

Where in the World is Carmen LawBreaker? Chasing Trends in Healthcare Fraud.

AAPA 2023
Nashville, Tn

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

Objectives

1. Describe the components and penalties of the False Claims Act and Anti-Kickback Statute.
2. Summarize federal compliance recommendations and discuss recent fraud healthcare cases.
3. Determine when healthcare fraud occurs within clinical and professional practice settings and how to report healthcare fraud concerns.

Question 1

A pharmaceutical manufacturer pays a PA to discuss the company's medication at dinners and events. The PA frequently prescribes this medication over competitors' similar medications, concerned over losing their speaking engagements by not prescribing enough of the medication.

What law is the PA violating?

- a. False Claims Act
- b. Anti-Kickback Statute
- c. Stark Law

Question 2

What is the best next step if you suspect fraudulent activity within your organization?

- a. Investigate the activity to have proof of your concerns.
- b. Contact an attorney and become a whistleblower.
- c. Discuss your concerns with human resources.
- d. Contact the compliance department.
- e. Email the organization's attorney outlining your observations and concerns.

Question 3

A clinic routinely submits claims under Medicare “incident to” guidelines. A PA routinely evaluates patients incident to the physician’s encounter despite a physician not being at the clinic. The clinic did not provide education and guidance on incident to guidelines as part of onboarding or continued education. Which of the following statements is correct?

- a. The organization did not educate the PA, so only the clinic is liable for the false claims.
- b. As the PA did not have knowledge of the incident to regulations, they cannot have liability under the False Claims Act as the False Claims Act requires knowledge of the violation.
- c. Ignorance of regulation doesn’t mitigate liability under the False Claims Act.

Disclosures

- All opinions presented are my own and do not represent those of my employer.
- 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 up-to-date information.
- All questions should be theoretical with the intent of an academic discussion.

Navigating the Map

- [False Claims Act Settlements and Judgments Exceed \\$2 Billion in Fiscal Year 2022 | OPA | Department of Justice](#)



(a) LIABILITY FOR CERTAIN ACTS.—

(1) IN GENERAL.—Subject to paragraph (2), any person who—

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

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

(C) conspires to commit a violation of subparagraph (A), (B), (D), (E), (F), or (G);

(D) has possession, custody, or control of property or money used, or to be used, by the Government and knowingly delivers, or causes to be delivered, less than all of that money or property;

(E) is authorized to make or deliver a document certifying receipt of property used, or to be used, by the Government and, intending to defraud the Government, makes or delivers the receipt without completely knowing that the information on the receipt is true;

(F) knowingly buys, or receives as a pledge of an obligation or debt, public property from an officer or employee of the Government, or a member of the Armed Forces, who lawfully may not sell or pledge property; or

(G) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government,

is liable to the United States Government for a civil penalty of not less than \$5,000 and not more than \$10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note; Public Law 104-410^[1]), plus 3 times the amount of damages which the Government sustains because of the act of that person.

False Claims Act

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

(b) DEFINITIONS.—For purposes of this section—

(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;

(2) the term “claim”—

(A) means any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property, that—

- (i)** is presented to an officer, employee, or agent of the United States; or
- (ii)** is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government’s behalf or to advance a Government program or interest, and if the United States Government—
 - (I)** provides or has provided any portion of the money or property requested or demanded; or
 - (II)** will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded; and

(B) does not include requests or demands for money or property that the Government has paid to an individual as compensation for Federal employment or as an income subsidy with no restrictions on that individual’s use of the money or property;

(3) the term “obligation” means an established duty, whether or not fixed, arising from an express or implied contractual, grantor-grantee, or licensor-licensee relationship, from a fee-based or similar relationship, from statute or regulation, or from the retention of any overpayment; and

(4) the term “material” means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.

