

Professionalism

Academic-industry compliance for healthcare professionals

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Acknowledgements

Except where noted, no compensation, in any form, was paid to these individuals

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--See more acknowledgements on next slide!--

Acknowledgements (continued)

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UI  Projects

UIDP Compliance Module

Purpose: To familiarize learners with federal law and institutional policies governing interactions between industry and health professionals.

Format: Pre-test, video testimony, case studies, list of resources, post-test, references

Estimated time to complete module: 20 minutes

ACADEMIC MEDICAL CENTER-INDUSTRY ENGAGEMENT WORKING WITH INDUSTRY COMPLIANCE

INSTRUCTIONS

Pre- and Post-module Assessment

Prior to viewing this module, please take the pre-module assessments. When you have completed the module, please take to post-assessment. Your responses will help UIDP to make improvements to this presentation for future viewers.

The link for the pre-module assessment is embedded on slide #7. Learners can also go directly to <https://www.surveymonkey.com/r/COIPRE> to take the assessment. The link for the post-module assessment is embedded on slide #48. Learners can also go directly to <https://www.surveymonkey.com/r/COIPOST> to take the assessment.

COMPLIANCE

WORKING WITH INDUSTRY

**ACADEMIC MEDICAL CENTER-INDUSTRY ENGAGEMENT
PROJECT**

Before viewing this module for the first time, so you can assess what knowledge you have learned, please take the pre-module assessment at

<https://www.surveymonkey.com/r/COIPRE>

Your responses will help UIDP to make improvements to this presentation for future viewers.

What are the Learning Objectives for this Module?

1. The learner will be acquainted with the existence of federal laws (**Anti-Kickback Statute**, **Stark Law** and The Physician Payments **Sunshine Act** and) and institutional transfer of value policies that affect health professionals' relationships with industry.
2. The learner will be aware that their hospital has specific policies for dealing with financial and non-financial incentives.
3. The learner will use critical thinking skills to help evaluate opportunities for relationships with industry with an overall goal of serving patients' interests.

In what ways are compliance and conflict of interest relevant to the practice of medicine?



Compliance and conflicts of interest are considerations that will always be with us as we have interactions with the government and the academy and the private sector industry.

A lot of times compliance is considered to be drudgery, and sometimes that's correct, but most of the time it's there to protect people from negative unintended consequences.

*William M. Pierce, Jr., PhD
Executive Vice President for Research and Innovation
University of Louisville*

In what ways are compliance and conflict of interest relevant to the practice of medicine?

Anti-Kickback Statute

U.S. criminal law enacted in 1972; also covered by Civil Statute (see following slide)

- The healthcare anti-bribery law designed to protect the Centers for Medicare and Medicaid Services (CMS) payment system.
 - Protects *federal payment programs* (i.e. Medicare and Medicaid) that reimburse healthcare costs from fraud and abuse caused by the influence of money or other things of value in inducing or rewarding referral decisions, increased costs to federal programs, or poor quality of care.
 - Protects *beneficiaries* (i.e. healthcare providers) from conflicts of interest in patient care, overutilization or inappropriate utilization of products. Patients are not beneficiaries and cannot violate the Anti-Kickback Statute.
- There is no lower threshold value that escapes the law; both the giver and the receiver can be liable for violation.
- Many states have their own anti-kickback laws
- Intent must be proven (knowing and willful)

Beneficiary Inducement Statute

Besides the Anti-Kickback Statute, the beneficiary inducement statute (42 U.S.C. § 1320a-7a(a)(5)) also imposes civil monetary penalties on physicians who offer remuneration to Medicare and Medicaid beneficiaries to influence them to use their services.

You can find additional information about this and other important federal statutes on the Department of Health and Human Services Office of the Inspector General website.

Stark Law

Civil law, enacted 1989

- Originally, aimed to deter physician referrals for clinical laboratory services.
- Prohibits a physician from referring patients to an entity for a designated health service (DHS), if the physician (or member of his/her immediate family) has a financial relationship with the entity.
- In 1993 and 1994, Congress expanded the prohibition to ten additional designated health services (e.g. outpatient prescription drug services physical and occupational therapy, and imaging) and applied certain aspects of the law to the Medicaid program.
- Ignorance of the law (and having no intent to break the law) is no excuse/no defense. Guilt may exist and penalties may apply even if no harm was intended and even if there was no or imperfect knowledge of the law.

