

# CONFLICTS OF INTEREST

HCCA CHARLOTTE REGIONAL PRESENTATION  
*MARCH 17, 2017*

Presentation Handout



# THE EVOLVING COI LANDSCAPE

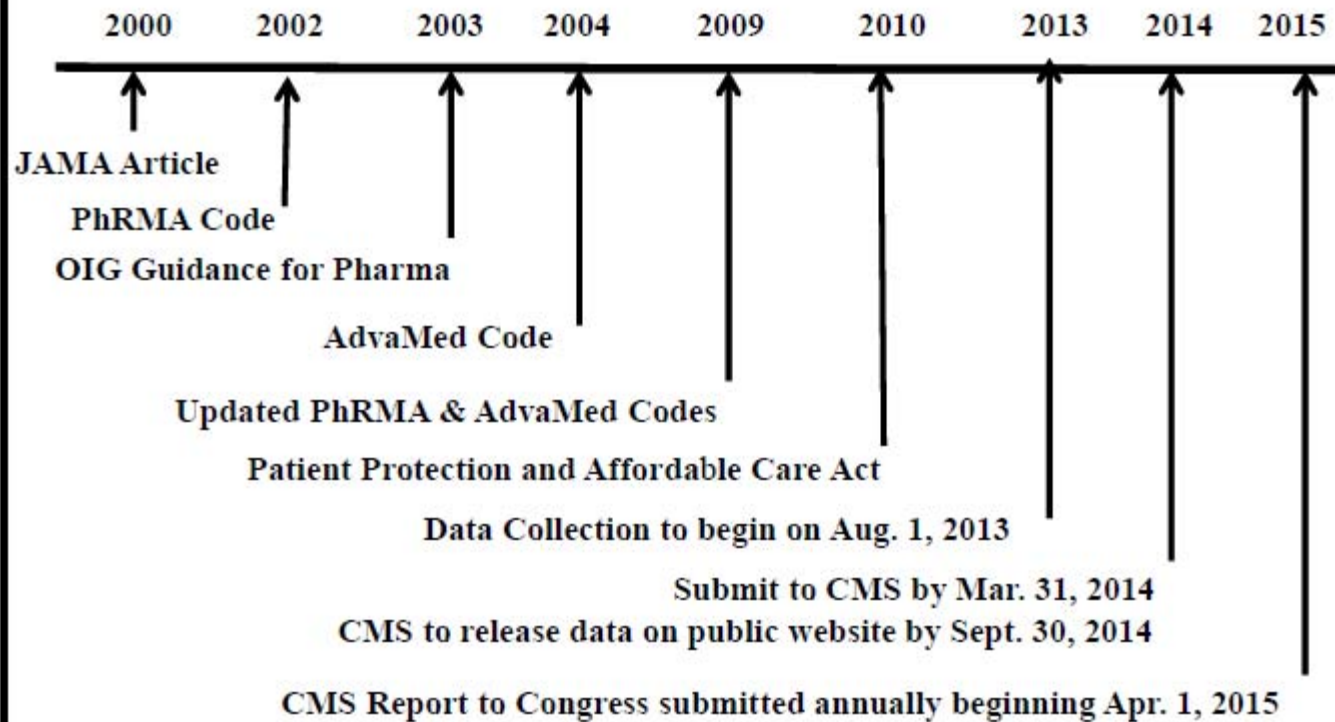
Awareness of and sensitivity to Conflicts of Interest (COI) in healthcare has heightened exponentially over the last 15 years.

Media attention given to events and cases have brought COI to the forefront of the minds of health care professionals and many consumers.

As awareness has increased, regulators have intensified their calls for **transparency** in relationships between health care providers and health care industry vendors and suppliers.

The net effect requires a more **vigilant response** from health care providers.<sup>1</sup>

## Brief Timeline of Industry COI Developments



# COI BACKGROUND & RESOURCES

## 1995:

- Conflicts of Interest in Research: Health and Human Services (HHS) promulgated the current Public Health Service (PHS) regulations (also known as the **financial conflict of interest, or FCOI, regulations** (42 CFR Part 50 Subpart F and 45 CFR Part 94):
  - “Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought”, and
  - “Responsible Prospective Contractors.”

**2003:** OIG Compliance Program Guidance for Pharmaceutical Manufacturers<sup>2</sup>

# COI BACKGROUND & RESOURCES

## **2005 – Present:**

- Increasing number of significant settlements with pharmaceutical and device manufacturers (see next slides) as well as with physicians related to inappropriate marketing, sales, and distribution of goods and services to Federal health program beneficiaries.

