Orange is Not Your Color: Staying Out of Trouble with the Law

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Disclosures



All opinions presented are my own and do not represent those of my employers.



This information is intended for educational purposes. The information presented should not be construed as legal advice, nor advice on state or federal laws and regulations. Legal counsel should be obtained for those needing legal clarification for professional practice concerns.



All attempts were made to present the most upto-date information.



All questions should be theoretical with the intent of an academic discussion.



Laws set boundaries for protection from or liability for punishment

Fences set boundaries to define and protect the garden from pest pressure

Morals motivate our speech and behavior

Water splits and spouts seeds.

Plants lean toward sunlight for nourishment

Ethics reveals and directs our decisions when a dilemma arises

Gardeners tend, train, and prune growth, and select ripened fruits

4

•

What Guides Our Actions?

 ${f law}$ = formal rules that govern how we behave, what we must and must not do, creating an enforceable standard of behavior $^{\rm C1}$

morality = framework of values, principles, beliefs, customs, & ways of living, not usually enforced by the state in the U.S., which usually guides us unconsciously ^{C1}

ethics = process of conscious reflection for determining what action to take based on values, principles and purpose ^{C1}

law ≠ morality ≠ ethics

 ${\tt C1}_{What is the difference \ between \ Ethics, \ Morality, \ and \ the \ Law? \ The \ Ethics \ Centre, \ 2020 \ \underline{https://www.youtube.com/watch?v=Xki2fRA0bY8}$

5

Morals in Medicine

Professional

- Public servants must act in the public interest. ^{C3}
- Nonmaleficence forbids selfish action or inaction ^{C4}
- Discernment entails recognizing ethical, legal, and moral dimensions of each healthcare decision ^{C4}

Personal

- PAs are people with morals
- Healers provide care with compassion - empathetic action to alleviate suffering ^{C5}
- Moral judgements are made in context ^{C6}
- Dissonance between morality and action is distressing ^{C6}

^{C3} Savulescu J.Conscientious objection in medicine. British Medical Journal, 332(7536);2016., 294 https://pubmed.ncbi.nlm.nih.gov/16455733/

 $^{^{\}text{C4}}\,\text{Lo B. Resolving Ethical Dilemmas: A Guide for Clinicians. 2020. Philadelphia: Wolters \,Kluwer\,elSBN\,9781975142155}$

https://meded.lwwhealthlibrary.com/book.aspx?bookid=823

 $^{^{\}rm C5}$ McGonigal K. The Practical Science of Compassion. Compassion in Therapy Summit. 2021

^{CS} Taylor CR, Dell'Oro R. Health & Human Flourishing: Religion, Medicine, and Moral Anthropology. 2006. Georgetown University Press ISBN 9781589010796 https://meded.luw/healthlibrary.com/book.aspx?bookid=823

Morals in Medicine

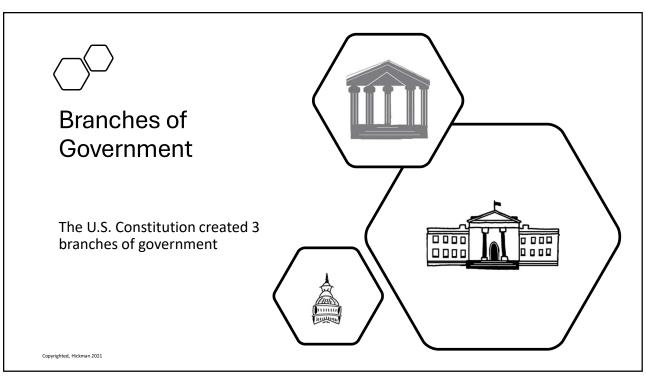
moral distress

- psychological distress of being in a situation in which one is constrained from acting on what one knows to be right ^{C7}
- leads to anger, anxiety, frustration, helplessness, fatigue, burnout C4

[!] Actions dissonant with conscience elicit moral distress

^{C7} Petriceks AH. A clinical catharsis: Moral distress and the uses of tragedy in palliative care. Palliative and Supportive Care. 2022:1-2. doi:10.1017/S1478951522000359 https://pubmed.ncbi.nlm.nih.gov/35317882/

 $^{^{\}text{C4}} \ Lo \ B. \ Resolving \ Ethical \ Ditemmas: A \ Guide for \ Clinicians. 2020. \ Philadelphia: \ Wolters \ Kluwer \ elSBN 9781975142155 \ https://meded.lwwhealthlibrary.com/book.aspx?bookid=823$



False Claims Act

The False Claims Act (FCA) is a federal law enacted during the Civil War in 1863 to combat fraud against the government

• Prohibits knowingly submitting false claims for payment to the government.

Broadly applies to various industries receiving federal funds, including healthcare, defense contracting, and government procurement.

Encompasses a wide range of fraudulent conduct,

- such as billing for services not rendered,
- $\bullet \ providing \ substandard \ goods,$
- making false certifications.

