


Speaking, and Payments
and Jail, Oh My:
Changes in the Sunshine Act

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Disclosures

- I have no financial or commercial relationships to disclose.
- All opinions presented are my own and do not represent those of my employer.
- All information is presented for general academic purposes and is not to be considered legal advice.
- All attempts were made to reflect the most up-to-date information. You should address any concerns with your legal counsel or the organization's compliance officer.





Learning Objectives

- Identify potential conflicts of interest that can arise in the healthcare industry and discuss application of the Sunshine Act to PAs and NPs
- Discuss elements of the Anti-Kickback Statute and False Claims Act which can apply to PA and NPs interacting with healthcare manufactures
- Analyze recent cases to identify how to mitigate violating the Anti-Kickback Statute and False Claims Act
- Apply the definition of a conflict of interest to identify issues that may arise in professional practice creating improper arrangements



Physician Payments Sunshine Act

- Affordable Care Act § 6002-1128G amending to the Social Security Act (the Act).
 - 42 U.S. Code § 1320a-7h
- Medical product manufactures and group that purchase organizations must disclose payments or transfer of value to covered recipients:
 - physician and teaching hospitals
- Includes disclosure of physician investment or ownerships in medical product manufactures and group purchasing organizations
- Information is published and searchable on a public site



Open Payments Data

- Disclosures are done annual to the Centers for Medicare and Medicaid Services (CMS)
- Publicly reported at: <https://openpaymentsdata.cms.gov>
- Physicians and teaching hospitals currently given to opportunity to review reported data from June 30- December 31.
 - Data is from the previous year
 - Reviewed at: <https://www.cms.gov/OpenPayments/Program-Participants/Physicians-and-Teaching-Hospitals/Registration>



Physician Payments Sunshine Act

- Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act) 2018
- Expanded the requirements of the Sunshine Act to include:
 - physician assistants
 - nurse practitioners
 - clinical nurse specialists
 - certified registered nurse anesthetists
 - certified nurse-midwives



Physician Payments Sunshine Act

- The Support Act expansion will be required for submissions to CMS starting January 1, 2022
- Information will be gathered during calendar year 2021 to be including in the March 2022 federal Sunshine Act submission.
- EXAMPLES:
 - Non-CME speaking fees
 - Travel
 - Advisory board
 - Consulting
 - Accredited CME speaking compensation is excluded from reporting.



Conflict of Interest

- Institute of Medicine
 - *A conflict of interest is a set of circumstances that creates a risk that professional judgment or actions regarding a primary interest will be unduly influenced by a secondary interest.*
- *How does this apply to health care clinicians?*



Conflict of Interest

- *Internal Revenue Service*
 - A conflict of interest occurs where individuals' obligation to further the organization's charitable purposes is at odds with their own financial interests.



Conflict of Interest

- IRS 501(c)(3)
- Operating under 501(c)(3) the charitable organization must not operate to benefit private interests.
- Earning cannot benefit a private stakeholder.
- Organizations are required to annually acknowledge a written conflict of interest policy on the 990 form.



<p>Dr. José Baselga, the chief medical officer of Memorial Sloan Kettering Cancer Center, resigned on Thursday amid reports that he had failed to disclose millions of dollars in payments from health care companies in dozens of research articles.</p>	<p style="text-align: center;">The New York Times</p> <hr/> <p style="text-align: center;"><i>Top Sloan Kettering Cancer Doctor Resigns After Failing to Disclose Industry Ties</i></p> 
<p>“It is my hope that this situation will inspire a doubling down on transparency in our field,” he said, adding that he hoped the medical community would work together to develop a more standardized system for reporting industry ties.</p>	

Insys: The case of sex, drugs, and kickbacks

- In 2012 the FDA approved Subsys for persistent breakthrough pain in adults with a cancer and tolerant to opioid therapy
- Subsys is a sublingual fentanyl spray manufactured by Insys Therapeutic, Inc.



Inysis: The case of sex, drugs, and kickbacks

- Beginning in 2012 a “speaker program” was initiated
 - Subsys prescribers paid to be speakers for the program
 - Most were not oncologist
- Programs were held in expensive restaurants, with gatherings in bars and strip clubs
- Programs had repeat attendees, office staff, or never occurred.



