

# Healthcare Fraud and Abuse Laws



Kim C. Stanger  
Holland & Hart LLP

(3-23)



This presentation is similar to any other legal education materials designed to provide general information on pertinent legal topics. The statements made as part of the presentation are provided for educational purposes only. They do not constitute legal advice nor do they necessarily reflect the views of Holland & Hart LLP or any of its attorneys other than the speaker. This presentation is not intended to create an attorney-client relationship between you and Holland & Hart LLP. If you have specific questions as to the application of law to your activities, you should seek the advice of your legal counsel.

# Health Law Webinar Series

Date	Webinar
<b>3/2/23</b>	<b>Fraud and Abuse I: The Laws</b>
3/16/23	Fraud and Abuse II: Applying the Laws
3/30/23	Fraud and Abuse III: Responding to Noncompliance
4/13/23	Telehealth
4/27/23	EMTALA
5/11/23	Reproductive Rights
5/25/23	Nondiscrimination Rules
6/1/23	HIPAA and Patient Privacy

<https://www.hollandhart.com/events>

# Key Fraud and Abuse Laws



- False Claims Act
- Anti-Kickback Statute (“AKS”)
- Eliminating Kickbacks in Referrals Statute (“EKRA”)
- Ethics in Physician Referrals Act (“Stark”)
- Civil Monetary Penalties Law (“CMPL”)
- Healthcare criminal statutes
- Common state statutes

# Caution

- This is a quick overview of the most relevant federal laws and regulations.
  - Beware other laws, including state laws
- Application may depend on—
  - Circumstances of your particular case
  - Payer involved (e.g., govt, insurer, patient)
  - Jurisdiction
- Be sure to confirm applicable laws and requirements when applying law to your facts.
- If you have questions,
  - Use chat feature, or
  - Email me at [kcstanger@hollandhart.com](mailto:kcstanger@hollandhart.com)

# Supplemental Resources

- .PPT slides
- OIG, *Avoiding Medicare and Medicaid Fraud and Abuse: A Roadmap for New Physician*, <https://oig.hhs.gov/compliance/physician-education/>
- OIG, *OIG Supplemental Compliance Program Guidance for Hospitals*, <https://www.hhs.gov/guidance/document/oig-supplemental-compliance-program-guidance-hospitals>
- OIG, *OIG Compliance Program Guidance for Individuals and Small Physician Practices*, <https://oig.hhs.gov/documents/compliance-guidance/801/physician.pdf>
- Stanger, *Beware Laws Affecting Healthcare Transactions*, <https://www.hollandhart.com/beware-laws-affecting-healthcare-transactions>



# False Claims Act (31 USC 3729)



# False Claims Act

- Cannot
  - Knowingly submit a false or fraudulent claim for payment to the federal govt.
  - Knowingly make or use a false record or statement.
- Must report and repay an overpayment within the later of 60 days or date cost report is due.

(31 USC 3729; 42 USC 1320a-7a(a); 42 CFR 1003.200)



# False Claims Act: Penalties

- Repayment plus interest
- Civil monetary penalties of \$11,803\* to \$23,607\* per claim
- Admin penalty \$22,427\* per claim failed to return
- 3x damages
- Exclusion from Medicare/Medicaid

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

➤ **Subject to *qui tam* claims**



## JUSTICE NEWS

Department of Justice

Office of Public Affairs

FOR IMMEDIATE RELEASE

Tuesday, February 7, 2023

### False Claims Act Settlements and Judgments Exceed \$2 Billion in Fiscal Year 2022

#### Second-Highest Number of Settlements in History

Settlements and judgments under the False Claims Act exceeded \$2.2 billion in the fiscal year ending Sept. 30, 2022, Principal Deputy Assistant Attorney General Brian M. Boynton, head of the Justice Department's Civil Division, announced today. The government and whistleblowers were party to 351 settlements and judgments, the second-highest number of settlements and judgments in a single year. Recoveries since 1986, when Congress substantially strengthened the civil False Claims Act, now total more than \$72 billion.

"Protecting taxpayer dollars by preventing fraud and abuse is a critical priority for the Department of Justice," said Principal Deputy Assistant Attorney General Boynton. "The large number of settlements and judgments this past year demonstrates that the False Claims Act remains one of the most important tools for ensuring that public funds are spent properly and advance the public interest."

The False Claims Act imposes treble damages and penalties on those who knowingly and falsely claim money from the United States or knowingly fail to pay money owed to the United States. The False Claims Act thus serves to safeguard government programs and operations that provide access to medical care, support our military and first responders, protect American businesses and workers, help build and repair infrastructure, offer disaster and other emergency relief, and provide many other critical services and benefits.

