

# HEALTHCARE FRAUD, WASTE, AND ABUSE: WHAT IS IT AND HOW DO YOU AVOID IT?

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## ABOUT ME

# Stephanie P. Ottenwess

**Stephanie P. Ottenwess, Esq., of Southfield, Michigan, is the managing partner of Ottenwess Law, a boutique firm serving a diverse clientele in litigation, regulatory and transactional matters with particular focus on medical malpractice, professional liability defense and health law.**

**Her healthcare practice includes counseling on transactional matters, licensing and healthcare litigation, as well as federal and state healthcare regulatory compliance including Stark and self-referral laws, and Anti-Kickback laws. Ms. Ottenwess's clients include executives, physicians and physician groups, hospitals, practice managers and other healthcare professionals. She also speaks and authors articles on legal issues impacting the healthcare industry.**

# HEALTHCARE FRAUD IS A SERIOUS PROBLEM

The Government spends almost a trillion dollars each year on the Medicare and Medicaid programs.

Healthcare fraud is estimated to cost taxpayers \$30 billion to \$100 billion each year.

An array of laws has been enacted to combat fraud, waste, and abuse and protect the integrity of the healthcare payment system.

# FRAUD

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- Knowingly submitting false or fraudulent information to get a benefit that you are not entitled to receive. Knowingly does NOT mean that the person submitting the claim must have actual knowledge the claim is false. A person acting in reckless disregard or in deliberate ignorance of the truth can be found liable as well.
- It is a criminal offense to knowingly defraud a healthcare program.
- Some examples of fraud:
  - Billing for services, prescriptions or supplies not provided
  - Billing for the same services more than once (duplication)
  - Billing for a higher level of service than was actually provided (up-coding)
  - Billing separately for services that should be a single service (unbundling)

# WASTE

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- Overusing services or other practices that result in unnecessary costs to federal healthcare programs. Waste is generally considered to be the misuse of resources due to improper management, practices, or controls.
- Some examples of Waste:
  - Ordering multiple tests when only one is necessary
  - Prescribing brand name drugs when generics are available
  - Prescribing more medications than necessary
  - Scheduling too many office visits

# ABUSE

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- Excessive or improper use of government resources (including funds) that are inconsistent with generally accepted practices, but where the provider has not knowingly or intentionally misrepresented facts to obtain payment.
- Some examples of Abuse:
  - Billing for services that are not medically necessary
  - Billing for brand name drugs when generics are dispensed
  - Charging excessively for services or supplies