## **2008 Revised Codes of Ethics:**

- Revised PhRMA Code of Ethics<sup>3</sup> on interactions with HCPs that relate to the marketing of products
- Revised AdvaMed Code of Ethics<sup>4</sup> on interactions between companies and HCPs for the safe and effective use of medical technologies
  - Prohibits distribution of non-educational items
  - Restrictions on company sponsored meals
  - Additional guidance for speaking/consulting relationships
  - Training and conduct of company representatives (on laws, regulations, and industry standards)

# Big Pharma's Big Fines

by *Lena Groeger, ProPublica*  
Feb. 24, 2014

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In the last few years pharmaceutical companies have agreed to pay over \$13 billion to resolve U.S. Department of Justice allegations of fraudulent marketing practices, including the promotion of medicines for uses that were not approved by the Food and Drug Administration. Here are summaries of some recent large settlements.

## Pfizer

SEPT 2009

Pfizer was fined \$2.3 billion, then the largest health care fraud settlement and the largest criminal fine ever imposed in the United States. Pfizer pled guilty to misbranding the painkiller Bextra with "the intent to defraud or mislead", promoting the drug to treat acute pain at dosages the FDA had previously deemed dangerously high. Bextra was pulled from the market in 2005 due to safety concerns. The government alleged that Pfizer also promoted three other drugs illegally: the antipsychotic Geodon, an antibiotic Zyvox, and the antiepileptic drug Lyrica.

[See Pfizer in Dollars For Docs](#)

## Merck

NOV 2011

Merck agreed to pay a fine of \$950 million related to the illegal promotion of the painkiller Vioxx, which was withdrawn from the market in 2004 after studies found the drug increased the risk of heart attacks. The company pled guilty to having promoted Vioxx as a treatment for rheumatoid arthritis before it had been approved for that use. The settlement also resolved allegations that Merck made false or misleading statements about the drug's heart safety to increase sales.

[See Merck in Dollars For Docs](#)

## GlaxoSmithKline

JULY 2012

GlaxoSmithKline agreed to pay a fine of \$3 billion to resolve civil and criminal liabilities regarding its promotion of drugs, as well as its failure to report safety data. This is the largest health care fraud settlement in the United States to date. The company pled guilty to misbranding the drug Paxil for treating depression in patients under 18, even though the drug had never been approved for that age group. GlaxoSmithKline also pled guilty to failing to disclose safety information about the diabetes drug Avandia to the FDA.

[See GlaxoSmithKline in Dollars For Docs](#)

## Sanofi-Aventis

DEC 2012

Sanofi-Aventis agreed to pay \$109 million to resolve allegations that the company gave doctors free units of Hyalgan (an injection to relieve knee pain) to encourage those doctors to buy their product. Sanofi lowered the effective price by promising these free samples to doctors, but at the same time got inflated prices from government programs by submitting false price reports, alleged the United States. Medicare and other government health care programs "paid millions of dollars in kickback-tainted claims for Hyalgan," according to the DOJ announcement.

## Johnson & Johnson

NOV 2013

Johnson & Johnson agreed to pay a \$2.2 billion fine to resolve criminal and civil allegations relating to the prescription drugs Risperdal, Invega and Natrecor. The government alleged that J&J promoted these drugs for uses not approved as safe and effective by the FDA, targeted elderly dementia patients in nursing homes, and paid kickbacks to physicians and to the nation's largest long-term care pharmacy provider, Omnicare Inc. As part of the agreement, Johnson & Johnson admitted that it promoted Risperdal for treatment of psychotic symptoms in non-schizophrenic patients, although the drug was approved only to treat schizophrenia.

[See J&J in Dollars For Docs](#)

## Eli Lilly

JAN 2009

Eli Lilly was fined \$1.42 billion to resolve a government investigation into the off-label promotion of the antipsychotic Zyprexa. Zyprexa had been approved for the treatment of certain psychotic disorders, but Lilly admitted to promoting the drug in elderly populations to treat dementia. The government also alleged that Lilly targeted primary care physicians to promote Zyprexa for unapproved uses and "trained its sales force to disregard the law."

See Eli Lilly in  
[Dollars For Docs](#)

## AstraZeneca

APRIL 2010

AstraZeneca was fined \$520 million to resolve allegations that it illegally promoted the antipsychotic drug Seroquel. The drug was approved for treating schizophrenia and later for bipolar mania, but the government alleged that AstraZeneca promoted Seroquel for a variety of unapproved uses, such as aggression, sleeplessness, anxiety, and depression. AstraZeneca denied the charges but agreed to pay the fine to end the investigation.