False Claims Act

False Claims Penalties

Civil

- Penalties \$13,508 to \$27,018/claim
 - Each service billed to Medicare/Medicaid is a claim
- Fines 3x's the amount of the government's loss
- Possible Exclusion from Federally Qualified Health Program

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

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

Billing Fraud



“Upcoding”

Incident-to billing

Split/Shared Billing

U.S. Attorneys » Eastern District of Tennessee » News

Department of Justice

U.S. Attorney's Office

Eastern District of Tennessee

SHARE ↗

FOR IMMEDIATE RELEASE

Friday, January 24, 2020

**Family Physician Pays \$285,000 To Settle False Claims Act
Allegations Of Billing Services At Inflated Rate**

[Family Physician Pays \\$285,000 To Settle False Claims Act
Allegations Of Billing Services At Inflated Rate | USAO-EDTN |
Department of Justice](#)

[Home](#) » [Office of Public Affairs](#) » [News](#)

JUSTICE NEWS

Department of Justice
Office of Public Affairs

FOR IMMEDIATE RELEASE

Friday, October 30, 2020

Memphis Physicians Agree To Pay More Than \$340,000 for Alleged Overbilling

[Memphis Physicians Agree To Pay More Than \\$340,000 for Alleged Overbilling | OPA | Department of Justice](#)

Doctors and Medical Facilities in Lehigh Valley Pay \$690,441 to Resolve Healthcare Fraud Allegations

Wednesday, August 17, 2016

Share >

For Immediate Release

U.S. Attorney's Office, Eastern District of Pennsylvania

[Eastern District of Pennsylvania | Doctors and Medical Facilities in Lehigh Valley Pay \\$690,441 to Resolve Healthcare Fraud Allegations | United States Department of Justice](#)

As part of the settlement agreement, the defendants also agreed that, for the next thirty months, they will not submit claims to federal payors for any services performed by non-physician providers under the rate that applies for services rendered "incident to" the services of a physician, regardless of whether or not the claims could be billed properly in that manner.

Inappropriate Prescribing



Opioid Crisis

Durable Medical Equipment

[Louisiana Physician's Assistant Sentenced to Prison for Scheme to Unlawfully Distribute Controlled Substances | OPA | Department of Justice](#)


JUSTICE NEWS

Department of Justice
Office of Public Affairs

FOR IMMEDIATE RELEASE

Thursday, August 29, 2019

Louisiana Physician's Assistant Sentenced to Prison for Scheme to Unlawfully Distribute Controlled Substances



JUSTICE NEWS

Department of Justice
Office of Public Affairs

FOR IMMEDIATE RELEASE

Friday, May 20, 2022

Physician Assistant Convicted of Distributing Over 1.2 Million Opioid Pills

A Texas physician assistant was convicted today for distributing more than 1.2 million opioid pills during his employment at two Houston-area clinics that operated as pill mills.

[Physician Assistant Convicted of Distributing Over 1.2 Million Opioid Pills | OPA | Department of Justice](#)

What About Our Vulnerable?

[Justice.gov](#) > [U.S. Attorneys](#) > [Southern District of Georgia](#) > [Press Releases](#) > [Georgia Nurse Practitioner Convicted of Health Care Fraud In Complex Telemedicine Fraud Scheme](#)

PRESS RELEASE

Georgia nurse practitioner convicted of health care fraud in complex telemedicine fraud scheme



Wednesday, February 2, 2022

For Immediate Release

[Southern District of Georgia | Georgia nurse practitioner convicted of health care fraud in complex telemedicine fraud scheme | United States Department of Justice](#)

- Patient identities were obtained through telemarketing scheme
- NP would:
 - Sign name to false medical record claiming evaluation
 - Placed orders for over 3,000 orthotics for these identities
 - Resulted in \$3million is fraudulent claims

Cost of Greed

- Convicted
 - 84 months in federal prison
 - \$1,635,161.61 in restitution
 - 3 years supervised release

“Sherley Beaufilet let greed take the wheel when she raked in massive profits by ordering unnecessary medical devices for patients she never examined or spoke to,” said U.S. Attorney Estes. “She targeted the elderly and medically vulnerable with her schemes, and is now being held accountable.”

