

Key Fraud and Abuse Laws: Understanding and Applying the Law

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(3.25)



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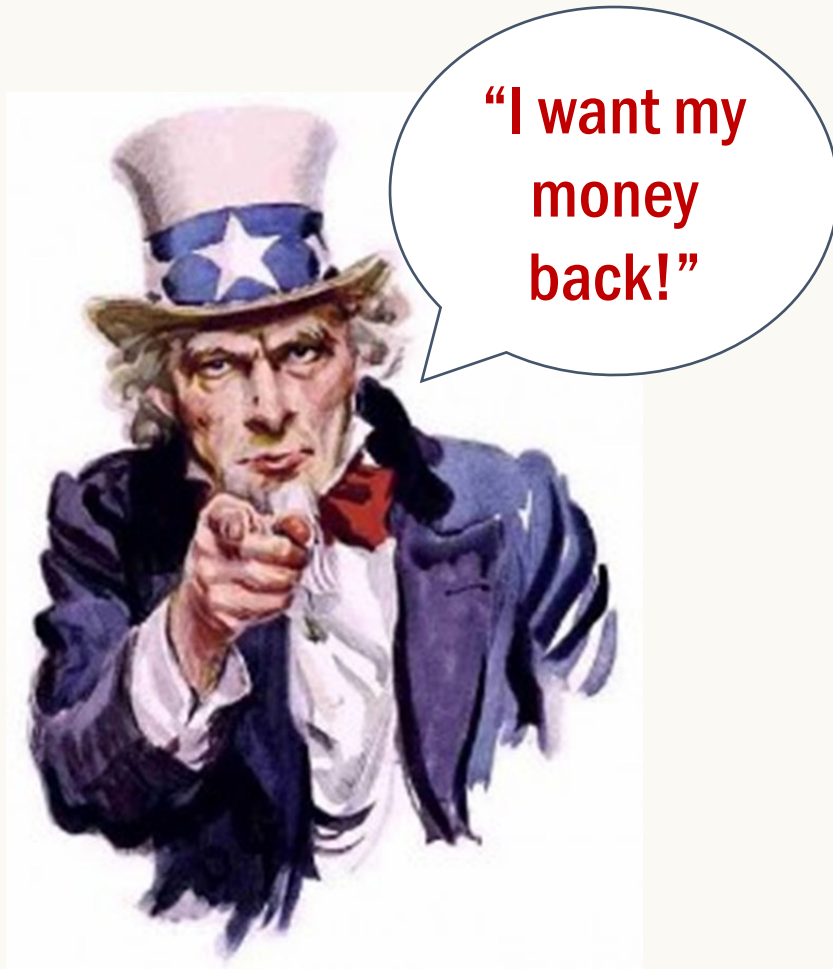
Supplemental Resources

- *OIG, Fraud & Abuse Laws*, <https://oig.hhs.gov/compliance/physician-education/fraud-abuse-laws/>
- *OIG, General Compliance Program Guidance*, <https://oig.hhs.gov/compliance/general-compliance-program-guidance/>
- *OIG, Supplemental Compliance Program Guidance for Hospitals*, 70 FR 4858 (1/31/05), <https://www.hhs.gov/guidance/document/oig-supplemental-compliance-program-guidance-hospitals>
- *OIG, Supplemental Compliance Program Guidance for Nursing Facilities*, 73 FR 56832 (9/30/08), https://oig.hhs.gov/documents/compliance-guidance/793/nhg_fr.pdf
- *OIG, Compliance Program for Individual and Small Group Physician Practices*, 65 FR 59434 (10/5/00), <https://oig.hhs.gov/documents/compliance-guidance/801/physician.pdf>
- *OIG, Avoiding Medicare and Medicaid Fraud and Abuse: A Roadmap for New Physician*, <https://oig.hhs.gov/compliance/physician-education/>
- *Stanger, Beware Laws Affecting Healthcare Transactions*, <https://www.hollandhart.com/beware-laws-affecting-healthcare-transactions>

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

Key Fraud and Abuse Laws



- False Claims Act (FCA)
- Anti-Kickback Statute (AKS)
- Eliminating Kickbacks in Referrals Statute (EKRA)
- Ethics in Physician Referrals Act (Stark)
- Civil Monetary Penalties Law (CMPL)
- Exclusion Statute
- Healthcare criminal statutes
- State laws and regulations