Open Payments Provisions (AKA Sunshine Act)

*A regulation intended to inform patients about industry payments to physicians
Enacted February, 2013*

- Requires reporting any “transfer of value” (with some exceptions) from an applicable manufacturer, made directly or indirectly, to a covered recipient;
 - Reporting to the Centers for Medicare & Medicaid (CMS) to be posted on a public website
- Aims to increase transparency of the financial relationships between physicians, teaching hospitals, and medical industry
- Residents are licensed physicians and subject to all rules governing covered recipients. Fellows are physicians that pursue additional training beyond their residency (surgery is a residency, pediatric surgery or cardiac surgery is a fellowship program). Because they are fully licensed physicians, fellows have the same covered recipient status as other physicians.

Transfers of Value – What does this entail?

(Included in Open Payments Provisions)

In the sales and marketing of medical products and in the context of anti-bribery, anti-kickback and transparency reporting, this simple phrase includes a lot of things:

- Cash or equivalents
- CEUs
- Consulting fees
- Food and drink
- Meals for guests
- Flowers
- Journal reprints
- Pens
- Tickets
- Debt forgiveness
- Equipment loaned over 90 days
- Product education and associated travel expenses
- Services, i.e., writing, data management, statistical analysis, practice building, advertising, etc.

What are common elements of a compliance policy?

Each institution is different, and the policy will vary in levels of detail.

Different documents may deal with these separate topics:

- Quality, Safety and Service
- Entertainment
- Gifts
- Kickbacks
- Payments
- Discounts
- Disclosure

What does YOUR institution's compliance policy include?

How Would You Report Compliance Related Matters at Your Institution?

Obtain via online search or directly from these sources:

- Compliance Office
- External Relations
- VP of Research
- Faculty Advisor

Do Academia and Industry have their own codes of conduct regarding their engagement?

The next few slides give some examples of these codes from Academia (ACCME) and Industry (AdvaMed)

Continuing Medical Education and Conflict of Interest

The Accreditation Council for Continuing Medical Education (ACCME), which serves as the body accrediting institutions and organizations offering continuing medical education, has also issued policy statements regarding conflict of interest.

Financial Relationships and Conflicts of Interest

Excerpts from ACCME Policy*

- *Financial relationships* are those relationships in which the individual benefits by receiving a salary, royalty, intellectual property rights, consulting fee, honoraria for promotional speakers' bureau, ownership interest (e.g., stocks, stock options or other ownership interest, excluding diversified mutual funds), or other financial benefit.
- Circumstances create a *conflict of interest* when an individual has an opportunity to affect CME content about products or services of a commercial interest with which he/she has a financial relationship.
- Read more on the ACCME website at <http://www.accme.org>.

* UIDP's use of materials from the Accreditation Council for Continuing Medical Education (ACCME) website does not imply endorsement from the ACCME.

AdvaMed

AdvaMed (the Advanced Medical Technology Association), a trade association whose international membership ranges from the largest to the smallest medical technology innovators and companies, represents the gold standard of organizations for compliance. The association acts as the common voice for companies producing medical devices, diagnostic products and health information systems. Is it recognized by the Accreditation Council for Graduate Medical Education, the Liaison Committee on Medical Education, the American Medical Association, the the U.S. Centers for Medicare & Medicaid Services, etc. View AdvaMed's code of ethics at <http://www.advamed.org> and/or view the code's introduction on next slide.



CODE OF ETHICS

The AdvaMed Code of Ethics on Interactions with Health Care Professionals ("AdvaMed Code") facilitates ethical interactions between Medtech Companies and Health Care Professionals to ensure that medical decisions are based on the best interests of the patient.



