

# Fraud and Abuse Laws

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(9/18)

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# Overview

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## The Statutes

- False Claims Act
- Anti-Kickback Statute
- Ethics in Patient Referrals Act (“Stark”)
- Civil Monetary Penalties Laws
- State Laws

## Applying the Statutes

- Free or discounted items to patients
- Waiving copays or deductibles
- Waiving bills
- Professional courtesies
- Contracts with referring providers
- Others


# Written Materials

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- .Ppt slides
- OIG Compliance Program Guidance
- OIG, *Avoiding Fraud and Abuse*
- HHS Report and Repay Rule
- OIG Self-Disclosure Protocol
- CMS Self-Referral Disclosure Protocol
- Sample Compliance Program
- Articles on various issues...

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**April 6, 2018**

**Contact: HHS Press Office**  
**202-690-6343**  
[media@hhs.gov](mailto:media@hhs.gov)

# Health and Human Services and the Department of Justice Return \$2.6 Billion in Taxpayer Savings from Efforts to Fight Healthcare Fraud

*Departments Work to Stamp out Pill Mills and Opioid Overprescribing*

Health and Human Services Secretary Alex Azar and Attorney General Jeff Sessions today released a fiscal year (FY) 2017 Health Care Fraud and Abuse Control Program report showing that for every dollar the federal government spent on healthcare related fraud and abuse investigations in the last three years, the government recovered \$4. Additionally, the report shows that the departments' FY 2017 Takedown event was the single largest healthcare fraud enforcement operation in history.

In FY 2017, the government's healthcare fraud prevention and enforcement efforts recovered \$2.6 billion in taxpayer dollars from individuals and entities attempting to defraud the federal government and Medicare and Medicaid beneficiaries. Some of these fraudulent practices include:

- Providers operating "pill mills" out of their medical offices.

 [top](#)

Recent Cases	Penalty/Settlement
Tenet and subsidiaries allegedly paid kickbacks to prenatal care clinics for referral of undocumented illegal aliens to deliver at hospitals	\$513,000,000; guilty pleas
Vibra allegedly bills for medically unnecessary services	\$32,700,000
North American Health Care allegedly bills for unnecessary rehab therapy services	\$28,500,000
Beth Israel Medical Center allegedly delays repaying \$800,000 in Medicare overpayments	\$2,950,000
Adventist Health allegedly pays physicians compensation above FMV, based on referrals	\$115,000,000
North Broward Hospital allegedly pays physicians above FMV, based on referrals	\$69,500,000
Citizens Medical Center allegedly pays excessive compensation to cardiologists based on formula that considers referrals	\$21,750,000
Halifax Hospital allegedly paid physicians above FMV and bonus based on drugs ordered by physicians	\$85,000,000
Tuomey Healthcare allegedly entered long term, part-time employment contracts that exceeded FMV and required referrals	\$74,000,000

*To make matters worse...*

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***You must narc  
on yourself!***

**Affordable Care Act  
report and repay  
requirement.**



# Fraud and Abuse Laws



- False Claims Act
- Anti-Kickback Statute (“AKS”)
- Ethics in Physician Referrals Act (“Stark”)
- Civil Monetary Penalties Law (“CMPL”)
- State Laws



# False Claims Act

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- **Cannot knowingly submit a false claim for payment to the federal government.**
- **Must report and repay an overpayment within 60 days.**
- **Penalties**
  - **Repayment plus interest**
  - **Civil monetary penalties of \$11,000 to \$22,000 per claim**
  - **3x damages**
  - **Exclusion from Medicare/Medicaid**

(18 USC 1347)

# False Claims Act

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

# False Claims Act

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- *U.S. ex rel. Drakeford v. Tuomey Healthcare System* (4<sup>th</sup> Cir. 2013)

- Part-time employment contracts violated Stark.

- \$39,313,065 x 3 damages = \$117,939,195

- 21,730 false claims x \$5,500 per claim = 119,515,000

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**\$237,454,195 judgment**

- Ultimately settled for \$72.4 million.
- Relator will receive \$18 million.

# False Claims Act: Examples

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- 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).

# 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 government program unless transaction fits within a regulatory safe harbor.

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

- “One purpose test”
  - Anti-Kickback Statute applies if one purpose of the remuneration is to induce referrals. (*U.S. v. Greber*, 760 F.2d 68 (3d Cir. 1985)).
  - Difficult to disprove.
- Ignorance of the law is no excuse.

# Anti-Kickback Statute

- Penalties
    - 5 years in prison
    - \$25,000 criminal fine
    - \$50,000 penalty
    - 3x damages
    - Exclusion from Medicare/Medicaid
  - Anti-Kickback violation = False Claims Act violation
    - Lower standard of proof
    - Subject to False Claims Act penalties
    - Subject to qui tam suit.
- (42 USC 1320a-7a(a)(7))
- OIG Self-Disclosure Protocol: minimum \$50,000 settlement.