False Claims Act (31 USC 3729)



False Claims Act (FCA)

- Cannot knowingly submit a false claim for payment to the federal govt, e.g.,
 - Not provided as claimed
 - Substandard care
 - Failure to comply with applicable regulations
- 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)

Penalties

- Repayment plus interest
- Civil penalty of \$13,946* to \$27,894* per claim
- Admin penalty \$24,947* per claim failed to return
- 3x damages
- Exclusion from Medicare/Medicaid
(42 USC 3729; 42 USC 1320a-7a(a); 42 CFR 1003.210; 45 CFR 102.3; 89 FR 9766)
- Potential *qui tam* lawsuits
 - ✓ *But see U.S. ex rel. Zafirov v. Florida Med. Associates LLC* (M. Dist. Fla. 9/30/24), holding *qui tam* lawsuits as unconstitutional.

False Claims Act

PRESS RELEASE

False Claims Act Settlements and Judgments Exceed \$2.9B in Fiscal Year 2024

Wednesday, January 15, 2025

For Immediate Release

Office of Public Affairs

Highest Number of **Qui Tam** Actions Filed in History

Settlements and judgments under the False Claims Act exceeded \$2.9 billion in the fiscal year ending Sept. 30, 2024, Principal Deputy Associate Attorney General Benjamin C. Mizer and 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 558 settlements and judgments, the second highest total after last year's record of 566 recoveries, and whistleblowers filed 979 **qui tam** lawsuits, the highest number in a single year. Settlements and judgments since 1986, when Congress substantially strengthened the civil False Claims Act, now total more than \$78 billion.

"The Department's enforcement of the False Claims Act this past year demonstrates its continued commitment to pursuing those who seek to defraud the American taxpayers," said Principal Deputy Associate Attorney General Mizer. "The False Claims Act and its whistleblower provisions remain a critical tool in protecting the public fisc and ensuring that taxpayer funds serve the purposes for which they were intended."



False Claims Act



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PRESS RELEASE

Community Health Network Agrees to Pay \$345 Million to Settle Alleged False Claims Act Violations

“the United States alleged that the compensation Community paid to its cardiologists, cardiothoracic surgeons, vascular surgeons, neurosurgeons, and breast surgeons was well above fair market value, that Community awarded bonuses to physicians that were tied to the number of their referrals, and that Community submitted claims to Medicare for services that resulted from these unlawful referrals.”

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 payable by govt program unless transaction fits within a regulatory safe harbor.

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

- “One purpose” test.
(*US v. Greber* (1985))

Penalties

- Felony
- 10 years in prison
- \$100,000 criminal fine
- \$124,732* civil penalty
- 3x damages
- Exclusion from Medicare/Medicaid
(42 USC 1320a-7b(b); 42 CFR 1003.310; 45 CFR 102.3)
- Automatic FCA violation
(42 USC 1320a-7a(a)(7))
- Minimum \$100,000 settlement with OIG.

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

Anti-Kickback Statute

- Applies to **anyone**.
 - Offeror, receiver, providers, patients, vendors, marketers, etc.
- 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. Ops. 23-06 and 21-10)

Anti-Kickback Statute

Applies to any form of remuneration to induce or reward referrals for federal program business.

- Money.
- Contract payments.
- Free or discounted items or services (e.g., perks, gifts, professional courtesies, space, equipment, meals, insurance, trips, subsidies, 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.
- 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 Analysis

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

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

AKS Safe Harbors

✓ ***Check the requirements for each!***

- Bona fide employment
- Personal services contracts
- Space and/or equipment rental
- Investments in small/large entities
- Investments in group practice
- Investments in ASCs
- Sale of practice
- Practitioner recruitment
- OB malpractice insurance subsidies
- Waiver of beneficiary copays and deductibles
- Transportation programs
- Electronic health record items or services
- Cybersecurity tech and related services
- Referral services
- **Value-based care arrangements**
- **Care coordination arrangements**
- **Patient engagement incentive**
- Others

(42 CFR 1001.952)

Advisory Opinions | x
 https://oig.hhs.gov/compliance/advisory-opinions/index.asp

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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 or proposed business arrangement. As required by the statute, these advisory opinions are being made available to the public through this OIG Web site.