Insys: The case of sex, drugs, and kickbacks

143. For example, at a national sales meeting held by the company in April 2013, Insys executive Karen Hill spoke with the audience about “how to throw something out to a doctor without sounding off-label.” At the same meeting, Insys executive Dan Tondre told the audience, “When a patient’s in pain and it’s a severe pain . . . is it different they have cancer pain . . . or is it different they got, like, back pain That’s the whole point, pain is pain.”



Insys: The case of sex, drugs, and kickbacks

145. In August 2013, Regional Sales Manager Richard Simon sent the following text to an Insys sales representative:

I need confirmation from YOU that you had a conversation with ... [the practitioner] where he will not ONLY promote for cancer patients. If he does this he will single handedly take down the whole company. He MUST creatively share how docs write this product everywhere. Please get back to me ASAP with confirmation that he will share with our other speakers how effective ... [the Fentanyl Spray] will be to treat ALL BTP [Breakthrough Pain].



Inysis: The case of sex, drugs, and kickbacks

144. At another national sales meeting, held by the company in or about 2014, Alec Burlakoff told the company's sales force:

[t]hese [doctors] will tell you all the time, well, I've only got like eight patients with cancer. Or, I only have, like, twelve patients that are on a rapid-onset opioids [sic]. Doc, I'm not talking about any of those patients. I don't want any of those patients. That's, that's small potatoes. That's nothing. That's not what I'm here doing. I'm here selling [unintelligible] for the breakthrough pain. If I can successfully sell you the [unintelligible] for the breakthrough pain, do you have a thousand people in your practice, a thousand patients, twelve of them are currently on a rapid-onset opioids [sic]. That leaves me with at least five hundred patients that can go on this drug.



“Insys Reimbursement Center”

- Staffed by Insys employees to process and obtain prior authorization of Subsys
- Demonstrated misleading information provided to obtain approval and reimbursement for:
 - Stating they were an employee of the prescriber
 - Inaccurate patient diagnosis



Anti-Kickback Statute

- Is a federal criminal law, although some states have state law
- The law applies to the federal health care program
- “Prohibits the knowing and willful payment of "remuneration" to induce or reward patient referrals or the generation of business involving any item or service payable by the Federal health care programs.”
- Remuneration includes anything of value and can take many forms besides cash, such as free rent, expensive hotel stays and meals, and excessive compensation for medical directorships or consultancies



False Claims Act

States. 31 U.S.C. § 3729(a)(1).

29. The False Claims Act provides, in pertinent part, that a person who:

(a)(1)(A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; [or]

(a)(1)(B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; . . .

is liable to the United States Government for a civil penalty of not less than \$5,500 and not more than \$11,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note; Public Law 104-410), plus 3 times the amount of damages which the Government sustains. . . .

- A federal law enacted in 1863 by Congress during the Civil War.



False Claims Act

31 U.S.C. § 3729.

30. For purposes of the False Claims Act,
- (1) the terms “knowing” and “knowingly”—
 - (A) mean that a person, with respect to information—
 - (i) has actual knowledge of the information;
 - (ii) acts in deliberate ignorance of the truth or falsity of the information; or
 - (iii) acts in reckless disregard of the truth or falsity of the information; and
 - (B) require no proof of specific intent to defraud[.]

31 U.S.C. § 3729(b)(1).

31. The standard of proof under the False Claims Act is preponderance of the evidence. 31 U.S.C. § 3731(d).



Insys: The case of sex, drugs, and kickbacks

- Since 2013: 5 complaints were filed against Insys from whistleblowers for violations of the False Claims Act
 - The government intervened in 2018



Alabama

- Between 2012-2015: Two physicians were paid a combined \$270,000 in speaking fees.
- Medicare and Medicaid programs paid \$9.6 million for Subsys prescribed by these two physicians.
- Physicians were sentenced to 20+ years in prison for federal criminal charges including
 - Illegally prescribing...for not legitimate medical purpose
 - Accepting kickbacks from Insys
- The sales rep plead guilty on criminal charges including payment of illegal kickbacks.
- Had weekly scheduled speaking engagements at expensive restaurants.
- Same audience, to the physician's practice, or did not speak at all.