(42 USC 1320a-7b(b); 42 CFR 1003.102)

# Anti-Kickback Statute



## WARNING

**Anytime you want to:**

- **Give or receive anything to induce or reward referrals, or**
- **Do any deal with a referral source.**



# 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, 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: Safe Harbors

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- No liability if satisfy all the requirements of a safe harbor.
- Not required to fit within safe harbor because ultimate question is whether “one purpose” of remuneration is to induce or reward referrals.
- The closer you come to satisfying regulatory requirements, the safer you will be.

# 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
- Referral services
- Referral arrangements for specialty services
- Warranties
- Discounts
- Others

(42 CFR 1001.952)

# Anti-Kickback Statute

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- No *de minimus* safe harbor.
  - But not too much risk if remuneration is nominal.
- No “fair market value” safe harbor.
  - “Fair market value” payment does not legitimize a payment if there is an illegal purpose. (70 FR 4864)
  - But fairly safe if remuneration represents fair market value for legitimate, needed services or items.
- Consider risk of federal program abuse.
  - Due to nature of transaction.
  - Incorporate safeguards to protect against abuse.

# Advisory Opinions

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- **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 probably fairly safe if you act consistently with favorable advisory opinion.**



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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.](#)

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**EXCLUSIONS DATABASE**



**REPORT FRAUD**

# Ethics in Patient Referrals Act (“Stark”) (42 USC 1395nn; 42 CFR 411.351 et seq.)



# Stark

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- If a physician (or their family member) has a financial relationship with an entity:
  - The physician may not refer patients to that entity for designated health services, and
  - The entity may not bill Medicare or Medicaid for such designated health services (“DHS”)

unless arrangement structured to fit within a regulatory exception.

(42 CFR 411.353)



# Stark

- Penalties
  - No payment for services provided per improper referral.
  - Repayment of payments improperly received within 60 days.
  - Civil penalties.
    - \$15,000 per claim submitted
    - \$100,000 per scheme

(42 CFR 411.353, 1001.102(a)(5), and 1001.103(b))

- May also constitute Anti-Kickback Statute violation
- May trigger False Claims Act.

# Stark

- Cannot bill or receive payment for services for prohibited referrals during the “period of disallowance.”
  - Begins when financial relationship fails to satisfy one of the safe harbors.
  - Ends when:
    - Relationship brought into compliance, and
    - Amounts overpaid or underpaid are repaid.
- Prospective compliance alone does not end the period of noncompliance.

(42 CFR 411.353(c)(1))

# Stark

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## WARNING

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



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## 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 referring physicians, like the ones in this case, undermine patient confidence and drive up healthcare costs for the Medicare program and its beneficiaries,” said Principal Deputy Assistant Attorney General Robert M. Cohen of the Department’s Civil Division. “This case demonstrates the United States’ commitment to protecting Medicare beneficiaries to hospitals for procedures, tests and other health services. The government’s primary concern is the patient’s best interest, and not because the physician stands to receive a large payment. Justice is determined to prevent the kind of abuses uncovered in this case that threaten the integrity of the Medicare program.”

The judgment is based on a statute that prohibits hospitals from billing Medicare for certain services that have been referred by physicians with whom the hospital has an arrangement that includes exceptions for many common hospital-physician arrangements. The statute requires that any payment a hospital makes to a referring physician be at fair market value for the physician’s services, and not based on the volume or value of the physician’s referrals to the hospital.

The government argued that Tuomey ignored and suppressed warnings from one of its attorneys that the physician contracts were “risky” and raised “red flags.”

Stark =  
False Claim;  
3x damages  
under FCA



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

- 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

- Applies to referrals by physician to entities with which physician (or their family member) has financial relationship.
  - Direct relationship.
  - Indirect relationship (e.g., through ownership in another entity).
- Financial relationship =
  - Ownership or investment: stocks, bonds, partnership, membership shares, secured loans, securities, etc.
  - Compensation: employment, contract, lease, payments, gifts, free or discounted items, and virtually any other exchange of remuneration.

(42 CFR 411.351 and .354)

# Stark

- Applies to referrals (orders, requests, plan of care, certification) by physician for DHS performed by others.
  - Other providers or facilities.
  - Others in physician's own group.
  - Other employees or contractors.
- Does not apply to services physician personally performs.
  - Physician may perform his own DHS.
  - Beware ancillary, technical, facility fees.
- Does not apply to many services performed by radiologists or pathologists because they usually do not make "referrals".