One purpose of the advisory opinion process is to provide meaningful advice on the application of the anti-kickback statute and other OIG sanction statutes in specific factual situations. Please note, however, that advisory opinions are binding and may legally be relied upon only by the requestor. Since each opinion will apply legal standards to a set of facts involving certain known persons who provide specific statements about key factual issues, no third parties are bound nor may they legally rely on these advisory opinions.

We have redacted specific information regarding the requestor and certain privileged, confidential, or financial information associated with the individual or entity, unless otherwise specified by the requestor.

Adobe® Acrobat® is required to read PDF files.

Quick Links/Resources

- Preliminary Checklist for Advisory Opinion Requests
- Recommended Preliminary Questions and Supplementary Information
- The full and current regulatory text of regulations governing requests for advisory opinions is available 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 payments for advisory opinion costs.

Related

- Recent Advisory Opinions
- Advisory Opinion FAQs
- CMS Advisory Opinion website ^{oig}
- Compliance Guidance
- Enforcement Actions
- Advisory Opinion Archive ^{oig}

I'm looking for

Let's start by choosing a topic

Select One

- Accountable Care Organizations
- Advisory Opinions
- Compliance 101 and Provider Education
- Compliance Guidance
- Corporate Integrity Agreements
- Open Letters
- RAT-STATS
- Safe Harbor Regulations
- Self-Disclosure Information
- Special Fraud Alerts, Bulletins, and Other Guidance

EXCLUSIONS DATABASE

REPORT FRAUD

- OIG may issue advisory opinions.
- Listed on OIG fraud and abuse website, 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.

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.*

<https://oig.hhs.gov/faqs/general-questions-regarding-certain-fraud-and-abuse-authorities/>

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General Questions Regarding Certain Fraud and Abuse Authorities

Added 5/31/2024

(1) When an arrangement does not satisfy a safe harbor under the Federal anti-kickback statute, does that mean it's automatically illegal? If an arrangement satisfies most of a safe harbor's conditions, does that mean it is lower risk?

The safe harbor regulations at 42 CFR § 1001.952 describe various payment and business practices that, although they potentially implicate the Federal anti-kickback statute, are not treated as offenses under the statute. Compliance with a safe harbor is voluntary; failure to satisfy a safe harbor does not mean that an arrangement is illegal.

There is no safe harbor protection for partial compliance with the conditions of a potentially applicable safe harbor. To receive the benefit of safe harbor protection, an arrangement must squarely satisfy

Eliminating Kickback in Recovery Act (EKRA)



EKRA

- 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 all payers (private or govt)
- Only applies to referrals to:
 - **Lab** = facility for 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, or the assessment of the health 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, pursuant to licensure or certification under State law.
 - **Recovery home** = shared living environment that is free from alcohol and illicit drug use and centered on peer support and connection to services that promote sustained recovery from substance use disorders.

(18 USC 220)



WARNING

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

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

EKRA

Safe Harbors

Check requirements for each safe harbor!

- 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))

Ethics in Patient Referrals Act (Stark)



Rep. Pete Stark



How do we protect Medicare from situations in which physicians refer business due to their financial interests?

Stark

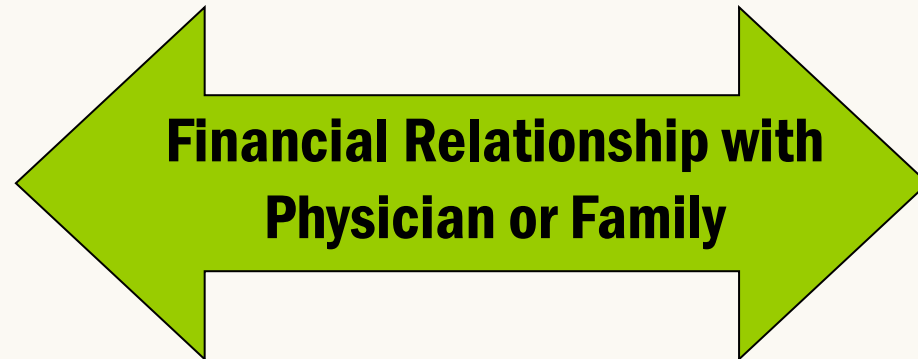
- If physician (or family member) has financial relationship with entity:
 - Physician may not refer patients to the entity for designated health services (DHS), and
 - Entity may not bill Medicare or Medicaid for such DHS

unless arrangement fits within a regulatory exception (safe harbor).
(42 USC 1395nn; 42 CFR 411.353 and 1003.300)