Of the more than \$2.2 billion in False Claims Act settlements and judgments reported by the Department of Justice this past fiscal year, over \$1.7 billion related to matters that involved the health care industry, including drug and medical device

#### RELATED LINKS

[Speeches and Press Releases](#)

[Videos](#)

[Photos](#)

[Blogs](#)

[Podcasts](#)

# False Claims Act: *Qui Tam* Suits

- Private entities (*e.g.*, employees, patients, providers, competitors, *etc.*) may sue under False Claims Act on behalf of the government.
  - Government may or may not intervene.
  - *Qui tam* relator:
    - Receives a percentage of any recovery (*e.g.*, 15%–30%)
    - Recovers their costs and attorneys' fees.

# False Claims Act: Examples

- Claims for services that were not provided or were different than claimed.
- Failure to comply with quality of care.
  - Express or implied certification of quality.
  - Provision of “worthless” care.
- Failure to comply with conditions of payment or relevant fraud and abuse laws.
  - Express or implied certification of compliance when submit claims, e.g., cost reports or claim forms. (See *Universal Health Serv., Inc. v. U.S. ex rel. Escobar* (S.Ct. 2016))

# Anti-Kickback Statute (42 USC 1320a-7b; 42 CFR 1001.952)





# Anti-Kickback Statute

- Cannot knowingly and willfully offer, pay, solicit or receive remuneration to induce referrals for items or services covered by govt program unless transaction fits within a regulatory safe harbor.

(42 USC 1320a-7b(b); 42 CFR 1003.300(d))

- “One purpose” test
  - If you cannot fit within a safe harbor, the test is whether one purpose of the remuneration to induce or reward referrals. (*US v. Greber* (1985))
  - Difficult to overcome.

# Anti-Kickback Statute: Penalties

- Felony
  - 10 years in prison
  - \$100,000 criminal fine
  - \$112,131\* civil penalty
  - 3x damages
  - Exclusion from Medicare/Medicaid
- (42 USC 1320a-7b(b); 42 CFR 1003.310; 45 CFR 102.3)
- OIG minimum settlement of AKS: \$100,000

(<https://oig.hhs.gov/documents/self-disclosure-info/1006/Self-Disclosure-Protocol-2021.pdf>)

- Automatic False Claims Act violation, i.e.
    - Repayment plus interest
    - Civil monetary penalties of \$11,803\* to \$23,607\* per claim
    - Admin penalty \$22,427\* per claim failed to return
    - 3x damages
    - Exclusion from Medicare/Medicaid
- (42 USC 1320a-7a(a)(7))

# Anti-Kickback Statute

- Applies to remuneration for items/services payable by federal programs.
  - E.g., Medicare, Medicaid, CHIP, etc.
- Beware carve-out programs
  - E.g., pay inducement to obtain private pay business, but carve out federal program business.
  - OIG: inducements for private pay business may also induce referrals for federal program business.

(OIG Adv. Op. 21-10)

# Anti-Kickback Statute

- Applies to any form of remuneration to induce or reward referrals for federal program business.
  - Money.
  - Free or discounted items or services (e.g., perks, gifts, courtesies, space, equipment, meals, insurance, trips, CME, etc.).
  - Overpayments or underpayments (e.g., not fair market value).
  - Payments for items or services that are not provided.
  - Payments for items or services that are not necessary.
  - Professional courtesies.
  - Waivers of copays or deductibles.
  - Low interest loans or subsidies.
  - Business opportunities that are not commercially reasonable.
  - Anything else of value...

# Anti-Kickback Statute



## WARNING

**Anytime you want to:**

- **Give or receive anything to induce referrals for federal health programs, or**
- **Do any deal with a referral source for federal health programs.**



# Anti-Kickback Statute

*U.S. v. Anderson* (10th Cir. 2001).

- Clinic paid two physicians who were substantial referral sources \$75,000/year to serve as co-directors and consultants for geriatric department, but physicians performed few services.
- Held:
  - Physician 1: 6 years + \$75,000 fine + \$142,000 restitution.
  - Physician 2: 3 years + \$25,000 fine.
  - Clinic CEO: 4 years + \$75,000 fine.
  - Clinic CFO: acquittal reversed.
  - Clinic attorney: acquitted.