CODE OF ETHICS

INTRODUCTION

Medtech Companies can serve the interests of patients through beneficial collaborations with Health Care Professionals (HCPs) to advance medical technologies, enhance the safe and effective use of medical technologies, encourage research and education, and foster charitable donations and giving. To ensure that these collaborative relationships meet the highest ethical standards, they must be conducted with appropriate transparency and in compliance with applicable laws, regulations and government guidance. **The AdvaMed Code of Ethics on Interactions with Health Care Professionals** ("AdvaMed Code") clarifies and distinguishes appropriate activity between health care professionals and representatives of AdvaMed member companies.

Considering what you have learned in the previous slides and your own institution's Transfers of Value policies, can you spot any conflicts of interest in the following scenarios?

Scenario #1

Maria is a sales representative for Air Tube Corporation.

She manages a line of disposable anesthesia products which have been shown in high-quality clinical trials to improve patient outcomes.

In an effort to increase utilization and benefit patients, she approaches the Chair of the Anesthesia Department at one of her top accounts whom she met during an annual meeting.

She offers to pay for five anesthesia residents to attend the meeting next year, if the Chair will start using the products from her company.

**What could be wrong with this scenario?
(Take a few minutes now to reflect.)**

Points of discussion/reflection for Scenario #1

- Companies are not allowed to directly sponsor healthcare professionals (HCPs) to attend meetings. This type of educational support should go through the company's funding process which should be separate from the sales and marketing functions. (*AdvaMed Code of Ethics*)
- Industry providing free meeting registrations for HCPs (even though they are residents and still in training) looks like an inducement to increase future sales. (*Anti-Kickback Statute*)
- Quid pro quo – if you do this for me (switch suppliers), I will do this for you (pay for registrations). (*Anti-Kickback Statute*)
- All applicable transfers of value need to be reported. (*Sunshine Act*)
- The best way to increase sales is by demonstrating better patient outcomes and greater value to the healthcare system without inducement.

Scenario #1: How would the compliance officers at your institution handle this?

Contact the compliance officer in your own institution and ask them to briefly describe how someone in your institution would be required to act if they encountered this and the following three scenarios.

Pop Quiz!

Choose one answer, then check the next slide to see if you are correct.

When Maria offers to pay for five anesthesia residents to attend the meeting next year on the condition that the chair will start using the products from her company, she may be in violation of the:

1. Anti-Kickback Statute
2. Stark Law
3. Open Payments Provisions (AKA Sunshine Act)
4. Transfers of Value

Correct Answer

1. **Anti-Kickback Statute**
2. Stark Law
3. Open Payments Provisions (AKA Sunshine Act)
4. Transfers of Value

Industry providing free meeting registrations for HCPs (even though they are residents and still in training) looks like an inducement to increase future sales. (Anti-Kickback Statute)

Scenario #2

Cardiologist Dr. Jefferson has recently been certified to implant a new type of ultra-safe and recently FDA-approved pacemaker.

She is eager to increase her procedure volume.

She meets with the local sales representative, Homer, who makes an essential accessory for the pacemaker and who has strong relationships with almost all of the general internists in the region.

Dr. Jefferson offers to rebate 10% of her procedure fee to Homer for every pacemaker referral he recruits from his Internist customers , and who have a pacemaker implanted by Dr. Jefferson.

**What could be wrong with this scenario?
(Take a few minutes now to reflect.)**

Points of discussion/reflection for Scenario #2:

- Dr. Jefferson is offering money for referrals. (*Anti-Kickback Statute*)
- Transfer of value can be broader than money alone, including such things as gifts, meals, entertainment, etc.

Scenario #2: How would the compliance officers at your institution handle this?

Pop Quiz!

Choose one answer, then check the next slide to see if you are correct.

When Dr. Jefferson offers to rebate 10% of her procedure fee to Homer for every pacemaker referral he recruits from his Internist customers, and who have their pacemaker implanted by Dr. Jefferson, she is in violation of the:

1. Anti-Kickback Statute
2. Stark Law
3. Open Payments Provisions (AKA Sunshine Act)
4. Transfers of Value

Correct Answer:

1. **Anti-Kickback Statute**
2. Stark Law
3. Open Payments Provisions (AKA Sunshine Act)
4. Transfers of Value

Dr. Jefferson is offering money for referrals. (*Anti-Kickback Statute*)

Scenario #3

Dr. Martin has enjoyed a productive consulting relationship with the Jupiter Company for five years. He has earned \$7,500 per year in fees for 30 hours of consultation.