# KEY FRAUD AND ABUSE LAWS

**False  
Claims  
Act**

**Anti-  
Kickback  
Statute**

**Physician  
Self-Referral  
Statute  
("Stark")**

**Exclusion  
Statute**

**Civil  
Monetary  
Penalties  
Law**

# BUT, DON'T FORGET ABOUT THESE. ..



**State laws**

**Provider contracts**

# WHO ENFORCES THESE LAWS?

**The Department of Justice**

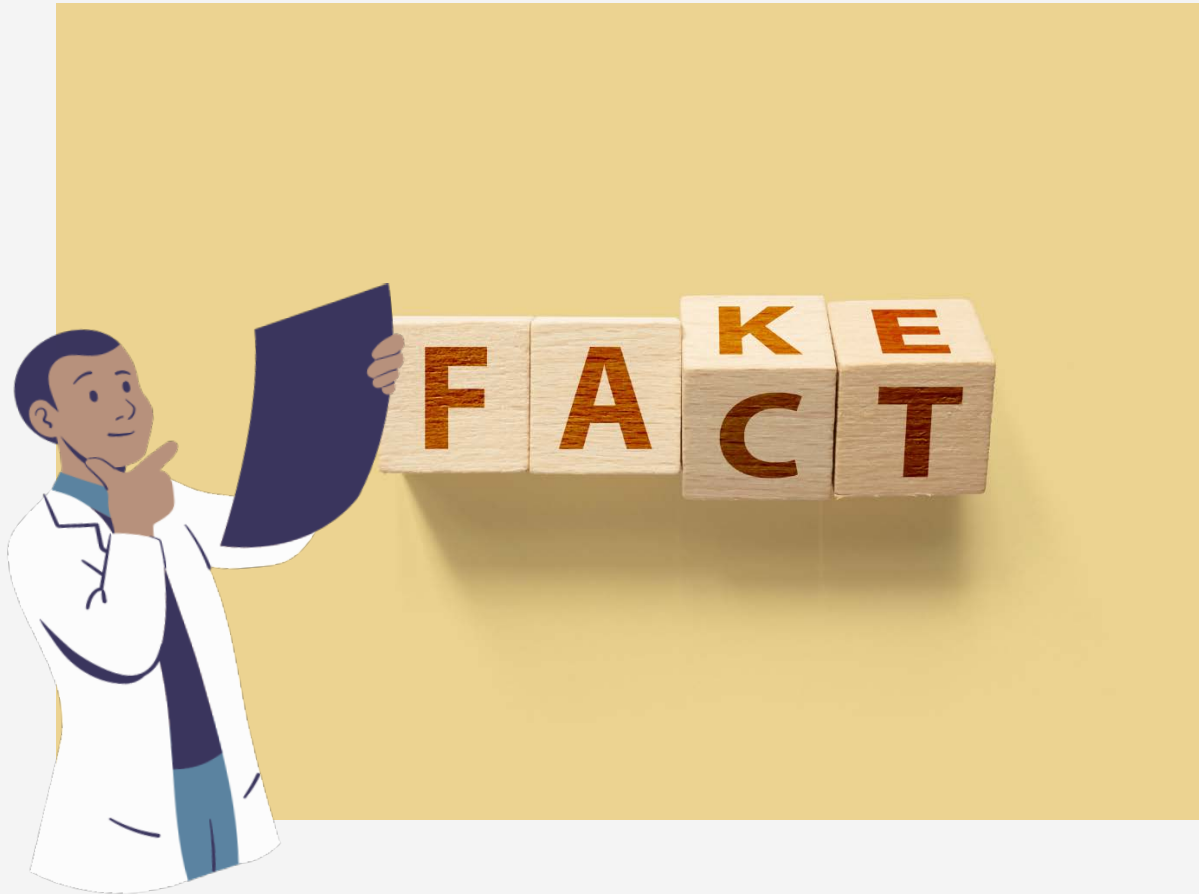
**The Department of Health & Human Services  
Office of Inspector General (OIG)**

**The Centers for Medicare &  
Medicaid Services (CMS)**

# FALSE CLAIMS ACT

- Prohibits the submission of false or fraudulent claims to the Federal Government
    - Claims may be false if
      - The service is not actually rendered to the patient
      - The service is provided but already covered under another claim
      - The service is miscoded
      - The services is not supported by the medical record
- Must report and repay an overpayment within the latter of 60 days or date cost report is due. (31 USC 3729; 42 USC 1320a-7a(a); 42 CFR 1003.200)