# Anti-Kickback Statute

**Remuneration  
+ Intent to induce  
referrals for items  
payable by federal  
programs  
AKS violation**

- ✓ **Safe Harbor, e.g.,**
  - **Employment**
  - **Personal services**
  - **Leases**
  - **Group practice**
  - **Others**
- ✓ **Advisory Opinion**

# Anti-Kickback Statute: Safe Harbors

- Bona fide employment
- Personal services and management contracts
- Space and/or equipment rental
- Investments in certain entities
- Investments in group practice
- Investments in ASCs
- Sale of practice
- Practitioner recruitment
- OB malpractice insurance subsidies

(42 CFR 1001.952)



**Check specific  
requirements for  
each safe harbor!**

# Anti-Kickback Statute: Safe Harbors

- Waiver of beneficiary copays, coinsurance and deductibles
- Transportation programs
- Electronic prescribing items and services
- Electronic health record items or services
- Cybersecurity technology and related services
- Ambulance replenishing
- Health centers
- Referral services
- Referral arrangements for specialty services
- Warranties
- Discounts
- Group purchasing organizations

(42 CFR 1001.952)

# Anti-Kickback Statute: Safe Harbors

- Value-based care arrangements
- Care coordination arrangements
- Patient engagement incentive
- ACO beneficiary incentive programs
- Medicare coverage gap discount programs
- Increased coverage, reduced cost-sharing amounts or reduced premium amounts offered by health plans
- Price reductions offered to health plans
- Price reductions offered to eligible managed care organizations
- Price reductions offered by contractors with substantial financial risk to managed care organizations
- Outcomes-based payment arrangements
- Point-of-sale reductions in price for prescription pharmaceuticals
- PBM service fees

(42 CFR 1001.952)





U.S. Department of Health &amp; Human Services

# Office of Inspector General

U.S. Department of Health & Human Services

Report#, Topic, Keyword.. Search

Advanced

About OIG

Reports &  
Publications

Fraud

Compliance

Recovery Act  
Oversight

Exclusions

Newsroom

Home &gt; Compliance &gt; Advisory Opinions

## Advisory Opinions

In accordance with section 1128(D)(b) of the Social Security Act (42 U.S.C. 1320a-7d(b)) and 42 CFR part 1008, OIG issues advisory opinions about the application of OIG's fraud and abuse authorities to the requesting party's existing arrangement. As required, advisory opinions are being made available to the public.

One purpose of the meaningful advice and other OIG sanctions. Note, however, that advisory opinions should be relied upon only for legal standards to which parties are bound by advisory opinions.

We have redacted information associated with this advisory opinion.

 Adobe® Acrobat®

### Quick Links/F

- ❏ Preliminary
- ❏ Recommendations
- ❏ The full and current text of the Code of Federal Regulations on the Code of Federal Regulations Web site. 42 CFR part 1008.
- ❏  The OIG Final Rule (73 Fed. Reg. 40982) revising the procedural aspects for submitting payments for advisory opinion costs.
- ❏  The OIG Interim Final Rule (73 Fed. Reg. 15937) revising the procedural aspects for submitting

### Related

### I'm looking for

Let's start by choosing a topic

Select One



- 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 participants to the opinion.
- But you are fairly safe if you act consistently with favorable advisory opinion.

**REPORT  
FRAUD**

# Anti-Kickback Statute: Additional Factors

- Although they do not guarantee protection, the OIG has identified a number of factors that may mitigate the risk of an AKS violation, e.g.:
  - Few or limited referrals
  - Low risk of adverse impact on federal program
  - Does not skew clinical decision making
  - Fair market value
  - Notice to patients
  - Do not compensate based on referrals
  - Do not track referrals
  - Others?
- Check OIG advisory opinions.

# Eliminating Kickback in Recovery Act (“EKRA”)



# EKRA (18 USC 220)

- Cannot solicit, receive, pay or offer any remuneration in return for referring a patient to a laboratory, recovery home or clinical treatment facility unless arrangement fits within statutory or regulatory exception.

(18 USC 220(a))

- Penalties
  - \$200,000 criminal fine
  - 10 years in prison

(18 USC 220(a))

# EKRA

- Applies to government + private payers.
- Only applies to labs, clinical treatment facilities and recovery homes.
  - “Laboratory” = facility for the biological, microbiological, serological, chemical, immuno-hematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing info for the diagnosis, prevention, or treatment of any disease or impairment of human beings.
  - “Clinical treatment facility” = a medical setting, other than a hospital, that provides detox, risk reduction, outpatient treatment, residential treatment, or rehabilitation for substance use.

