system of operational approvals
- Educate medical staff members about the **expectations**

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Transparency

COI Disclosure

1. Who is required to disclose?
 1. All members of the Medical Staff?
 2. Just Physicians? Part-time, Full-time, Contract, Volunteer, Residents?
 3. Mid-levels?
2. What?
 1. What do you want them to disclose?
 2. Anything of Value?
 3. All relationships? Even family member relationships with vendors or receiving items of value?
3. When?
 1. Annually?
 2. When anything changes?
 3. At credentialing or re-credentialing?

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You Ask, but Will They Tell?

A recent research study says not really.

JAMA Surgery online publication August 15, 2018 "**Association of Compensation From the Surgical and Medical Device Industry to Physicians and Self-declared Conflict of Interest**"

<https://jamanetwork.com/journals/jamasurgery/article-abstract/2696610>

Researchers cross referenced 2016 conflict of interest disclosure information for publications with CMS Open Payments Disclosure information for 100 physicians receiving the highest compensation from the 10 largest surgical medical device companies as listed in the CMS database.

Conflicts of interest were declared by the authors in 37.3% of the publications (84 of 225 reviewed).

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Trust but Verify

- Review COI disclosures
- Review research COI disclosures
- Compare COI disclosures to the CMS Open Payments data
- Identify gaps
- Collect more information on the identified gaps (conduct interviews, pull accounts payable information, pull purchasing committee minutes, purchasing records, etc.)

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Respond and Mitigate

- Create a mitigation plan
- Communicate (as necessary)
 - To the individual
 - To supervisor/manager of the individual
 - Appropriate executives
 - Human Resources and/or Medical Staff leadership
 - Appropriate committees (purchasing, P&T, etc.)
 - Compliance Committees
 - Board Committees
- Verify the mitigation plan is in place and effective
- Ensure appropriate corrective actions when warranted
- Document, document, document

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Scenario

One of the top Urology surgeons at your hospital disclosed on his annual COI form that in the last year he participated in a paid consulting relationship with Olympus regarding a new laser that can break up kidney stones. According to your organization's policies, consulting relationships like these are allowable, and honorariums may be personally accepted while on personal time as long as the appropriate approvals are obtained. The hospital is in the midst of purchasing a new laser and Olympus is one of the vendors included as an option.

- What steps would you take to evaluate this relationship and ensure no COIs are influencing decision-making?
- Who would you disclose the potential COI to?
- What recommendations would you make to mitigate the potential conflict?

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Keys to Success

- A clear and strong policy and procedure is key
- Educate your physicians on reviewing and disputing payment information in their name on CMS Open Payments website
- Physician champions/leaders are necessary
- Use data support
- Be direct and clear in mitigation
- Include appropriate medical staff leadership

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Changes Coming

Substance Use–Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act

Passed the Senate on 10/3/18 with bipartisan vote of 98-1 and previous vote in the House of Representatives on 9/28/2018 of 393-8

- Includes an expansion of the scope of the Sunshine Act (**effective 1/1/22**) to apply to:
 - physician assistants
 - nurse practitioners
 - clinical nurse specialists
 - certified registered nurse anesthetists
 - certified nurse-midwives

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Discussion/Questions?

Thank you!