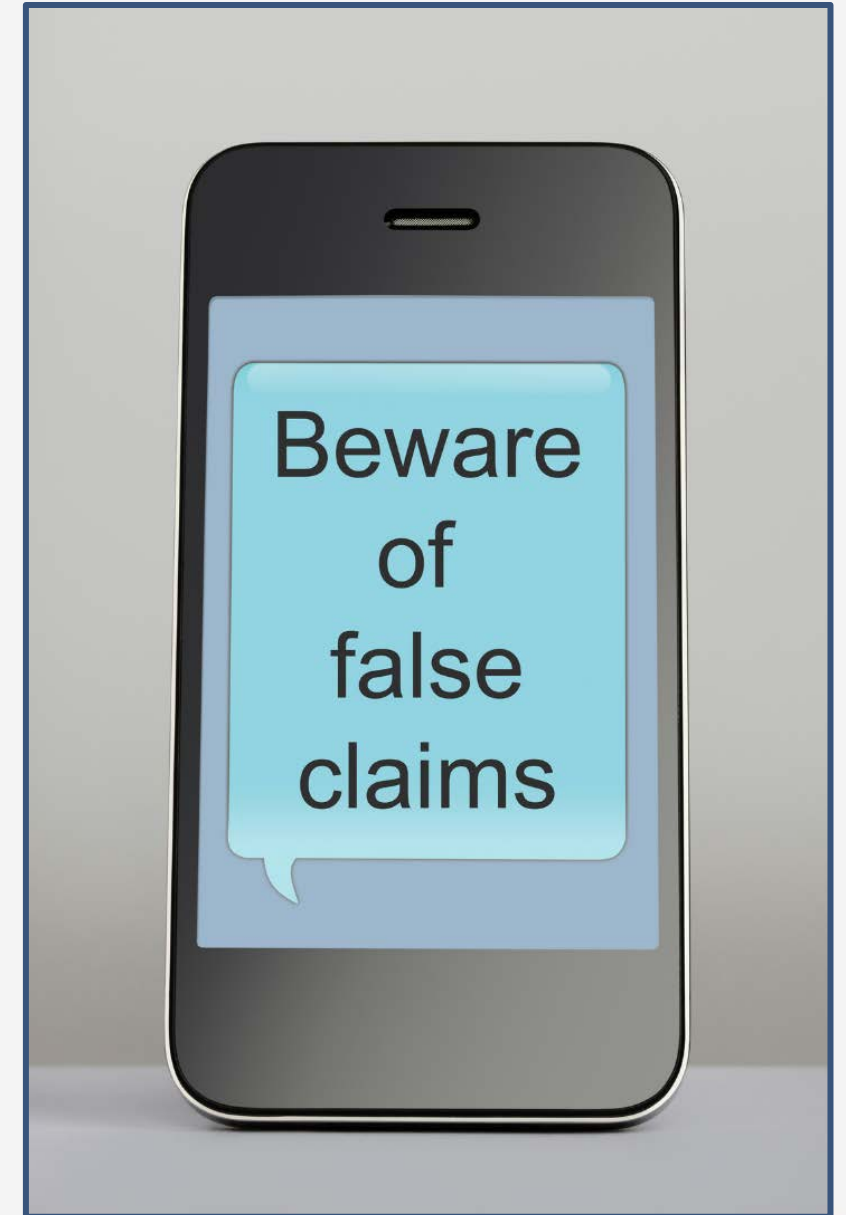
## FALSE CLAIMS ACT

- You do not have to *intend* to defraud the Government to violate the FCA
- You can be punished if you act with deliberate ignorance or reckless disregard of the truth
  - You cannot hide your head in the sand and avoid liability!

# FALSE CLAIMS ACT

- Civil Penalties
  - Repayment plus interest
  - Civil monetary penalties of \$13,508\* to \$27,018\* per claim
  - Admin penalty \$23,996\* per claim failed to return
  - 3x damages
  - Exclusion from Medicare/Medicaid
- Criminal Penalties:
  - Imprisonment
  - Criminal fines

(42 USC 1320a-7a(a); 18 USC 287; 42 CFR 1003.210; 45 CFR 102.3; 86 FR 70740)



# FALSE CLAIMS ACT



- Whistleblowers
- FCA provision that allows a private individual to file a lawsuit on behalf of the U.S.
  - Provides a strong financial incentive to whistleblowers to report fraud
    - Can receive up to 30% of any FCA recovery

Whistleblowers can be... Ex-business partners, hospital or office staff, competitors, or even patients.

# ANTI-KICKBACK STATUTE

- Criminal Statute
- Cannot knowingly and willfully offer, pay, solicit or receive remuneration to induce referrals for items or services covered by Federal health care program unless transaction fits within a regulatory safe harbor. (42 USC 1320a-7b(b); 42 CFR 1003.300(d))
- Remuneration includes anything of value; not just cash.
  - Free rent, expensive hotel stays; excessive compensation for medical directorships
- “One purpose” test (US v. Greber (1985))

## Penalties

- Felony
- 10 years in prison
- \$100,000 criminal fine
- Civil monetary penalties
- 3x damages
- Exclusion from Medicare/Medicaid
- *Automatic False Claims Act violation*
- 42 USC 1320a-7a(a)(7); 42 USC 1320a-7b(b); 42 CFR 1003.310; 45 CFR 102.3