(18 USC 220(e))





# WARNING

**If you operate a lab, clinical treatment facility or recovery home:**

- **Beware any inducement to generate or reward business.**

# EKRA Safe Harbors

- Payment to employee or independent contractor
  - *Compensation cannot vary per business generated.*
- Discount under certain health care benefit programs.
- Waiver or discount of copays.
- Subsidies to health centers
- Remuneration under alternative payment models.
- Other situations approved in regulations.
  - *No regulations yet.*

(18 USC 220(b))

➤ *Check requirements for each safe harbor!*

# Ethics in Patient Referrals Act (“Stark”)



# Rep. Pete Stark



# Stark

(42 USC 1395nn; 42 CFR 411)

- If physician (or family member) has financial relationship with an entity:
  - physician may not refer patients to entity for designated health services (“DHS”) payable by Medicare or Medicaid, and
  - entity may not bill Medicare or Medicaid for such DHS unless arrangement fits within a regulatory safe harbor.
- If Medicare or Medicaid improperly billed, must repay within 60 days.

(42 USC 1395nn; 42 CFR 411.353 and 1003.300)

# Stark: Penalties

- No payment for services provided per improper referral.
- Repayment w/in 60 days.
- Civil penalties.
  - \$27,750\* per claim
  - \$174,172\* per scheme
- Likely also—
  - False Claims Act violation
  - Anti-Kickback Statute violation

(42 CFR 411.353, 1003.310; 45 CFR 102.3)

# Stark

- Applies to referrals by physician to entities with which the physician (or their family member) has financial relationship.
- Physician =
  - MDs
  - DOs
  - Oral surgeons
  - Dentists
  - Podiatrists
  - Optometrists
  - Chiropractors
- Family member =
  - Spouse
  - Parent, child
  - Sibling
  - Stepparent, stepchild, stepsibling
  - Grandparent, grandchild
  - In-law

(42 CFR 411.351)

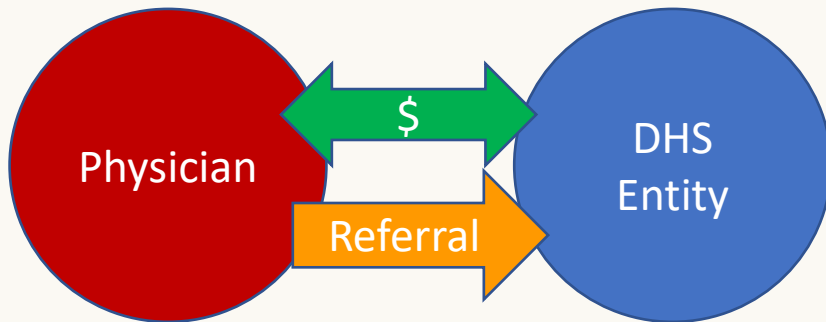
# Stark: Financial Relationships

- Applies to any relationship involving remuneration, i.e., any payment or other benefit, e.g.,
  - Money (e.g., contracts, leases, joint ventures, etc.)
  - Free or discounted items or services (e.g., perks, gifts, courtesies, space, equipment, meals, insurance, trips, CME, etc.).
  - Overpayments or underpayments (e.g., not fair market value).
  - Payments for items or services that are not provided.
  - Payments for items or services that are not necessary.
  - Professional courtesies.
  - Waivers of copays or deductibles.
  - Low interest loans or subsidies.
  - Business opportunities that are not commercially reasonable.
  - Anything else of value...