(42 CFR 411.351)

# Stark

- Applies to referrals for designated health services (“DHS”) payable in whole or part by Medicare.
  - 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.  
(42 CFR 411.351)



# Stark: Safe Harbors

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- Stark contains numerous safe harbors.
  - Applicable to both ownership/investment and compensation arrangements.
  - Applicable to only ownership/investment arrangements.
  - Applicable to only compensation arrangements.
- No liability if comply with all the requirements of an applicable safe harbor.
- Need only comply with one safe harbor for each financial relationship.

(42 CFR 411.355-.357)

# Stark: Exceptions for Both Ownership and Compensation

- Physician services rendered by another physician in same group practice\* or under such physician's supervision.
- In-office ancillary services provided through group practice\*.
- Prepaid health plans.
- Certain services furnished in academic medical center.
- Implants in ASC.
- Preventive screening tests, immunizations, and vaccines.
- EPO and other dialysis-related drugs.
- Eyeglasses and contact lenses following cataract surgery.
- Intra-family rural referrals.

(42 CFR 411.355)

\* Must qualify as "group practice" under 42 CFR 411.352.

# Stark: Exceptions for Only Ownership or Investments

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Ownership or investment interests in:

- Rural providers.
- The whole hospital, not a part of the hospital.
  - Subject to limits in 42 CFR 411.362.
- Publicly traded securities.
- Large, regulated mutual funds.

(42 CFR 411.356)

# Stark: Exceptions for Only Compensation Arrangements

- Bona fide employment relationships.
  - Personal services contracts.
  - Space or equipment rental.
  - Timeshare arrangement
  - Physician or midlevel recruitment.
  - Physician retention.
  - Remuneration unrelated to DHS.
  - Fair market value.
- (42 CFR 411.357)
- Non-monetary compensation up to \$300.
  - Medical staff incidental benefits.
  - Compliance training.
  - Community-wide health information system.
  - Professional courtesy.
  - Certain payments by a physician for items or services at FMV.
  - Others.

# Stark: Analysis

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1. Is there a financial relationship between the DHS provider and the physician or their family member?
  - **Direct or indirect relationship?**
  - **Ownership or investment interest?**
  - **Compensation arrangement?**
2. Does the physician make or has she made referrals to the entity for DHS payable by Medicare?
3. Does a safe harbor apply?
4. Has the entity billed for items/services pursuant to improper referral, and if so, did the entity have knowledge of physician's identity?

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

Physician Self Referral | Centers for Medicare & Medicaid Services - Windows Internet Explorer provided by Holland and Hart, LL

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

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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.
2. Physical therapy services.
3. Occupational therapy services.
4. Outpatient speech-language pathology services.
5. Radiology and certain other imaging services.
6. Radiation therapy services and supplies.
7. Durable medical equipment and supplies.
8. Prosthetic and orthotic devices, equipment, and supplies.

• Advisory opinions

• FAQs

• DHS by CPT code

• Self-Referral Disclosure Protocol

• Recent settlements

# Civil Monetary Penalties Law (42 USC 1320a-7a)

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# 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 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

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- Penalties vary based on conduct, but generally range from:
  - \$2,000 to \$100,000 fines
  - 3x amount claimed
  - Denial of payment
  - Repayment of amounts improperly paid
  - Exclusion from government programs
- CMPL violations may also violate:
  - False Claims Act
  - Anti-Kickback Statute
  - Stark

# Inducements to Govt Program Patients

- **Cannot offer or transfer remuneration to Medicare or state program beneficiaries if you know or should know that the remuneration is likely to influence the beneficiaries to order or receive items or services payable by federal or state programs from a particular provider.**
- **Penalty:**
  - **\$10,000 for each item or service.**
  - **3x amount claimed.**
  - **Repayment of amounts paid.**
  - **Exclusion from Medicare and Medicaid.**
- **Also a likely violation of the Anti-Kickback Statute**

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

# Inducements to Govt Program Patients

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

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- “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 delivery of preventative care if certain conditions met.
  - Payments meeting Anti-Kickback Statute safe harbor.
  - Retailer coupons, rebates or rewards offered to public.
  - Any 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)

# Payment to Limit Services

- 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.
  - May include many “gainsharing” programs.
  - MACRA amendments ease the prohibition.
- Penalties:
  - \$2000 for each individual with respect to whom payment made.
  - Any other penalty allowed by law.