# ANTI-KICKBACK STATUTE



Kickbacks can lead to:

- Overutilization
- Increased costs
- Corruption of medical decision making
- Patient steering
- Unfair competition

# ANTI-KICKBACK STATUTE: SAFE HARBORS

- Bona fide employment
- Personal services contracts
- Leases for space or equipment
- Investments in group practice
- Investments in ASCs
- Sale of practice
- Recruitment
- Certain investment interests

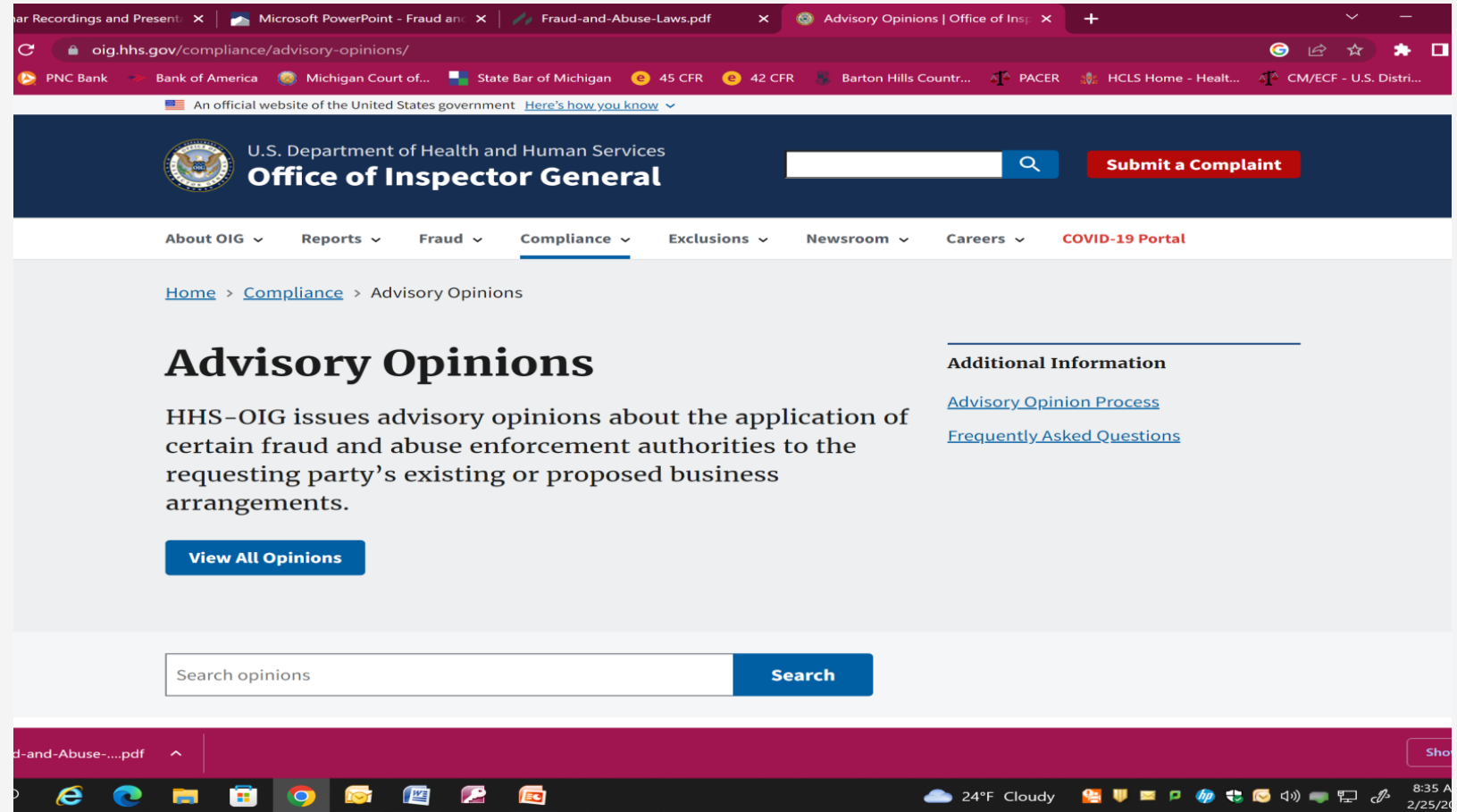
- Waiver of beneficiary coinsurance and deductible amounts.
- Transportation programs
- OB malpractice insurance subsidies
- Electronic health record items or services
- Cybersecurity technology
- Warranties
- Discounts