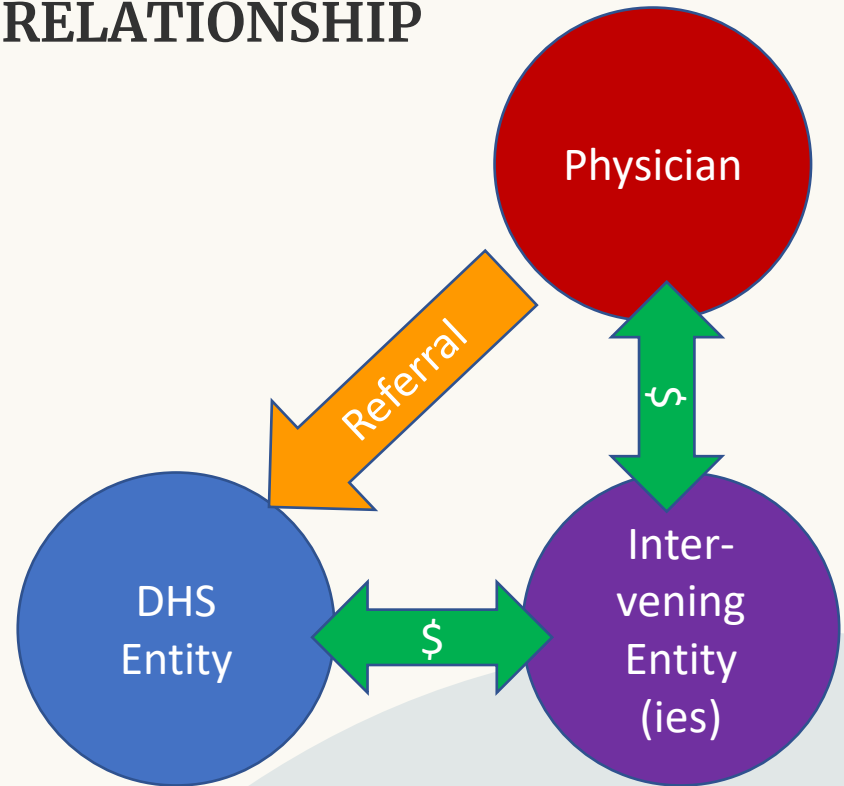


# Stark: Financial Relationship

## DIRECT FINANCIAL RELATIONSHIP



## INDIRECT FINANCIAL RELATIONSHIP



# Stark: Designated Health Services

- 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
- CMS website lists some of the affected CPT codes (e.g., radiology) but it is not all-inclusive.

*Check  
definitions at  
42 CFR 411.351*

(42 CFR 411.351)



## WARNING

**Any financial relationship or item of value between a physician (or their family) and an entity providing DHS.**



Home » Office of Public Affairs » Briefing Room » Justice News

## JUSTICE NEWS

Department of Justice

Office of Public Affairs

FOR IMMEDIATE RELEASE

Friday, October 16, 2015

### United States Resolves \$237 Million False Claims Act Judgment against South Carolina Hospital that Made Illegal Payments to Referring Physicians

The Department of Justice announced today that it has resolved a \$237 million judgment against Tuomey Healthcare System for illegally billing the Medicare program for services referred by physicians with whom the hospital had improper financial relationships. Under the terms of the settlement agreement, the United States will receive \$72.4 million and Tuomey, based in Sumter, South Carolina, will be sold to Palmetto Health, a multi-hospital healthcare system based in Columbia, South Carolina.

“Secret sweetheart deals between hospitals and physicians, like the ones in this case, undermine patient confidence and drive up healthcare costs for everybody, including the Medicare program and its beneficiaries,” said Principal Deputy Assistant Attorney General Benjamin C. Mizer, head of the Justice Department’s Civil Division. “This case demonstrates the United States’ commitment to ensuring that doctors who refer Medicare beneficiaries to hospitals for procedures, tests and other health services do so only because they believe the service is in the patient’s best interest, and not because the physician stands to gain financially from the referral. The Department of Justice is determined to prevent the kind of abuses uncovered in this case, and we are willing to take such cases to trial to protect the integrity of the Medicare program.”

The judgment against Tuomey related to violations of the Stark Law, a statute that prohibits hospitals from billing Medicare for certain services (including inpatient and outpatient hospital care) that have been referred by physicians with whom the hospital has an improper financial relationship. The Stark Law includes exceptions for many common hospital-physician arrangements, but generally requires that any payments that a hospital makes to a referring physician be at fair market value for the physician’s actual services, and not take into account the volume or value of the physician’s referrals to the hospital.

The government argued in this case that Tuomey, fearing that it could lose lucrative outpatient procedure referrals to a new freestanding surgery center, entered into contracts with 19 specialist physicians that required the physicians to refer their outpatient procedures to Tuomey and, in exchange, paid them compensation that far exceeded fair market value and included part of the money Tuomey received from Medicare for the referred procedures. The government argued that Tuomey ignored and suppressed warnings from one of its attorneys that the physician contracts were “risky” and raised “red flags.”

DEPARTMENT OF JUSTICE  
ACCOMPLISHMENTS

OPEN GOVERNMENT  
AT THE  
DEPARTMENT OF JUSTICE

SMART  
ON  
CRIME



DEPARTMENT OF JUSTICE  
ACTION CENTER

[Report a Crime](#)

[Get a Job](#)

[Locate a Prison, Inmate, or Sex Offender](#)

[Apply for a Grant](#)

[Submit a Complaint](#)

[Report Waste, Fraud, Abuse or Misconduct to the Inspector General](#)

# Stark

- *U.S. ex rel. Drakeford v. Tuomey Healthcare System* (4<sup>th</sup> Cir. 2013)
    - Part-time employment contracts violated Stark.
      - \$39,313,065 paid per improper referrals
      - x 3 damages = \$117,939,195
      - 21,730 false claims x \$5,500 per claim = \$119,515,000
- 
- \$237,454,195 judgment**
- Ultimately settled for \$72.4 million.
  - Relator received \$18 million.