Penalties

- No payment for services provided per improper referral.
 - Repayment w/in 60 days.
 - Civil penalties.
 - \$30,868* per claim
 - \$205,799* per scheme
- (42 CFR 411.353, 1003.310; 45 CFR 102.3)
- Likely FCA violation
 - Likely AKS violation

Stark



Physician cannot refer and DHS provider cannot bill for DHS unless transaction fits in safe harbor.

Stark: Physicians or Family Members

- 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

COMPENSATION ARRANGEMENT

- Employment
- Independent contractor
- Leases
- Gifts
- Free items or services (e.g., space, equipment, practice support)
- Subsidies
- Professional courtesies
- Loans
- Any other thing else of value

OWNERSHIP OR INVESTMENT

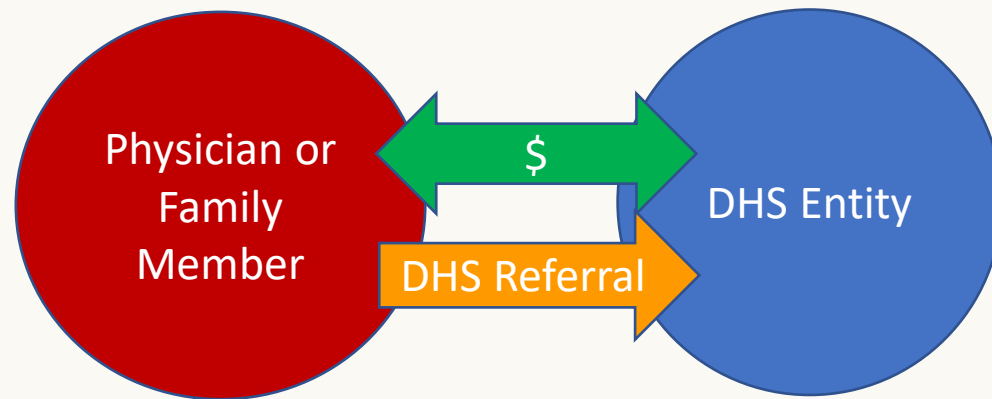
- Shareholder
- LLC member
- Partner
- Investor

(42 CFR 411.351 and .354)

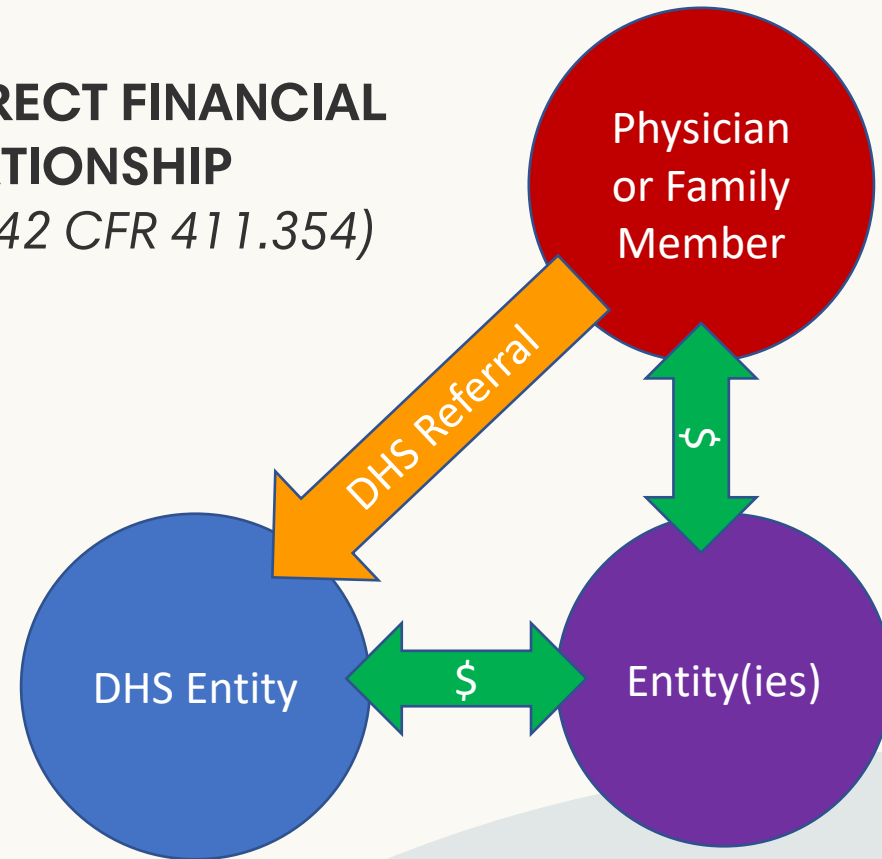
✓ *Check definitions in 411.351 and special rules in 411.354; some arrangements may fall outside definitions.*