- Electronic health record items or Value-based care arrangements
- Care coordination arrangements
- Patient engagement incentive
- 42 CFR 1001.952
- OIG's Safe Harbor Regulations:  
<https://oig.hhs.gov/compliance/safe-harbor-regulations/>

**OIG may issue advisory opinions.  
Listed on OIG fraud and abuse website, [www.oig.hhs.gov/fraud](http://www.oig.hhs.gov/fraud).**

Not binding on anyone other  
than the participants to the  
opinion.

But you are fairly safe if you  
act consistently with a  
favorable advisory opinion



# PHYSICIAN SELF-REFERRAL LAW (STARK)

- If the physician (or family member) has a financial relationship with the entity:
  - Physician may not refer patients to entity for designated health services (“DHS”), and
  - Entity may not bill Medicare or Medicaid for such DHS unless the arrangement fits within a regulatory exception (safe harbor).
  - Financial relationship includes both ownership/investment interests and compensation arrangements
  - Strict liability statute: proof of specific intent to violate law not required! (42 USC 1395nn; 42 CFR 411.353; 1003.300)

## Penalties

- No payment for services provided per improper referral.
- Repayment w/in 60 days.
- Civil penalties. – \$28,000\* per claim – \$175,000\* per scheme
- 42 CFR 411.353, 1003.310; 45 CFR 102.3

*Likely False Claims Act violation*

*Likely Anti-Kickback Statute violation*

# STARK

This applies to referrals by a physician to entities with which the physician (or their family member) has a financial relationship.

- Physician = as defined in 42 USC 1395x(r), i.e.,
- MDs
- DOs
- Oral surgeons
- Dentists
- Podiatrists
- Optometrists
- Chiropractors
- (42 CFR 411.351)

- Family member =
  - Spouse
  - Parent, child
  - Sibling
  - Stepparent, stepchild, stepsibling
  - Grandparent, grandchild
  - In-law

# STARK

- Applies to referrals for designated health services (“DHS”) payable in whole or part by Medicare or Medicaid.
- Inpatient and outpatient hospital services
- Outpatient prescription drugs
- Clinical laboratory services
- Physical, occupational, or speech therapy
- Home health services
- Radiology and certain imaging services

- Radiation therapy and supplies
- Durable medical equipment and supplies
- Parenteral and enteral nutrients, equipment, and supplies
- Prosthetics and orthotics
- Check definitions to confirm scope and exceptions.
- CMS website lists some of the affected CPT codes.
  - (42 CFR 411.351)

# STARK SAFE HARBORS: OWNERSHIP

*Must satisfy all the requirements to receive safe harbor protection*

- **Ownership & Compensation Arrangements**

- Physician services
- In-office ancillary services
- Prepaid health plans
- Academic medical centers
- Implants by an ASC
- EPO and dialysis drugs
- Preventative screening tests, immunizations and vaccines
- Eyeglasses and contact lenses following surgery (42 CFR 411.355)

- **Ownership Arrangements**

- Publicly traded securities
- Mutual funds
- Rural providers
- Whole hospital
- Intra-family rural referrals
- Others
- (42 CFR 411.356)

# STARK SAFE HARBORS: COMPENSATION

- Employment
- Personal services contracts
- Remuneration to physician <\$5000/yr
- FMV
- Space or equipment leases
- Timeshare arrangements
- Recruitment and retention
- Non-monetary comp up to \$429
- Medical staff incidental benefits
- Professional courtesy
- OB malpractice subsidies