[Southern District of Georgia | Georgia nurse practitioner sentenced to prison, ordered to pay more than \\$1.6 million in restitution in complex telemedicine fraud scheme | United States Department of Justice](#)

Legal & Regulatory Issues

BECKER'S
HOSPITAL REVIEW

Join us online at our virtual
events.

Stay Engaged. Stay Connected.

LEARN MORE

NPs get prison time for telemedicine fraud

Ayla Ellison - Monday, August 2nd, 2021

- 1 year & 9 month incarceration sentences for conspiracy to commit healthcare fraud
- 13.4 million in restitution

[NPs get prison time for telemedicine fraud
\(beckershospitalreview.com\)](https://www.beckershospitalreview.com/news/np-convicted-of-telemedicine-fraud)

Manufacturer Relationship

- Are legal
- Can take many forms
- Must be within fair market value

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.”

Inysis: 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”

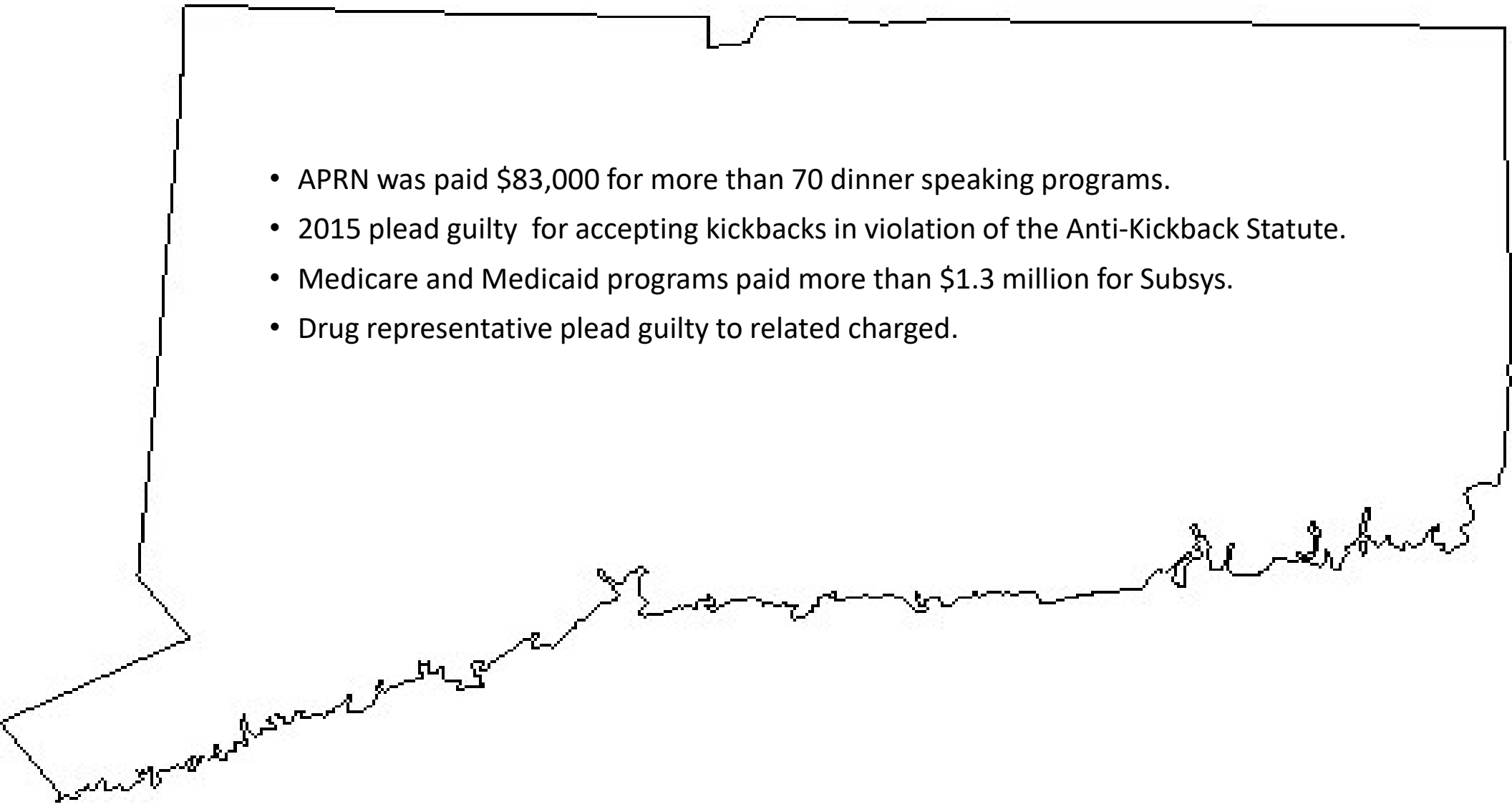
- Staffed by Insys employees to process and obtain prior authorization of Subsys
- Demonstrated misleading information provided to obtain approval and reimbursement for:
 - Stating they were an employee of the prescriber
 - Inaccurate patient diagnosis