See AstraZeneca in  
[Dollars For Docs](#)

## Abbott

MAY 2012

Abbott was fined \$1.5 billion in connection to the illegal promotion of the antipsychotic drug Depakote. Abbott admitted to having trained a special sales force to target nursing homes, marketing the drug for the control of aggression and agitation in elderly dementia patients. Depakote had never been approved for that purpose, and Abbott lacked evidence that the drug was safe or effective for those uses. The company also admitted to marketing Depakote to treat schizophrenia, even though no study had found it effective for that purpose.

See Abbott in  
[Dollars For Docs](#)

## Boehringer Ingelheim

OCT 2012

Boehringer Ingelheim Pharmaceuticals Inc agreed to pay \$95 million to resolve allegations that the company promoted several drugs for non- medically accepted uses. These drugs included the stroke-prevention drug Aggrenox, the lung disease drugs Atrovent and Combivent, and Micardis, a drug to treat high blood pressure. The FDA alleged that Boehringer improperly marketed the drugs and "caused false claims to be submitted to government health care programs."

## Amgen

DEC 2012

Amgen agreed to pay a \$762 million fine to resolve criminal and civil charges that the company illegally introduced and promoted several drugs including Aranesp, a drug to treat anemia. Amgen pleaded guilty to illegally selling Aranesp to be used at doses that the FDA had explicitly rejected, and for an off-label treatment that had never been FDA-approved.

## Endo

FEB 2014

Endo Health Solutions Inc. and its subsidiary Endo Pharmaceuticals Inc. agreed to pay \$192.7 million to resolve criminal and civil liability arising from Endo's marketing of the prescription drug Lidoderm. As part of the agreement, Endo admitted that it intended that Lidoderm be used for unapproved indications and that it promoted Lidoderm to healthcare providers this way.

Source: The Department of Justice.

ProPublica: <http://projects.propublica.org/graphics/bigpharma>, accessed 3 March 2017

# COI BACKGROUND & RESOURCES

**2011:** HHS published its final rule to amend the original 1995 regulations<sup>5</sup>. Major changes to the 1995 regulations include:

- Lower financial disclosure thresholds
- New conflict of interest training
- New public accessibility requirements
- Increased transparency for travel reimbursement

North Carolina General Statutes for Public Hospitals: Conflict of Interest (§131E-14.2)<sup>6</sup>



# PEW REPORT ON COI

## 2013: The Pew Charitable Trusts Task Force issues recommendations on relationships with industry<sup>7</sup>

Domain	Pew Expert Task Force Recommendation
Conflict of interest disclosure	Disclose relevant financial COIs to faculty, trainees, patients, and the public.
Industry-funded speaking	Prohibit participation by faculty and trainees in all promotional speaking.
Industry support of accredited CME	With rare exceptions, AMCs should not accept industry funding for accredited CME.
Attendance at industry-sponsored lectures and meetings	Faculty, students, and trainees should not attend promotional programs.
Pharmaceutical sales representative presence in AMCs	Pharmaceutical sales representatives should not be allowed access to faculty, students, or trainees; however, pharmaceutical scientists are allowed by invitation for scientific discussion.
Medical device representative presence in AMCs	Medical device representatives should be permitted in patient care areas only to provide in-service training and technical assistance on devices and equipment and then only by appointment.
Curriculum on conflict of interest	Education in the diverse manifestations and settings of COI should be required for all medical students, residents, clinical fellows, and faculty.
Extension of institutional COI policies to community educational settings	COI policies established by AMCs should apply to all faculty and trainees both on-site and off-site, and to affiliated institutions participating in the AMC's training programs.
Gifts (defined as free items, excluding meals)	No industry gifts of any value should be accepted.
Meals (including CME and non-CME related meals, whether onsite or offsite)	No meals or drinks of any value associated with industry-funded marketing activities or CME should be accepted.
Consulting relationships for marketing	Faculty and trainees should be prohibited from engaging in consulting relationships that are solely or primarily for commercial marketing purposes.
Consulting and advising relationships for scientific activities	Faculty and trainees are permitted to engage in consulting relationships with industry about research and scientific matters.
Pharmaceutical samples	Institutions should not accept samples. If an institution determines that there are compelling circumstances, it should implement mechanisms for accepting samples that prevent their use as marketing tools.
Pharmacy and therapeutics committee	Ideally, voting members of P&T committees should not have a financial relationship with industry. In circumstances when this cannot be achieved, members with financial relationships should be recused from discussion of, or voting on, a related or competing product.
Ghostwriting and honorary authorship	Faculty and trainees should follow institutional and ICMJE (International Committee of Medical Journal Editors) standards, which forbid ghostwriting and honorary authorship.
Industry-supported fellowships	Trainees may not accept industry-sponsored fellowships earmarked for clinical training but may compete for industry fellowships awarded for scientific training.