- Isolated transactions
- Payments by a physician
- Charitable donations by a physician
- Compliance training
- Indirect compensation arrangements
- Referral services
- Health information tech and support
- Cyber security technology
- Valued-based comp arrangements
- (42 CFR 411.357)

Webinar Recordings and Presentations | Microsoft PowerPoint - Fraud and Abuse | Fraud-and-Abuse-Laws.pdf | Physician Self Referral | CMS

cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/index?redirect=/physicianselfreferral/

An official website of the United States government [Here's how you know](#)

**CMS.gov** Centers for Medicare & Medicaid Services

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Home > Medicare > Physician Self Referral

## Physician Self Referral

Section 1877 of the Social Security Act (the Act) (42 U.S.C. 1395nn), also known as the physician self-referral law and commonly referred to as the "Stark Law":

1. Prohibits a physician from making referrals for certain designated health services (DHS) payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship (ownership, investment, or compensation), unless an exception applies.
2. Prohibits the entity from presenting or causing to be presented claims to Medicare (or billing another individual, entity, or third party payer) for those referred services.
3. Establishes a number of specific exceptions and grants the Secretary the authority to create regulatory exceptions for financial relationships that do not pose a risk of program or patient abuse.

The following items or services are DHS:

1. Clinical laboratory services.

Physician Self Referral

Spotlight

Advisory Opinions (AOs)

Call Center

List of CPT/HCPCS Codes

CPI-U Updates

Current Law and Regulations

Definition of Entity

Fraud and Abuse Webinars

Fraud-and-Abuse-....pdf

Snow off and on

9:09 AM  
2/25/2023

Show all

Feedback

# EXCLUSION FROM MEDICARE & MEDICAID

- Under the Exclusion Authorities, OIG may exclude providers from participation in the Federal health care programs.
  - [42 USC 1320a-7]
    - » Mandatory Exclusions
    - » Permissive Exclusions

# CIVIL MONETARY PENALTIES LAW

- Prohibits certain specified conduct, e.g.:
- Submitting false or fraudulent claims, misrepresenting facts relevant to services, or engaging in other fraudulent practices.
- Violating Anti-Kickback Statute or Stark law.
- Violating EMTALA.
- Failing to report and repay an overpayment.
- Failing to report adverse action against providers.
- Offering inducements to program beneficiaries.
- Offering inducements to physicians to limit services.
- Submitting claims for services ordered by, or contracting with, an excluded entity.
- 42 USC 1320a-7a; 42 CFR 1003.200-1100
  - Penalties range from \$10,000-\$50,000 per violation; Exclusion from Medicare & Medicaid

# CHECK THE LEIE REGULARLY!

The screenshot shows a web browser window displaying the "LEIE Downloadable Databases" page on the U.S. Department of Health and Human Services Office of Inspector General website. The browser's address bar shows the URL "oig.hhs.gov/exclusions/exclusions\_list.asp". The page features a dark blue header with the OIG logo and navigation links for "About OIG", "Reports", "Fraud", "Compliance", "Exclusions", "Newsroom", "Careers", and "COVID-19 Portal". A search bar and a "Submit a Complaint" button are also present. The main content area is divided into three columns. The left column contains a sidebar with links to "Exclusions Program", "Online Searchable Database", "LEIE Downloadable Databases" (highlighted), "Monthly Supplement Downloads", "Quick Tips", "Waivers", "Background Information", "Applying for Reinstatement", "Contact the Exclusions Program", "Frequently Asked Questions", and "Special Advisory Bulletin". The middle column is titled "LEIE Downloadable Databases" and features a light blue box with an information icon and the text "02-10-2023 Last Update". Below this are sections for "LEIE Database" (with a link to "01-2023 Updated LEIE Database (CSV)"), "Profile Updates" (with a link to "01-2023 Profile Corrections"), "Current Record Layout" (with a link to "Current Database Record Layout"), and "Looking for Monthly Supplements?". The right column is titled "Related Information" and contains links for "Instructions and information About the LEIE Files.", "File-Type Questions?" (with a link to "Frequently Asked Questions concerning the CSV file type."), and "Frequently Asked Questions". The bottom of the screenshot shows a Windows taskbar with various application icons and a system tray displaying the time as 9:40 AM on 2/25/2023.