Stark: Financial Relationships

DIRECT FINANCIAL RELATIONSHIP



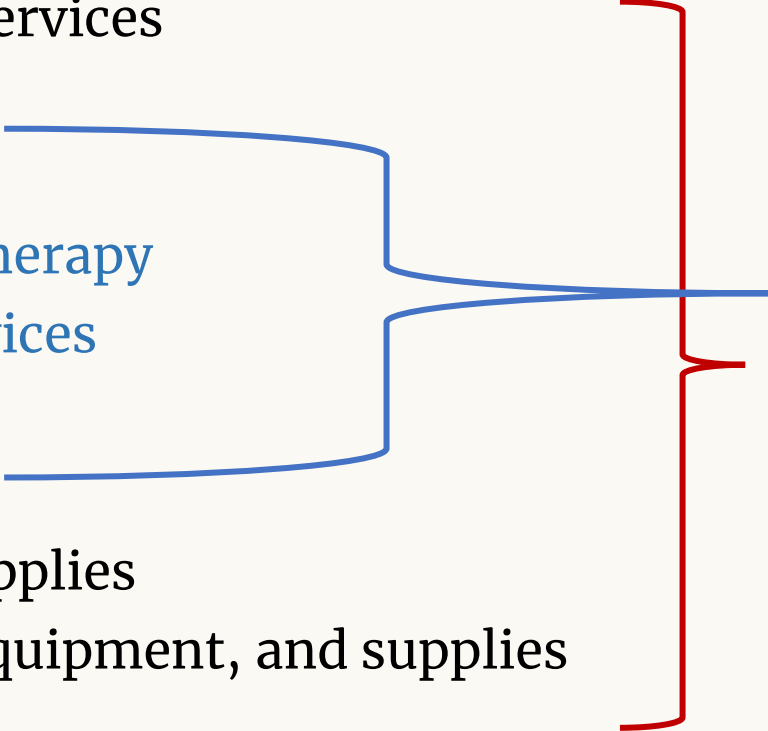
INDIRECT FINANCIAL RELATIONSHIP (See 42 CFR 411.354)



Stark: Designated Health Services (DHS)

- Applies to **referrals** for **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
- Radiology and certain imaging services
- Radiation therapy and supplies
- Home health services
- Durable medical equipment and supplies
- Parenteral and enteral nutrients, equipment, and supplies
- Prosthetics and orthotics



*Check definitions at
42 CFR 411.351 and
<https://www.cms.gov/medicare/regulations-guidance/physician-self-referral/list-cpt-hcpcs-codes>*

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

(42 CFR 411.351)



WARNING

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



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."

On May 8, 2013, after a month-long trial, a South Carolina jury determined that the contracts violated the Stark Law. The jury also concluded that Tuomey had filed more than 21,000 false claims with Medicare. On Oct. 2, 2013, the trial court entered a judgment under the False Claims Act in favor of the United States for more than \$237 million. The United States Court of Appeals for the Fourth Circuit affirmed the judgment on July 2, 2015.

Stark

- *U.S. ex rel. Drakeford v. Tuomey Healthcare System* (4th 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

Intent is irrelevant

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

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

Stark Safe Harbors: Ownership + Compensation

Must satisfy all the all the requirements of the safe harbor.

- 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
- Usually must qualify as a “group practice”
under 42 CFR 411.352*

(42 CFR 411.355)

Stark Safe Harbors: Ownership Only

Must satisfy all the requirements of the safe harbor.