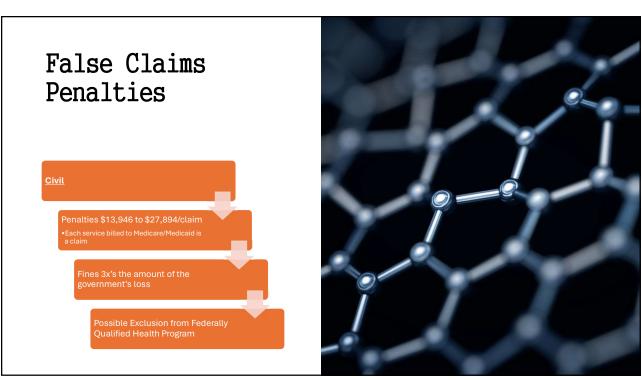
False Claims Act

Imposes liability for "false" or "fraudulent" claims,

• including those made with deliberate ignorance or reckless disregard for the truth.

Allows whistleblowers (qui tam relators) to file lawsuits on behalf of the government and receive a portion of recovered damages.

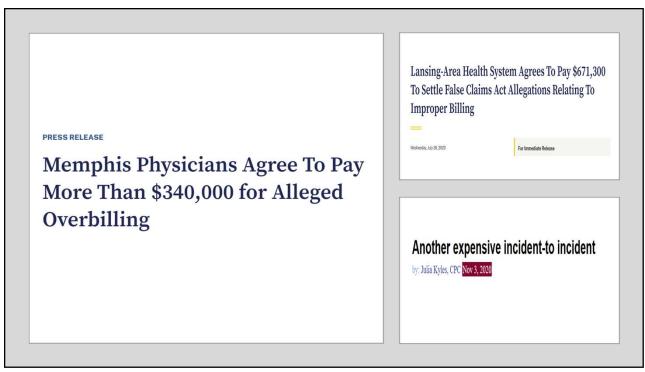
Investigated and prosecuted by various federal agencies

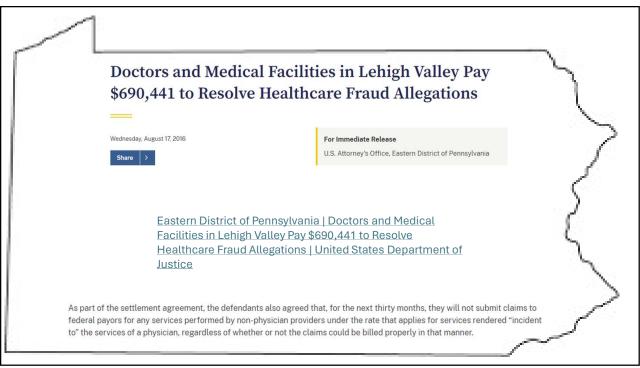




inSite Digestive Health Care Agreed to Pay \$1.7 Million for Allegedly Violating the Civil Monetary Penalties Law by Submitting Claims for Services by Uncredentialed Providers and Claims Out of Compliance with Incident-To or Split/Share Rules

The Mythical, Magical 15%





Anti-Kickback Statute

01

Is a federal criminal law, although some states have state law 02

The law applies to the federal health care program

03

"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."

• INTENT

04

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

Anti-Kickback Statute

Up to 5 years in prison

\$25,000/claim

Additional \$10,000-\$50,000 under Civil Monetary Penalties Law

Mandatory Exclusion Federally Qualified Health Program

AND Penalties under the False Claims Act

PRESS RELEASE

Telemedicine Nurse Practitioner Charged with \$7.8 Million Durable Medical Equipment Fraud Scheme

Friday, October 6, 2023

For Immediate Release
U.S. Attorney's Office, District of Massachusetts

- Individuals acquired through telemarketing to Medicare beneficiaries
- Signed prepopulated orders for braces with an established patientprovider relationship
- Orders were sold to DME suppliers and laboratories, and claims were submitted to Medicare
- Resulted in \$7.8 million in claims
- Facing
 - 10 years in prison
 - 3 years of supervised release
 - Fine up to \$250,000

Nurse Practitioner Sentenced for \$192M Medicare Fraud Scheme

Thursday, December 21, 2023
Share >

For Immediate Release
Office of Public Affairs

- Individuals acquired through telemarketing to Medicare beneficiaries
- Signed orders for genetic testing and braces
- During the conspiracy timeframe she ordered the most genetic cancer screening in the country
- Billed over 24hr in a day for telemedicine
- Received \$1.6 million used for expensive cars, jewelry, travel, and home renovations.
- \$192 million in claims
- Sentenced: 20 years.

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

• "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."