# COI BACKGROUND & RESOURCES

## Public Health Service (PHS) Funded Research

- Financial Conflict of Interest (FCOI) Policy<sup>8</sup>
  - Safeguarding research objectivity
  - Protecting human subjects and researchers exposed to COI situations
  - Enabling compliance with laws and regulations
- Regulations
  - Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding Is Sought
  - National Institutes of Health – FCOI Regulations

# COI BACKGROUND & RESOURCES

## RESEARCH: FINANCIAL CONFLICTS OF INTEREST

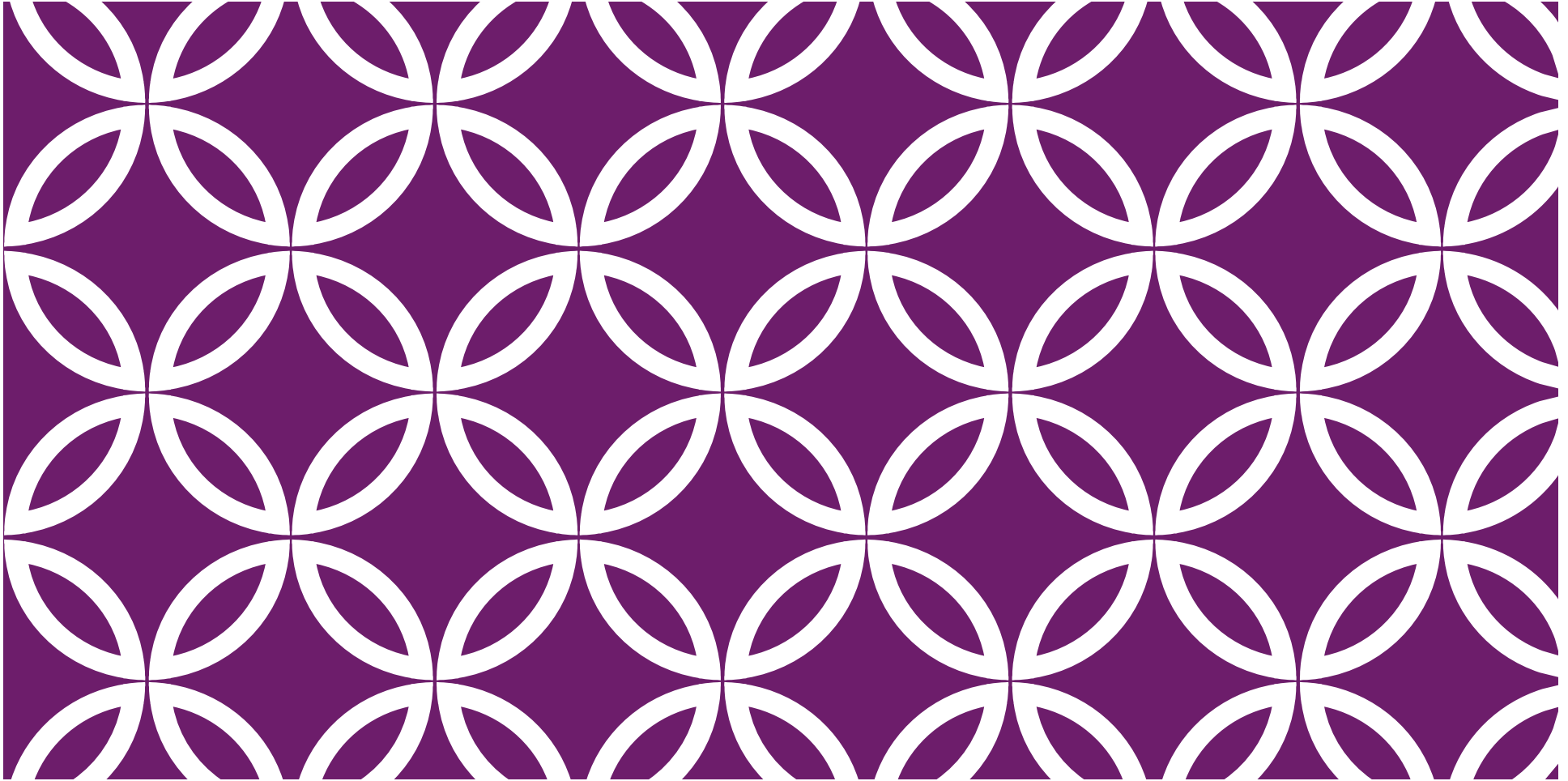
“An Institution applying for or receiving NIH funding from a grant or cooperative agreement must be in compliance with all of the revised regulatory requirements no later than 365 days after publication of the regulation in the Federal Register, i.e., August 24, 2012, and immediately upon making the Institution’s Financial Conflict of Interest policy publicly accessible as described in 42 CFR part 50.604(a). Institutions must comply with the 1995 financial conflict of interest regulation until the Institution fully implements all of the regulatory requirements of the 2011 revised regulation.”<sup>8</sup>