**DON'T  
FORGET!**

Other Federal Statutes

State Laws

Private Payors

# APPLYING THE LAWS TO COMMON PHYSICIAN RELATIONSHIPS

## Relationships with:

- Payers: Medicare, Medicaid, and private insurance companies
- Other providers & Referral Sources: physicians, hospitals, patients
- Vendors: drug, biologic and medical device companies



# PAYERS

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- Fraudulent billings – accurately documenting the services you provide
- Proper Coding and Billing
- Maintain accurate and complete medical records to support payment of claims
- Good documentation is a must!

# RELATIONSHIPS WITH PROVIDERS



**Physician  
Colleagues**  
Investments

**Nursing Homes**  
Medical Directorship

**Hospitals**  
Recruitment

# RELATIONSHIPS WITH PATIENTS: FREE OR DISCOUNTED ITEMS OR SERVICES

- Gifts to patients (e.g., gift basket, gift card, basket of products for new mothers, etc.)
- "Refer a friend" incentive
- Free exam or service
- Free equipment, supplies or drugs
- Free meals
- Free transportation
- Parking reimbursement
- Waiver of copay or deductible
- Write-offs
- Paying premiums
- Anything else of value that does not reflect fair market value ("FMV")

- Potential violations of
- AKS?
- CMP?
- State laws?

# RELATIONSHIPS WITH PATIENTS: FREE OR DISCOUNTED ITEMS OR SERVICES

- May offer free or discounted items to government beneficiaries if:
  - Remuneration is not likely to influence the beneficiary to order or receive items or services payable by federal or state health care program.
  - Item or service is of low value, i.e., each item/service is less than \$15 and aggregate is less than \$75 per patient per year.
  - There is a financial need
    - Good faith determination that beneficiary has financial need or after reasonable collection efforts have failed;
    - Not offered as part of any advertisement or solicitation;
    - Not tied to provision of other federal program business; and
    - Reasonable connection between item or service and medical care of beneficiary.

# RELATIONSHIPS WITH VENDORS



**Free drug  
samples**

**Promotional  
speaking**

**Gifts and gift  
reporting  
requirements**

# ACTION ITEMS



# CHECK YOUR RELATIONSHIPS

## With Patients & Referral Sources

- Billing Policies
  - Waiving copays
  - Write-offs
  - Prompt pay or self-pay discounts
  - Free or discounted items
- Contracts and leases
  - Fair market value
  - Compensation not based on referrals
  - Services actually provided

## With Payors & Vendors

- Overpayments or payment for items not provided
- Accurate coding, billing, records
- Proper handling of drug samples
- Proper consulting agreements
- Transparency in relationships

# COMPLIANCE PLAN

## **Actually have a Compliance Plan!**

- Ensure it has required elements
- Policies, procedures and standards of conduct
- Designated compliance officer and committee
- Conduct effective training and education
- Develop effective lines of communication, e.g., complaint hotline
- Conduct internal monitoring and auditing
- Enforce through publicized disciplinary guidelines
- Respond promptly to offenses and implement corrective action.
- See OIG's Compliance Program Guidance documents Available at <https://oig.hhs.gov/compliance/compliance-guidance/>



# TRAIN KEY PERSONNEL

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Include the following people:

- Administration.
- Compliance officers and committees.
- Human resources.
- Physician relations and medical staff officers.
- Marketing / public relations.
- Governing board members.
- Purchasing.
- Accounts payable.
- Document training.
- Review and repeat.

# IF YOU THINK YOU HAVE A PROBLEM

- Suspend payments or claims until resolved.
- Investigate the problem per the compliance plan.
- Consider involving an attorney to maintain privilege.
- Unwind the problematic investment.
- Disentangle yourself from the suspicious relationship.
- Implement appropriate corrective action.
- But remember that prospective compliance may not be enough.
- If repayment is due:
  - Report and repay per applicable law.
  - Self-disclosure program.
  - To OIG, if there was a knowing violation of FCA, AKS, or CMPL.
  - To CMS, if there was a violation of Stark.

# THANK YOU

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