# Stark

**Financial arrangement  
with physician or  
family member  
+ Referrals for DHS  
Stark violation**

- ✓ **Safe Harbor, e.g.,**
  - **Employment**
  - **Personal services**
  - **Leases**
  - **Group practice**
  - **Others**
- ✓ **Advisory Opinion**

# Stark Safe Harbors: Ownership + Compensation

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

*Must qualify as a “group practice” under 42 CFR 411.352*

➤ *Must satisfy all of the elements of the safe harbor!*

# Stark Safe Harbors: Ownership Only

- Publicly traded securities
- Mutual funds
- Rural providers
- Whole hospital
- Publicly traded securities
- Intra-family rural referrals
- Others

(42 CFR 411.356)

*Must satisfy the  
elements of the  
relevant safe  
harbor*



# Stark Safe Harbors: Compensation

- Employment relationships
- Personal services contracts
- Remuneration to physician < \$5000 per year
- Fair market value
- Space or equipment leases
- Timeshare arrangements
- Recruitment and retention
- Non-monetary compensation up to \$429
- Medical staff incidental benefits
- Professional courtesy
- OB malpractice subsidies
- Isolated transactions, e.g., sale of practice or settlement
- Payments by a physician

(42 CFR 411.357)

*Must satisfy  
the elements  
of the  
relevant safe  
harbor*

# Stark Safe Harbors: Compensation

- Certain arrangements with hospitals
- Group practice arrangements with hospitals
- Charitable donations by a physician
- Compliance training
- Indirect compensation arrangements
- Risk-sharing arrangements
- Referral services
- Health information technology and support
- Cybersecurity technology
- Valued based compensation arrangements

(42 CFR 411.357)

# Group Practices

- To qualify as a “group practice” and fit within physician services or in-office ancillary services safe harbors:
  - Single legal entity.
  - 2+ physicians.
  - 75% of services provided by physicians who are members of the group.
  - Operated as unified business.
  - Distribution of expenses and income determined in advance.
  - Compensation not based directly on volume or value of referrals except:
    - Personal productivity, or
    - Share of overall profits (at least 5 physicians)
    - Other exceptions

*Beware “eat what you kill” models*

(42 CFR 411.352)

<https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/index>

https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/index

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

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

[About CMS](#) [Newsroom](#)

Search CMS.gov

[Medicare](#)

[Medicaid/CHIP](#)

[Medicare-Medicaid Coordination](#)

[Private Insurance](#)

[Innovation Center](#)

[Regulations & Guidance](#)

[Research, Statistics, Data & Systems](#)

[Outreach & Education](#)

[Home](#) > [Medicare](#) > [Physician Self Referral](#)

## Physician Self Referral

[Spotlight](#)

[Advisory Opinions \(AOs\)](#)

[Call Center](#)

[List of CPT/HCPCS Codes](#)

[CPI-U Updates](#)

[Current Law and Regulations](#)

[Definition of Entity](#)

## Physician Self Referral

Section 1877 of the Social Security Act, commonly referred to as the self-referral law and commonly referred to as the Stark Law, prohibits a physician from referring Medicare patients to an entity with which the physician has a financial relationship.

1. Prohibits a physician from referring Medicare patients to an entity with which the physician has a financial relationship.

2. Establishes a number of specific exceptions for financial relationships.

The following items or services are prohibited:

1. Clinical laboratory services

- Frequently asked questions
- List of CPT Codes
- Advisory Opinions
- Self-Referral Disclosure Protocol

# Stark Analysis

1. Is there a financial relationship with a physician or family member?
  - Direct or indirect
  - Ownership, investment, compensation, or any other payment or benefit
2. Does the physician refer DHS payable by federal healthcare programs?
3. Does the arrangement fit within a regulatory safe harbor?
4. Have you obtained a favorable advisory opinion?

# Civil Monetary Penalties Law (“CMPL”)



# CMPL

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 grant timely access.
- Misusing “HHS”, “CMS”, “Medicare”, “Medicaid”, etc.
- 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)

# Civil Monetary Penalties Law

- Prohibits offering remuneration to a Medicare/Medicaid beneficiary if know or should know that it is likely to influence such beneficiary to order or receive services from a particular provider or supplier.

(42 USC 1320a-7a(5); 42 CFR 1003.1000(a))

## Penalties

- \$22,427\* per violation.
- Exclusion from Medicare and Medicaid  
(42 CFR 1003.1010(a); 45 CFR 102.3)
- Likely also an Anti-Kickback Statute violation



# Inducements to Govt Program Patients

- “Remuneration” = anything of value, including but not limited to:
  - Items or services for free or less than fair market value unless satisfy certain conditions; and
  - Waiver of co-pays and deductibles unless satisfy certain conditions.