SPECIAL ARTICLE

Flying too close to the sun: Navigating changes to CMS' Open Payments program

Kevin A. Hickman, PA-C, MHA, MJ (Health Law), CHC

ABSTRACT

Increasingly, physician assistants (PAs), advanced practice nurses, and physicians are financially involved with healthcare product manufacturers. Although the relationships themselves might not be illegal, when the transaction influences the healthcare provider's medical decision-making, patients can be harmed and the healthcare provider and manufacturer can face accusations of violating federal and state law. In 2019, the federal government recouped \$2.6 billion from healthcare fraud and abuse by healthcare stakeholders. PAs' and NPs' behaviors violating the Anti-Kickback Statute (AKS) and False Claims Act (FCA) were partially responsible for the reported amount. To increase the transparency of the financial relationships between healthcare providers and healthcare manufacturers, the federal Centers for Medicare and Medicaid Services, under statutory obligation, created the Open Payments program, which will begin reporting PAs' and advanced practice nurses' financial relationships with manufacturers in 2022.

Keywords: physician assistant, NP, False Claims Act, Antikickback Statute, healthcare fraud, Open Payments program

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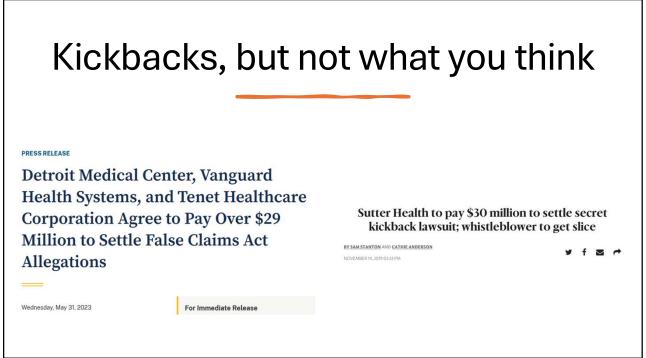


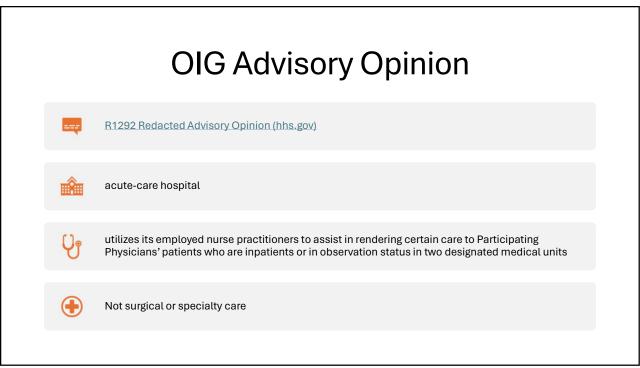
Sunshine Act

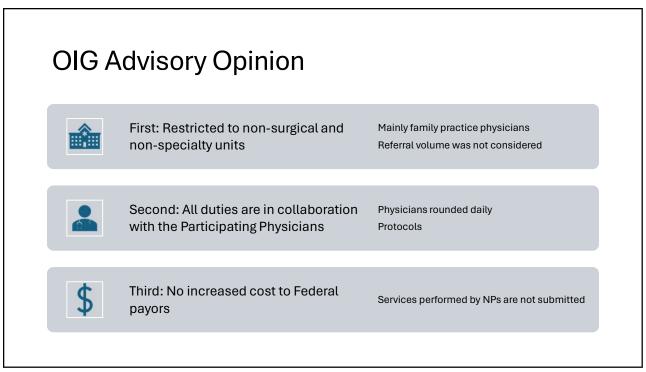
Kickbacks, but not what you think

But the defendants took the conspiracy to the next level when they began loaning out mid-level medical professionals — physicians assistants and nurse practitioners — to doctors free-of-charge in return for patients, the government <u>argued in its own closing statement</u> on Thursday, calling it "kickbacks on steroids."

- United States v. Edward Novak, et al.
- United States District Court, Northern District of Illinois, Eastern Division (2015)
 - SACRED HEART HOSPITAL









Qui Tam Relators

- Typically, an employee of the organization
- Brings a suit on behalf of the government
- Government decides whether to join the case after investigating
- Relators are awarded 15-25% of what the government collects
- 25-30% if the government did not join the case
- False Claims Act protects against retaliation against those attempting to prevent fraud



How do we move forward?

- Review your policy and procedures.
 - · Don't assume PAs/NPs were considered
- Are PAs/NPs represented on the Medical Exec Committee?
- Stay alert to state regulatory changes.
 - · Reach out to PA/NP State Academies
- Partner with PA/NP leadership for staff education
- Engage your PAs/NPs in shared billing practice education
- PAs and NPs should be filling out annual Conflict of Interest
- PAs should report through the medical leadership
- NPs typically report through nursing leadership
- PAs and NPs are becoming more aware of healthcare delivery
 - Mitigate your risk



Questions?

- Follow me on LinkedIn
 - https://www.linkedin.com/in/kevinhickman-PAC/
- Feel free to contact me in the future!

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Resources & References

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