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

(42 CFR 411.356)

Stark Safe Harbors: Compensation

Must satisfy all the elements of the safe harbor

- 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
- 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 enterprise arrangements
- Others

(42 CFR 411.357)

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

- FAQs
- List of CPT Codes
- Advisory Opinions
- Self-Disclosure Protocol

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

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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.

Medicare/Fraud-and-Abuse/PhysicianSelfReferral/index

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 Medicare/Medicaid?
3. Does the arrangement fit within a regulatory safe harbor?
 - ✓ *Check specific requirements of the safe harbor.*
 - ✓ *Must satisfy all the elements of the 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)

CMPL: Beneficiary Inducements

- 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

- \$24,947* per violation.
- Exclusion from Medicare and Medicaid

(42 CFR 1003.1010(a); 45 CFR 102.3)

- Likely also an AKS violation

CMPL: Beneficiary Inducements

- “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*)

CMPL: Beneficiary Inducements

- “Remuneration” does not include:
 - Items or services less than \$15/item and \$75 aggregate/person/year.
 - Waivers of copays based on financial need or failed collection efforts.
 - Items or services if financial need and certain conditions met.
 - Incentives to promote certain kinds of preventative care.
 - Payments meeting AKS 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.
- *Must satisfy conditions of the exceptions.*

(42 USC 1320a-7a(i); 42 CFR 1003.110, OIG, *Policy Statement Regarding Gifts of Nominal Value to Medicare and Medicaid Beneficiaries* (12/7/16))



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- Preliminary Checklist for Advisory Opinion Requests
- Recommended Preliminary Questions and Supplementary Information
- The full and current regulatory text of regulations governing requests for advisory opinions is available 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 payments for advisory opinion costs.

Related

- Recent Advisory Opinions
- Advisory Opinion FAQs
- CMS Advisory Opinion website
- Compliance Guidance
- Enforcement Actions
- Advisory Opinion Archive

I'm looking for

Let's start by choosing a topic

Select One

- Accountable Care Organizations
- Advisory Opinions
- Compliance 101 and Provider Education
- Compliance Guidance
- Corporate Integrity Agreements
- Open Letters
- RAT-STATS
- Safe Harbor Regulations
- Self-Disclosure Information
- Special Fraud Alerts, Bulletins, and Other Guidance

EXCLUSIONS DATABASE



REPORT FRAUD

- OIG may issue advisory opinions.
- Listed on OIG fraud and abuse website, 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.

CMPL: Physician Inducements

- 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

- \$6,236* per violation.
- Exclusion from Medicare and Medicaid
(42 CFR 1003.1010(a); 45 CFR 102.3)
- *Beware gainsharing arrangements.*

Exclusion Statute



Exclusion Statute

- 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

- \$24,947* 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*)



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

-  Current Database Record Layout

Instructions

Related Information

- > [Waiver Info](#)
- > [Search the Online LEIE Database](#)

How To Use These Files

View a video tutorial on using the downloadable files.