Michigan


- Neurologist paid \$89,000 for over 70 speeches
- Prior to becoming a speaker less than 13 prescription/month
- After 118/month
- Medicare and Medicaid program paid over \$6 million for Subsys
- Sentenced to 32 months in prison and to pay \$4 million in restitution



Connecticut

- APRN was paid \$83,000 for more than 70 dinner speaking programs.
- 2015 plead guilty for accepting kickbacks in violation of the Anti-Kickback Statute.
- Medicare and Medicaid programs paid more than \$1.3 million for Subsys.
- Drug representative plead guilty to related charged.






NP tells jury Insys gave her \$82K in kickbacks for overprescribing opioids
Mackenzie Bean - Tuesday, February 12th, 2019 Print | Email

Insys: The case of sex, drugs, and kickbacks

“If I was going to choose between one drug or another, I would choose the Subsys because that’s what I was getting paid for.”



New Hampshire

- Physician assistant paid more than \$40,000 for over 30 speeches between 2013-2014
- 2015 the PA was reprimanded by the Board of Medicine for overprescribing opioid drug and barred him from prescribing opioids.
- License eventually permanently revoked
- He was indicted in 2017
- Medicare and Medicaid programs paid \$2.6 million for Subsys.
- Sentenced to four years in federal prison



Common Theme

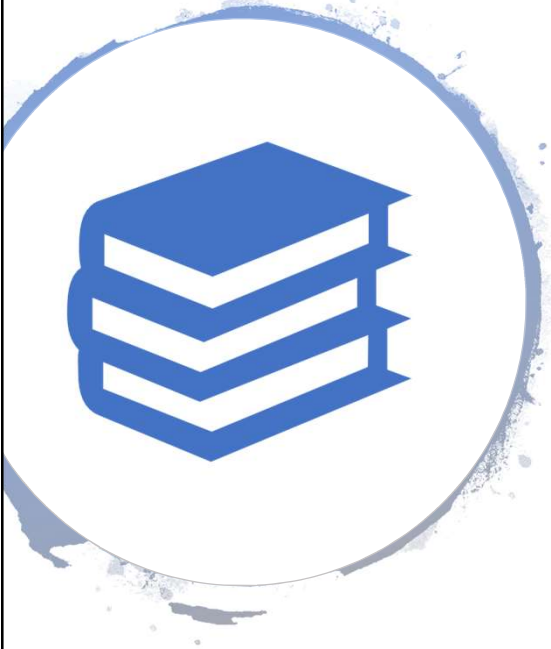
- Most of the speakers were not oncologist
- A small amount of the attendees were oncologist
- Insys encouraged its sales team to promote prescribing Subsys for patients from pain unrelated to cancer
- Programs and inducements were held in expensive restaurants, bars, and strip clubs.



Take-Aways


1. Review your organization's Conflict of Interest Policy.
2. Review what constitutes a gift.
3. Review invitations to dinner and events. Is the product relevant to your clinical practice?
4. Review the contract for being a consultant.
5. Review your own and others reported Open Payment Data from CMS.

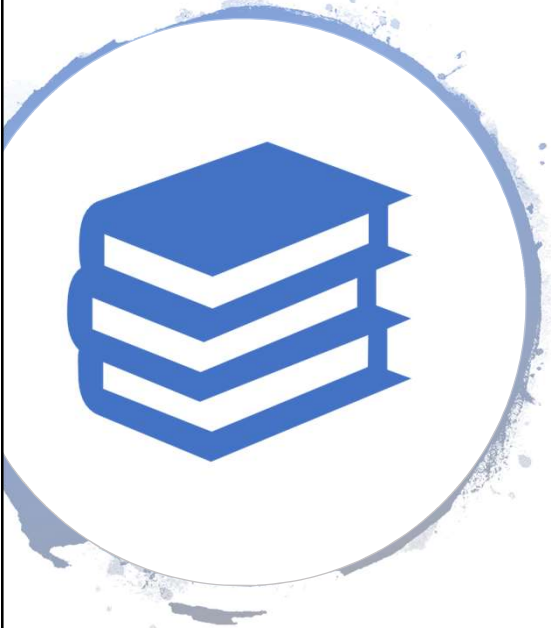




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Questions?

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