NP tells jury Insys gave her \$82K in kickbacks for overprescribing opioids

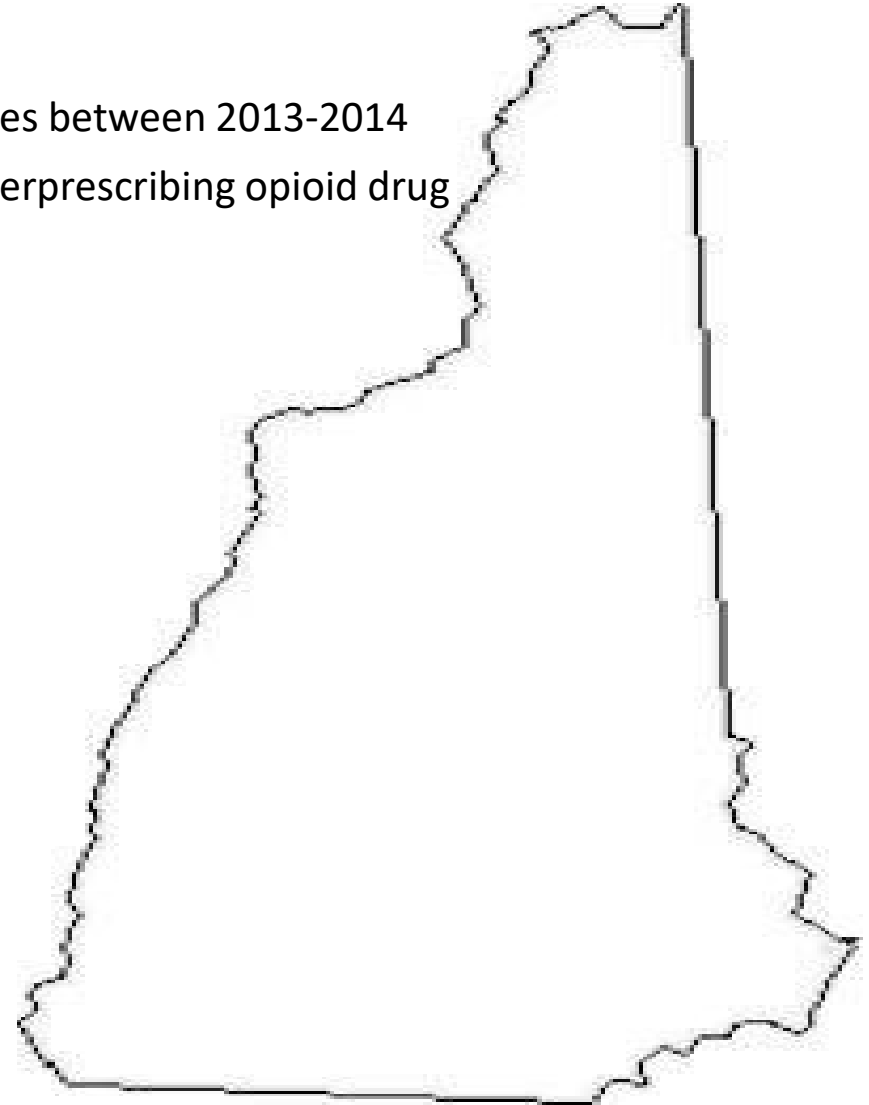
Mackenzie Bean - Tuesday, February 12th, 2019 [Print](#) | [Email](#)