I'm looking for

Let's start by choosing a topic

Select One

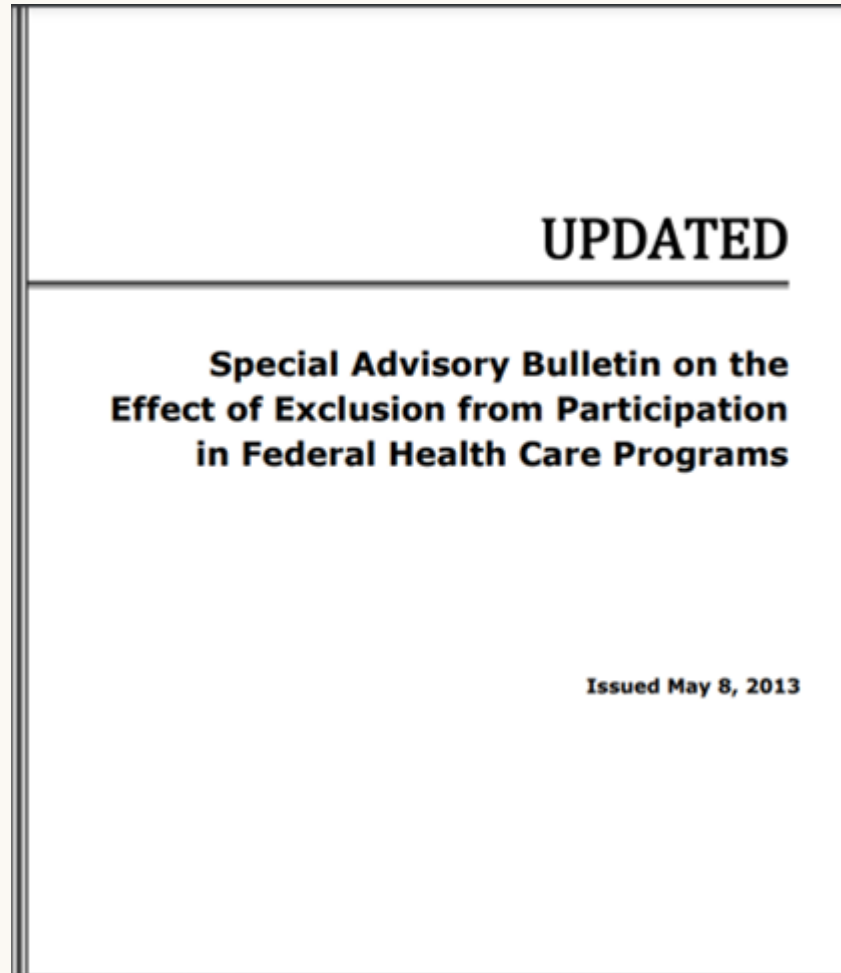
- [Online Searchable Database](#)
- [LEIE Downloadable Databases](#)
- [Monthly Supplement Archive](#)
- [Waivers](#)
- [Quick Tips](#)
- [Background Information](#)
- [Applying for Reinstatement](#)
- [Contact the Exclusions Program](#)
- [Frequently Asked Questions](#)
- [Special Advisory Bulletin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



REPORT FRAUD

*Check the
LEIE on
regular
basis!*

Effect of Program Exclusion



- Available at
<https://oig.hhs.gov/exclusions/files/sab-05092013.pdf>

<https://oig.hhs.gov/faqs/exclusions-faq/>

The screenshot shows the website header for the U.S. Department of Health and Human Services Office of Inspector General. It includes a search bar and a "Submit a Complaint" button. The navigation menu lists "About OIG", "Reports", "Fraud", "Compliance", "Exclusions", "Newsroom", and "Careers". The breadcrumb trail is "Home > Frequently Asked Questions > Exclusions FAQs".

Exclusions FAQs

Answers to Questions Concerning Exclusions

- Contractor Self-Disclosure
- Corporate Integrity Agreement
- Exclusions**
- Student Volunteer Service Program
- Whistleblower Protection Coordinator

What authority does OIG have to exclude individuals or entities? Are there different types of exclusions?	+
What is OIG's Administrative Process for Imposing Exclusions?	+
What is the scope and effect of a section 1128 exclusion?	+
What is the scope and effect of a section 1156 exclusion?	+

Other Fraud and Abuse Laws



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 Laws and Regulations

- False claims acts
- Anti-kickback statutes
- Self-referral prohibitions
- Fee splitting prohibition
- Disclosure of financial interests
- Insurance statutes
- Medicaid conditions
- Fraud or misrepresentation
- Consumer protection laws
- Bribery (may trigger Travel Act claims)
- Others?

Penalties

- Civil penalties
- Criminal penalties
- Adverse licensure action
- Other?

Beware:

- *May apply to private payers in addition to govt programs.*
- *May not contain the same exceptions or safe harbors as federal statutes*

Private Payor Concerns

- State statutes
- Private claims
 - Report and repayment terms in payer contract
 - Breach of contract
 - Common law fraud or misrepresentation
 - Unfair trade practices
 - Unjust enrichment
 - Restitution
- Interference with contract
- Others?

Action Items



Check Your Relationships

WITH PATIENTS

- Billing policies
 - Waiving copays
 - Write offs
 - Prompt pay or self-pay discounts
 - Free or discounted items
- Marketing /advertising
 - Thank-you gifts
 - Loss leaders
 - Free screening programs
 - “Refer a friend” programs
 - Others?

WITH REFERRAL SOURCES

- Contracts and leases
 - Fair market value
 - Compensation not based on referrals
 - Services actually provided
- Visiting specialists
- Overpayments or payment for items not provided
- Gainsharing
- Joint ventures
- Practice support
- Professional courtesies
- Others?