(42 USC 1320a-7a(i); 42 CFR 1003.110; OIG Bulletin, *Gifts to Beneficiaries*)

# Inducements to Govt Program Patients

- “Remuneration” does not include:
  - Waivers or co-pays based on financial need or after failed collection efforts if certain conditions met.
  - Items or services if financial need and certain conditions met.
  - Incentives to promote certain kinds of preventative care.
  - Payments meeting Anti-Kickback Statute safe harbor.
  - Retailer coupons, rebates or rewards offered to public.
  - Other remuneration that promotes access to care and poses a low risk of harm to patients and federal health care programs.
  - Certain other situations.

(42 USC 1320a-7a(i); 42 CFR 1003.110)

# Civil Monetary Penalties Law

- Hospital or CAH cannot knowingly make a payment, directly or indirectly, to a physician as an inducement to reduce or limit medically necessary services provided to Medicare or Medicaid beneficiaries who are under the direct care of the physician.

(42 USC 1320a-7a(b))

## Penalties

- \$5,606\* per violation.
  - Exclusion from Medicare and Medicaid  
(42 CFR 1003.1010(a); 45 CFR 102.3)
- *Beware gainsharing arrangements.*

# Civil Monetary Penalties Law

- Excluded person cannot order or prescribe items payable by federal healthcare program.
- Cannot submit claim for item ordered or furnished by an excluded person.
- Excluded owners cannot retain ownership interest in entity that participates in Medicare.
- Cannot hire or contract with excluded entity to provide items payable by federal programs.

(42 USC 1320a-7a(a)(8); 42 CFR 1003.200(a)(3), (b)(3)-(6))

## Penalties

- \$22,427\* per item or service ordered.
- 3x amount claimed.
- Repayment of amounts paid.
- Exclusion from Medicare and Medicaid (42 USC 1320a-7a(a)(8); 42 CFR 1003.210; 45 CFR 102.3; OIG Bulletin, *Effect of Exclusion*)



U.S. Department of Health & Human Services

# Office of Inspector General

U.S. Department of Health & Human Services

Report #, Topic, Keyword..   
Advanced

- About OIG
- Reports & Publications
- Fraud
- Compliance
- Recovery Act Oversight
- Exclusions
- Newsroom

Home > Exclusions > LEIE Downloadable Databases

## LEIE Downloadable Databases

E-mail me when this page is updated.

### Download the LEIE Database

**ANNOUNCEMENT:** As of the September 2013 update, only the LEIE files containing the NPI, Waiver, and Waiver States fields will be available.

[Instructions and information About the LEIE Files.](#)

Below files updated: 05-08-2015

#### LEIE Database

- 04-2015 Updated LEIE Database: EXE | ZIP

#### Current Monthly Supplements

- 04-2015 Exclusions: EXE | ZIP
- 04-2015 Reinstatements: EXE | ZIP
- Monthly Supplement Archive

#### Profile Updates

-  04-2015 Profile Corrections

#### Current Record Layout

### I'm looking for

Let's start by choosing a topic

Select One

*Check the LEIE on regular basis!*

- Online Searchable Database
- LEIE Downloadable Databases
- Monthly Supplement Archive
- Waivers
- Check Tips
- Background Information
- Applying for Reinstatement
- Contact the Exclusions Program
- Frequently Asked Questions
- Special Advisory Bulletin and Other Guidance



# Other Federal Statutes

- Health Care Fraud, 18 USC 1347
- False Statements Relating to Health Care Matters, 18 USC 1035
- Mail and Wire Fraud, 18 USC 1341 and 1343
- Theft or Embezzlement in Connection with Health Care, 18 USC 669
- Racketeer Influenced and Corrupt Organizations Act (“RICO”), 18 USC 1961–1968
- Travel Act, 18 USC 1952
- Others?

(See OIG Compliance Program for Individual and Small Group Physician Practices, 65 FR 49448 et seq.)

# Common State Statutes

- Medicaid false claims statutes
  - Prohibits submitting false claims
  - Requires repayment
- Anti-kickback statutes
  - Perhaps extend to private payers
- Self-referral prohibitions (“mini-Stark”)
- Fee-splitting
- Notice of financial interests
- Offering rebates, discounts, incentives
- Unfair trade practices
- Others?

## *Check:*

- *Medicaid statutes, regs, or provider agreements*
- *Professional practice acts*
- *Licensing statutes or regs*
- *Insurance statutes*
- *Consumer fraud statutes*
- *Other?*

➤ *Know your state law!*



# Private Payors

## Statutes

- Federal
  - Healthcare fraud
  - EKRA
  - Travel Act
- State statutes
  - Anti-kickbacks
  - Self-referrals
  - Fee-splitting
  - Insurance fraud
  - Consumer protection
- Others?