# HEALTH CARE'S APPROACH TO COI

April 2009, the Institute of Medicine (IOM) concluded, *“the goals of COI policies in medicine are primarily to protect the integrity of professional judgment and to preserve public trust rather than to try to remediate bias or mistrust after they occur”*.<sup>9</sup>

- *With regard to clinical practice, the IOM found that “the risk of undue industry influence ... is significant”*.

The NIH has stated *“it is critical for [health care organizations] to recognize that institutional conflicts of interest exist, to establish an environment of vigilance against the appearance of institutional conflicts of interest, to identify such conflicts in a timely manner and to manage such conflicts”*.<sup>10</sup>



# PHYSICIAN PAYMENT SUNSHINE ACT

“Open Payments”

# SUNSHINE ACT GOAL

Peter Budetti, MD (former CMS Deputy Administrator for Program Integrity):

*“You should know when your doctor has a financial relationship with the companies that manufacture or supply the medicines or medical devices you may need. Disclosure of these relationships allow patients to have more informed discussions with their doctors.”*

Source: *Conflicts of Interest: The Compliance Officer's Role in Assuring the Process of Disclosure is Effective*; Sheryl Vacca, April 8, 2013

# OPEN PAYMENTS PROGRAM INCREASES TRANSPARENCY IN HEALTH CARE

## Open Payments Program Increases Transparency in Health Care

By, Richard E. Wild, MD, JD, MBA, FACEP, Chief Medical Officer, Centers for Medicare & Medicaid Services, Atlanta Regional Office.

The Centers for Medicare & Medicaid Services' (CMS) Open Payments program collects data from drug and device manufacturers and group purchasing organizations (GPOs) about payments they make to physicians and teaching hospitals. The program also reports information about ownership interests in drug and device manufacturers and GPOs held by physicians and their immediate family members. It's important that physicians and teaching hospitals confirm the accuracy of the financial relationships reported about them.

CMS encourages all physicians - including medical doctors, doctors of osteopathy, dentists, chiropractors and others - and teaching hospitals to register and review any payments reported about them. There are [instructions and quick tips](#) to help. **The review period opened on April 6, 2015, and will be open for at least 45 days.** Reporting inaccuracies helps to make sure that the information posted to the Open Payments website is correct. The only way for physicians and teaching hospitals to confirm that the data reported about them is correct is to register and review that data now during the current review period.

Last fall, CMS reported 4.45 million payments valued at \$3.7 billion which were made in the last five months of 2013. These payments were for items such as medical research, conference travel and lodging, gifts and consulting (along with physician ownership or investment interest in industry). CMS will collect this data annually and continue to make it publicly available, downloadable, and searchable. **Data from the full 12 months of 2014 has been collected and will be released publicly by CMS on June 30, 2015.**

Collaboration benefits physicians, teaching hospitals and drug/device manufacturers in the design and delivery of many life-saving drugs and devices. Open Payments gives patients a tool to become more involved and informed health care consumers by empowering them to discuss these relationships with their physicians. CMS has had nearly 6 million views of [Open Payments data](#) and we're pleased with the continuing engagement of stakeholders on this important transparency initiative.

Learn more about the [Open Payments program](#) or send questions to [openpayments@cms.hhs.gov](mailto:openpayments@cms.hhs.gov).