Inysis: 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.”

- 
- 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.

- 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.

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, Anti-kickback Statute, healthcare fraud, Open Payments program



© DELCARMATSHUTTERSTOCK.COM

Kevin A. Hickman practices in neurosurgery at Geisinger Medical Center in Scranton, Pa., and is a doctoral student at A.T. Still University. The author has disclosed no potential conflicts of interest, financial or otherwise.

Acknowledgment: The author would like to thank **Sarah Elizabeth Campbell, JD, MHA, CHC, CHRC; Tricia Marriott, PA-C, MPAS, MJ (Health Law), CHC, DFAAPA;** and **Sondra M. DePalma, DHSc, PA-C, DFAAPA,** for their assistance with this manuscript.

DOI:10.1097/01.JAA.0000735780.35691.e5

Copyright © 2021 American Academy of PAs

How do we do better?

1. PAs and NPs are unique practitioners

- Review your Medical Staff ByLaws, Policies and Procedures
- Every time you see the word physician,



- Do you need to add PAs and NPs with physicians?
- PAs/NPs provide “physician services”
 - Do not group PAs/NPs with professional that are not Part B providers

How do we do better?

2. Who is leading your PAs and NPs?

- Do you have a PA and NP leader?
- PAs are not nurses.
- Who is advising on PA and NP practice.

How do we do better?

3. How does the organization treat PAs and NPs?
 - Are they a member of the Med Exec Committee?
 - Do PAs/NPs do an annual Conflict of Interest Disclosure?

How do we do better?

4. Is there annual education specific to PA and NP practice?
 - Split/Shared Billing, “incident to”
 - Supervision/Collaboration requirement
 - Do you meet with PAs/NPs as a group?

How do we do better?

5. What is the culture?

Seven Elements of an Effective Compliance Program

Does everyone know how to bring concerns forward?

[HEALTH CARE COMPLIANCE PROGRAM TIPS \(hhs.gov\)](https://www.hhs.gov/health-care-compliance-program-tips)

Question 1

A pharmaceutical manufacturer pays a PA to discuss the company's medication at dinners and events. The PA frequently prescribes this medication over competitors' similar medications, concerned over losing their speaking engagements by not prescribing enough of the medication.

What law is the PA company violating?

- a. False Claims Act
- b. Anti-Kickback Statute**
- c. Stark Law

Question 2

What is the best next step if you suspect fraudulent activity within your organization?

- a. Investigate the activity to have proof of your concerns.
- b. Contact an attorney and become a whistleblower.
- c. Discuss your concerns with human resources.
- d. Contact the compliance department.**
- e. Email the organization's attorney outlining your observations and concerns.

Question 3

A clinic routinely submits claims under Medicare “incident to” guidelines. A PA routinely evaluates patients incident to the physician’s encounter despite a physician not being at the clinic. The clinic did not provide education and guidance on incident to guidelines as part of onboarding or continued education. Which of the following statements is correct?

- a. The organization did not educate the PA, so only the clinic is liable for the false claims.
- b. As the PA did not have knowledge of the incident to regulations, they cannot have liability under the False Claims Act as the False Claims Act requires knowledge of the violation.
- c. **Ignorance of regulation doesn’t mitigate reliability under the False Claims Act.**

Questions?

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

kevin.a.hickman.pac@gmail.com