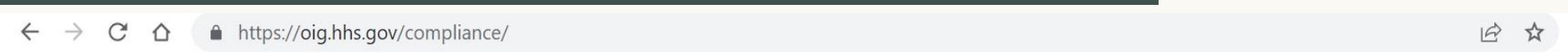
## Private lawsuit

- Breach of contract
  - Conditions of payment
  - Repayment
- Common law fraud or misrepresentation
- Unjust enrichment
- Restitution
- Interference with contract
- Others?

# Additional Resources



<https://oig.hhs.gov/compliance/>



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



U.S. Department of Health and Human Services  
**Office of Inspector General**



[Submit a Complaint](#)

[About OIG](#) ▾

[Reports](#) ▾

[Fraud](#) ▾

[Compliance](#) ▾

[Exclusions](#) ▾

[Newsroom](#) ▾

[Careers](#) ▾

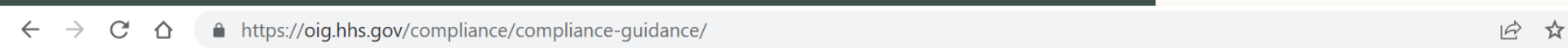
[COVID-19 Portal](#)


## Compliance

To help healthcare providers such as hospitals and physicians comply with relevant Federal health care laws and regulations, OIG creates compliance resources, which are often tailored to particular providers.

OIG's compliance documents include special fraud alerts, advisory bulletins, podcasts, videos, brochures, and papers providing guidance on compliance with Federal health care program standards. OIG also issues advisory opinions, which cover the application of the Federal anti-kickback statute and OIG's other fraud and abuse authorities to the requesting party's existing or proposed business arrangement.

<https://oig.hhs.gov/compliance/compliance-guidance/>



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



U.S. Department of Health and Human Services  
**Office of Inspector General**



**Submit a Complaint**

[About OIG](#) ▾

[Reports](#) ▾

[Fraud](#) ▾

[Compliance](#) ▾

[Exclusions](#) ▾

[Newsroom](#) ▾

[Careers](#) ▾

[COVID-19 Portal](#)

Compliance

Accountable Care Organizations

Advisory Opinions

**Compliance Guidance**

Corporate Integrity Agreements

Open Letters

RAT-STATS

Safe Harbor Regulations

Self-Disclosure

# Compliance Guidance

OIG has developed a series of voluntary compliance program guidance documents directed at various segments of the health care industry, such as hospitals, nursing homes, third-party billers, and durable medical equipment suppliers, to encourage the development and use of internal controls to monitor adherence to applicable statutes, regulations, and program requirements.

The compliance program guidance documents are listed below.

**09-30-2008**

- [Supplemental Compliance Program Guidance for Nursing](#)

## Related

[Compliance Resources for Health Care Boards](#)

# www.hollandhart.com/ healthcare



**Kim Stanger**  
Partner  
Boise



**Blaine Benard**  
Partner  
Salt Lake City



## WEBINAR RECORDINGS

Click here to get access to our health law webinar recordings.



## PUBLICATIONS

Click here to get access to our health law publications and more on our Health Law blog.



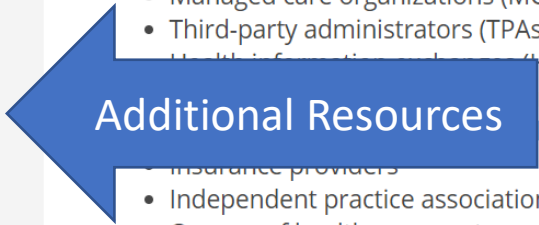
## CLICK HERE FOR COVID-19 RESOURCES FOR HEALTHCARE PROFESSIONALS

**The Healthcare Industry is poised to continue its rapid evolution. With this sector now making up close to 20 percent of GDP, our lawyers stand ready to help as changes unfold.**

Issues such as rising healthcare costs, healthcare reform, data and privacy security, and innovations in healthcare delivery, device and pharmaceutical designs are forefront in the minds of many of our clients. We are here to guide our clients through the challenges and opportunities that arise in this dynamic industry.

### Clients We Serve

- Hospitals
- Individual medical providers
- Medical groups
- Managed care organizations (MCOs)
- Third-party administrators (TPAs)
- Health Information Exchanges (HIEs)
- Health Plan Administrators
- Insurance providers
- Independent practice associations (IPAs)
- Owners of healthcare assets
- Imaging centers
- Ambulatory surgery centers



# Questions?

Kim C. Stanger

Holland & Hart LLP

Office: (208) 383-3913

Cell: (208) 409-7907

[kcstanger@hollandhart.com](mailto:kcstanger@hollandhart.com)