Review and Update Compliance Plan

Ensure it has required elements

1. Written policies and procedures
2. Compliance leadership and oversight
3. Training and education
4. Effective lines of communication with compliance officer and disclosure program
5. Enforcing standards: consequences and incentives
6. Risk assessment, auditing and monitoring
7. Responding to detected offenses and developing corrective action initiatives

See OIG General Compliance Program Guidance at <https://oig.hhs.gov/compliance/general-compliance-program-guidance/>

Train Key Personnel

- Include 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 problem per compliance plan.
 - Consider involving attorney to maintain privilege.
- Implement appropriate corrective action.
 - But remember that prospective compliance may not be enough.
- If repayment is due:
 - Report and repay per applicable law.
 - To carrier.
 - To OIG, if there was knowing violation of FCA, AKS, or CMPL.
 - To CMS, if there was violation of Stark.

Additional resources



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

The screenshot shows the homepage of the U.S. Department of Health and Human Services Office of Inspector General (OIG) Compliance section. The browser address bar displays the URL <https://oig.hhs.gov/compliance/>. The page header includes the U.S. Department of Health and Human Services logo, the text "U.S. Department of Health and Human Services Office of Inspector General", a search bar, and a red "Submit a Complaint" button. The navigation menu includes "About OIG", "Reports", "Fraud", "Compliance" (which is underlined), "Exclusions", "Newsroom", "Careers", and "COVID-19 Portal". The main content area features a large blue banner with the word "Compliance" in white text. Below the banner, the text reads: "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." Further down, it states: "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".

<https://oig.hhs.gov/compliance/physician-education/fraud-abuse-laws/>

The screenshot shows the website for the U.S. Department of Health and Human Services Office of Inspector General. The header includes the department's logo, name, a search bar, and a "Submit a Complaint" button. The navigation menu lists "About OIG", "Reports", "Fraud", "Compliance", "Exclusions", "Newsroom", and "Careers". The breadcrumb trail is "Home > Compliance > A Roadmap for New Physicians > Fraud & Abuse Laws".

Physician Education

- A Roadmap for New Physicians
- Introduction
- Fraud & Abuse Laws**
- I. Physician Relationships With Payers
- II. Physician Relationships With Fellow Providers: Physicians, Hospitals, Nursing Homes, Etc.
- III. Physician Relationships With

Fraud & Abuse Laws

The five most important Federal fraud and abuse laws that apply to physicians are the False Claims Act (FCA), the Anti-Kickback Statute (AKS), the Physician Self-Referral Law (Stark law), the Exclusion Authorities, and the Civil Monetary Penalties Law (CMPL). Government agencies, including the Department of Justice, the Department of Health & Human Services Office of Inspector General (OIG), and the Centers for Medicare & Medicaid Services (CMS), are charged with enforcing these laws. As you begin your career, it is crucial to understand these laws not only because following them is the right thing to do, but also because violating them could result in criminal penalties, civil fines, exclusion from the Federal health care programs, or loss of your medical license from your State medical board.

False Claims Act [31 U.S.C. § § 3729-3733]

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

The screenshot shows the homepage for the Office of Inspector General's Compliance Guidance. The header includes the U.S. Department of Health and Human Services logo and the text "U.S. Department of Health and Human Services Office of Inspector General". A search bar and a "Submit a Complaint" button are also present. The navigation menu includes "About OIG", "Reports", "Fraud", "Compliance", "Exclusions", "Newsroom", "Careers", and "COVID-19 Portal". The "Compliance" section is active, and the "Compliance Guidance" link is highlighted in the left sidebar. The main content area features the heading "Compliance Guidance" and a paragraph stating: "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." Below this, it says "The compliance program guidance documents are listed below." and "09-30-2008". A single bullet point is visible: "• [Supplemental Compliance Program Guidance for Nursing](#)".

- OIG focuses on key statutes, e.g.,
1. Anti-Kickback Statute
 2. Stark
 3. False Claims Act
 4. Civil Monetary Penalty Authority
 - Beneficiary Inducements
 - Information Blocking
 - Exclusion Authority
 5. HIPAA Privacy and Security Rules

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

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Primary Contacts

Kim Stanger

Free content:

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- Other

Questions?

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