Jupiter's product manager, Wendy, has some questions about whether a new arterial access product design is safe and offers to buy dinner so the two can discuss away from distractions in the hospital and office.

Wendy goes online and finds a \$\$ rated (out of possible \$\$\$) restaurant and books a reservation for dinner.

During the meal, Wendy's ideas about the product design are approved and Dr. Martin does not have any meaningful improvements to add. Wendy pays for dinner on her company credit card and lists Dr. Martin as her guest.

Dr. Martin submits the two-hour dinner conversation on his consultation timesheet.

**What could be wrong with this scenario?
(Take a few minutes now to discuss or reflect.)**

Points of discussion/reflection for Scenario #3

- Wendy was diligent in selecting a moderately-priced restaurant for her meeting with Dr. Martin.
- Even though no changes to the process came about as a result of the meeting, Dr. Martin did discuss the product with her and rightfully added the meeting to his consultation timesheet.
- Since the process was discussed during the meeting, Wendy rightfully charged the meal to her company card, listing Dr. Martin as her guest.
- There were legitimate transfers of value transactions that were properly documented. There are no compliance or conflict of interest issues in this scenario.

Scenario #3: How would the compliance officers at your institution handle this?

Pop Quiz!

Choose one answer, then check the next slide to see if you are correct.

When Jupiter's product manager, Wendy, offers to buy dinner so the two can discuss away from distractions in the hospital and office, she:

1. Violated the Stark Law
2. Violated the Open Payments Provisions (AKA Sunshine Act)
3. Violated Transfers of Value
4. Did not violate any conflict of interest laws

Correct Answer

1. Violated the Stark Law
2. Violated the Open Payments Provisions (AKA Sunshine Act)
3. Violated Transfers of Value
4. Did not violate any conflict of interest laws

There were legitimate transfers of value transactions that were properly documented. There are no compliance or conflict of interest issues in this scenario.

What Do Other Experts in Academia Say?

Anantha Shekhar, MD, PhD, executive associate dean for research at the Indiana University School of Medicine and director of the Indiana Clinical and Translational Sciences Institute, talks about additional common potential pitfalls you may encounter.

To view video, click here: <https://vimeo.com/203183625/437c9fff4c>.

A transcript of the video is on the following page.

What Do Other Experts in Academia Say?

Video Transcript

If you viewed the video on the previous page, you can skip this page.

The biggest thing to remember for a clinician is that there are very specific guidelines as to what one should do. So, for example, any kind of direct income, whether it's for actually doing the research, or being a consultant on a research protocol, or any other activities that involve financial transaction between an industry and a physician, it has to be completely disclosed. Now, of course the industry is also expected to disclose that through the Sunshine Act, so the fact that one receives a check from company X but you didn't report that is no longer going to be acceptable, because it'll be reported in the Sunshine Act, down on the website. So once you disclose that right up front, the second thing that people mistake often is that they sort of think that if you did not receive any money, but provided consultations or provided some kind of guidance, then you don't have to declare a conflict. Well, that's, again, not true. A conflict can be nonfinancial. It could be intellectual; it could be sharing different kinds of downstream credit, etc. So one should disclose those kinds of interactions as well, that they are a consultant without pay, or those relationships, because oftentimes the perception of conflict is the most damaging thing to a credibility. So a disclosed conflict is by far – it immunizes you from any kind of reputational damage.

What does industry say about compliance?

What does industry say about compliance?

In this video, **Mark Breedlove**, vice president and global business leader for peripheral intervention at Cook Medical, gives advice for medial academics who want to work with industry.

To view video, click here: <https://vimeo.com/203183806/f5fb397241>

A transcript of the video is on the following page.

What does industry say about compliance?

If you viewed the video on the previous page, you can skip this page.