*This information is provided by the United States Department of Health and Human Services.*

# SUNSHINE ACT ORIGINS AND GOALS

Adopted as part of the Affordable Care Act of 2010

- 42 USC 1302
- 42 USC 1395hh

Final Rule issued February 8, 2013 (23 significant definitions!)

- 42 CFR 403.900 – 910

## Key Dates:

- August 1, 2013: Transfers and ownerships TRACKING began
- March 31, 2014: “Abbreviated” 5-month data provided to CMS
- September 30, 2014: data was made public via dedicated CMS website
- ***Future reporting cycles will include 12-months (January to December) of data for the preceding calendar year, submitted “by” the 90th day of each year.***

Source: *Conflicts of Interest: The Compliance Officer’s Role in Assuring the Process of Disclosure is Effective*; Sheryl Vacca, April 8, 2013



# PHYSICIAN PAYMENTS SUNSHINE ACT

The National Physician Payment Transparency (Open Payments) Program (NPPT), more commonly referred to as the “**Physician Payments Sunshine Act**”, is a national disclosure program created by the Affordable Care Act to “promote transparency and accountability in the health care industry.”

Requires pharmaceutical, medical device, biological, and medical supply manufacturers operating in the United States to report to the Secretary of the United States Department of Health and Human Services payments or transfers of value that they made to covered recipients (**physicians, teaching hospitals**) during the previous calendar year.

# PHYSICIAN PAYMENTS SUNSHINE ACT

## *What Is Reported / Who Is Impacted?*

**“Transfers of Value”** - Individual payments over \$10 in value or payments that exceed \$100 in total annual value to:

- **Physicians**
  - Doctors of medicine and osteopathy, dental surgeons, dentists, licensed chiropractors, optometrists, podiatrists (consistent with Medicare statutory definition)
  - Excludes residents
- **Teaching Hospitals** - Institutions that receive:
  - Indirect medical education (IME)
  - Direct graduate medical education (GME)
  - Psychiatric hospital IME

**Ownership Interests** - Direct or indirect ownership interest of at least 5 percent held by:

- **Physicians**
- **Physicians’ Immediate Family Members**

# PENALTIES FOR NON-COMPLIANCE

*CMS and OIG authorized to impose civil monetary penalties and both will be charged with investigating failures to report*

***Strict Liability:*** \$1000 - \$10,000 per failure to report; aggregate cap of \$150,000

***Level of Knowledge*** (parallels False Claims Act): \$10,000 - \$100,000; aggregate cap of \$1.15M

***All Penalties are on the Reporting Entity!***

*Source: Conflicts of Interest: The Compliance Officer's Role in Assuring the Process of Disclosure is Effective; Sheryl Vacca, April 8, 2013*

# REFERENCES

1. <http://oig.hhs.gov/testimony/docs/2010/IGCOIAHLA-1-2010.pdf>
2. <http://oig.hhs.gov/authorities/docs/050503FRCPGPharmac.pdf>
3. [http://www.phrma.org/sites/default/files/pdf/phrma\\_marketing\\_code\\_2008.pdf](http://www.phrma.org/sites/default/files/pdf/phrma_marketing_code_2008.pdf)
4. <http://advamed.org/res.download/112>
5. [http://grants.nih.gov/grants/policy/coi/fcoi\\_final\\_rule.pdf](http://grants.nih.gov/grants/policy/coi/fcoi_final_rule.pdf)
6. [http://www.ncga.state.nc.us/EnactedLegislation/Statutes/pdf/ByChapter/Chapter\\_131E.pdf](http://www.ncga.state.nc.us/EnactedLegislation/Statutes/pdf/ByChapter/Chapter_131E.pdf)
7. <http://www.pewtrusts.org/en/multimedia/data-visualizations/2013/task-force-recommendations-on-relationships-with-industry>
8. <https://grants.nih.gov/grants/policy/coi/index.htm>
9. [http://www.shipmangoodwin.com/files/27936\\_AC\\_1001-2\\_Crumel.pdf](http://www.shipmangoodwin.com/files/27936_AC_1001-2_Crumel.pdf)
10. <http://oig.hhs.gov/testimony/docs/2010/IGCOIAHLA-1-2010.pdf>
11. [http://www.hcca-info.org/Portals/0/PDFs/Resources/Conference\\_Handouts/Compliance\\_Institute/2014/mon/110print3.pdf](http://www.hcca-info.org/Portals/0/PDFs/Resources/Conference_Handouts/Compliance_Institute/2014/mon/110print3.pdf)