If you want to deal with industry, my advice to you would be don't be afraid of it. I think in a lot of ways, we've all been kind of conditioned that industry is bad, or you know, you've got to be very, very careful. It's okay to engage in a conversation and understand, that's how innovation happens. That's how great ideas get born. We bring in – together – expertise from academia, and researchers to companies that have a long history of building innovative products and bringing solutions to patients. So don't be afraid of it, number one. The second thing is, there's a process that every manufacturer has to go through when they're providing funds. Take the time to understand that process. It's on everybody's website.

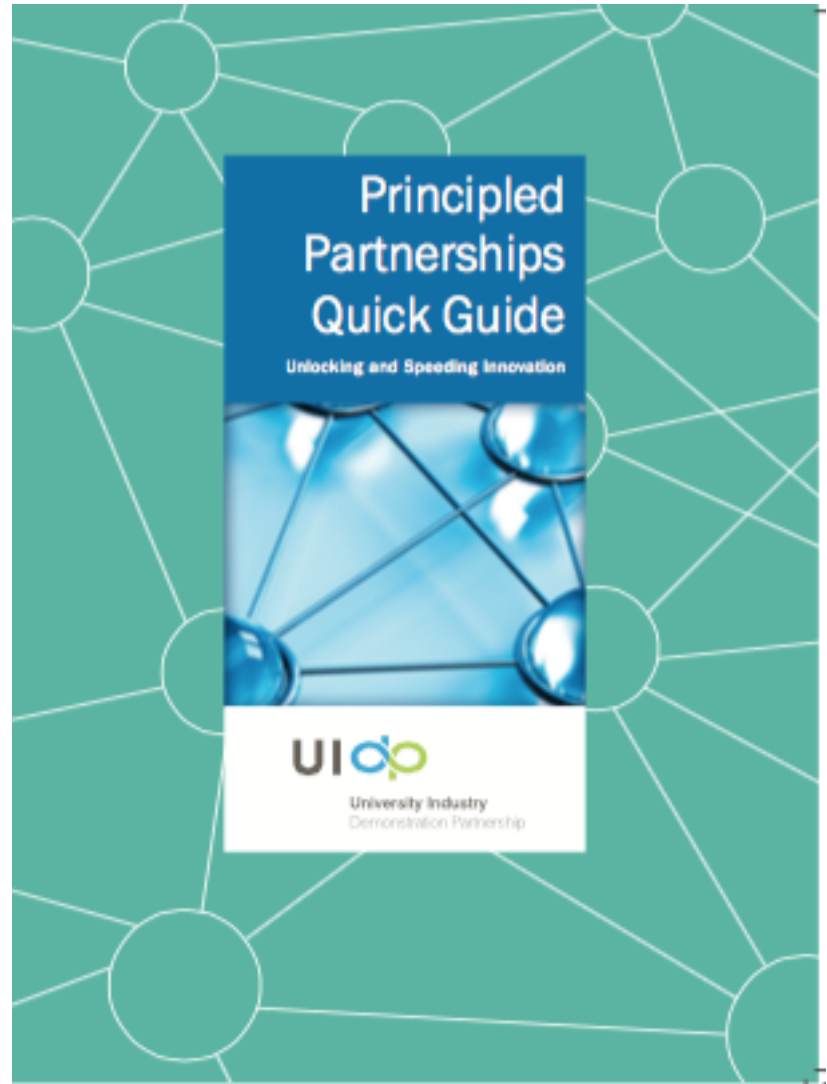
Mark Breedlove
Vice President and Global Business Leader for Peripheral Intervention
Cook Medical

Another resource is the *UIDP Principled Partnerships Quick Guide*

A dedicated team of academic and corporate practitioners crafted the Principled Partnerships Quick Guide to clarify financial conflict of interest in research.

The team has reframed the issue so that partners, the public, and other individuals can develop a clearer understanding of why university-industry research partnerships are crucial and **how potential financial conflicts can be effectively addressed and managed.**

The publication can be downloaded at <https://www.uidp.org/publication/principled-partnerships-quick-guide>



Congratulations!

If understanding compliance and conflict of interest has helped you to think critically and identify the issues that would come up in the situations presented in this module, you have successfully met the learning goals of this module.

PLEASE CONTINUE TO SCROLL THROUGH THE NEXT FEW SLIDES TO THE END AND TAKE THE POST-MODULE ASSESSMENT!

Concluding Comments

To view video, click here: <https://vimeo.com/203184016/59bc68a1f8>.

A transcript of the video is on the following page.

Concluding Comments

If you viewed the video on the previous page, you can skip this page.

It's not a game of "gotcha", it's not a police action--and we have thousands of people in the university who make these disclosures and in reality there are just a few dozen that have to have significant management plans. So it may be a bit of burden but it's not something that stops people from accomplishing what they set out to do.

*William M. Pierce, Jr., PhD
Executive Vice President for Research and Innovation
University of Louisville*

Interviewees (in order of appearance)
No compensation, in any form, was paid to any of the speakers in this module.

To view video, click here: <https://vimeo.com/203183851/dd2b2fafb3>

A transcript of the video is on the following page.

Interviewees (in order of appearance)

No compensation, in any form, was paid to any of the speakers in this module.

If you viewed the video on the previous page, you can skip this page.

William Pierce: I'm Dr. Bill Pierce, I am the Executive Vice President for Research and Innovation at the University of Louisville. By training I'm a chemist and a pharmacologist and after about 25 or 30 years of doing that and founding a company of my own I was asked by the President to drop that and help other people. And now, as Vice President, that's what I do—help our faculty, and trainees, and students get their research out into the world.

Anantha Shekhar: ...I'm Anantha Shekhar, Executive Associate Dean for Research at IU School of Medicine. I'm a professor of medical research and psychiatry and neuroscience, and I'm also the Director of the Indiana Clinical and Translational Sciences Institute.

Mark Breedlove: I'm Mark Breedlove. I'm Vice President and Global Business Unit Leader for Peripheral Intervention at Cook Medical.

Annotated Bibliography of Further Reading

Brennan, T., Rothman, D., Blank, L., Blumenthal, D., Chimonas, S., Cohen, J. ... Smelser, N. (2006 January 25). Health industry practices that create conflicts of interest: A policy proposal for academic medical centers [Special communication]. *Journal of the American Medical Association*, 295(4): 429–433.
The authors put forth an argument about the need for more stringent conflict of interest requirements

Rosenbaum, L. (2015, May 7). Malina D. (Ed.). Conflicts of interest — part 1.

Reconnecting the dots—Reinterpreting industry– physician relations. *The New England Journal of Medicine*, 372:1860–1864. doi: 10.1056/NEJMms1502493
Physicians who receive money from industry aren't necessarily biased.

Rosenbaum, L. (2015, May 14). Malina D. (Ed.) Conflicts of interest — part 2. Understanding bias—the case for careful study. *The New England Journal of Medicine*, 372:1959-1963. doi: 10.1056/NEJMms1502497
The author questions whether there is enough data to decide if physicians are biased towards industries that fund their research.

Annotated Bibliography of Further Reading (cont.)

Rosenbaum, L. (2015, May 21). Malina D. (Ed.) Conflicts of interest — part 3. Beyond moral outrage — Weighing the trade-offs of COI regulation. *The New England Journal of Medicine*, 372:2064–2068. doi: 10.1056/NEJMms1502498

The author questions whether scientific virtue justifies an anti-industry bias.

Rothman, K. (1993). Conflict of Interest: The New McCarthyism in Science. *Journal of the American Medical Association*, 269(21):2782–2784. doi:10.1056/NEJMms1502493

The author proposes judging journal articles on the merit of the work described, without negatively influencing the reader with disclosures about industry support for the research.

Please take the post-module assessment at
<https://www.surveymonkey.com/r/COIPOST>

About UIDP

The UIDP is a unique project-oriented forum where representatives from academia and industry seek opportunities to develop new approaches to working together.

Representatives of UIDP member organizations work together to:

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- Build new networks and opportunities for future collaborations
- Remove barriers to joint research project success

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