(42 USC 1320a-7a(b)(1), as amended by MACRA; 81 FR 88370)

# Excluded Entities

- **Cannot submit claim for item or service ordered or furnished by an excluded person.**
- **Cannot hire or contract with an excluded entity or arrange for excluded entity to provide items or services payable by federal programs.**
- **Penalties**
  - **\$10,000 per item or service.**
  - **3x amount claimed.**
  - **Repayment of amounts paid.**
  - **Exclusion from Medicare and Medicaid**

(42 USC 1320a-7a(a)(8); 42 CFR 1003.200; OIG Bulletin, Effect of Exclusion)

# Excluded Entities

- Medicare, Medicaid, or other federal program will not pay claim if person “knew or should have known” of exclusion.
  - **Exception for certain emergency services.**  
(42 CFR 1001.1901(b) and .1003.200(a))
- Knowledge =
  - **Knew or should have known of exclusion.**
  - **Notified by HHS of exclusion, e.g., in response to claim.**
  - **Listed on the List of Excluded Individuals or Entities (“LEIE”).**



U.S. Department of Health & Human Services

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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

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- Waiver Info
- Search the Online LEIE Database

#### How To Use These Files

View a video tutorial on using the downloadable files.



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# List of Excluded Individuals and Entities ("LEIE")

- OIG maintains LEIE and updates monthly:  
[https://oig.hhs.gov/exclusions/exclusions\\_list.asp](https://oig.hhs.gov/exclusions/exclusions_list.asp)
  - Check LEIE before hiring or contracting with entities.
    - Employees, contractors, vendors, medical staff, etc.
  - Check LEIE periodically to determine status.
    - Employees, providers, vendors, medical staff members, ordering providers, others?
- Condition contracts and medical staff membership on non-exclusion.
- Respond promptly if receive notice of excluded entity.

# Advisory Opinions

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- **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 probably fairly safe if you act consistently with favorable advisory opinion.**

# State Laws



# Common State Laws

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- False claims acts
- Anti-kickback statutes
- Self-referral limitations
  - “Mini-Stark” laws
- Fee splitting
- Others...
- May apply to govt programs and/or private payers

# Applying the Rules





## Free or Discounted Items or Services to Patients

For example:

- Marketing that offers free or discounted items.
- Free items or services, especially when tied to other services that are payable by govt payers.
- “Insurance only” billing.
- Writing off bills.
- “Refer a friend” rewards programs.
- “Thank you” gifts.
- Drawings, etc.

# Freebies to Patients

May offer free or discounted items to **govt 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.  
(42 USC 1320a-7a(5))
- Item or service is of low value, i.e.,
  - Each item or service is less than 15, and
  - Aggregate is less than \$75 per patient per year.

(OIG Bulletin, *Offering Gifts and Inducements to Beneficiaries* (8/02); 66 FR 24410-11; OIG Policy Statement Regarding Gifts of Nominal Value (12/7/16))

# Freebies to Patients

May offer free or discounted services to **govt beneficiaries** if:

- 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.

(42 CFR 1320a-7a(i); 42 CFR 1003.101; *see also* OIG Bulletin, *Hospital Discounts Offered to Patients Who Cannot Afford to Pay Their Hospital Bills*)



# Freebies to Patients

- May offer free or discounted items to govt beneficiaries if:
  - Incentives to promote delivery of preventative care.
  - Payments meeting AKS safe harbor.
  - Any other remuneration that promotes access to care and poses a low risk of harm to patients and federal health care programs.
  - Retailer coupons, rebates or rewards offered to public.
  - Certain other situations.

(42 USC 1320a-7a(i); 42 CFR 1003.101)



# Free Tests or Screening

- OIG has approved free screening services or tests (e.g., free blood pressure check by hospital) where:
  - Not conditioned on the use of any items or services from any particular provider.
  - Patient not directed to any particular provider.
  - Patient not offered any special discounts or follow-up services.
  - If test shows abnormal results, visitor is advised to see his or her own health care professional.

(Adv. Op. 09-11)

- *Advisory Opinions are not binding, but provide guidance.*

# Free Transportation



- AKS safe harbor: local transportation
  - Set forth in policy applied uniformly
  - Not determined based on volume or value of referrals
  - Not air, luxury, or ambulance-level transport
  - Not publicly marketed or advertised
  - Drivers not paid per beneficiary
  - Only for established patients within 25 miles or, in rural area, 50 miles
  - Costs not shifted to payers or individuals

(42 CFR 1001.952(bb))

# Free Transportation

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- **AKS safe harbor: shuttle service that operates on set schedule**
  - **Not air, luxury, or ambulance-level transport**
  - **Not publicly marketed or advertised**
  - **Drivers not paid per beneficiary**
  - **Only within provider's local area, i.e., within 25 miles or, in rural area, 50 miles**
  - **Costs not shifted to payers or individuals**

(42 CFR 1001.952(bb))

# Waiving Copays or Deductibles



May waive or discount **govt** copays or deductibles if:

- Not offered as part of any advertisement or solicitation;
- Do not routinely waive copays or deductibles; and
- Waive or discount after
  - **good faith determination that the beneficiary is in financial need, or**
  - **unable to collect after reasonable collection efforts.**

(42 USC 1320a-7a(i)(6); 42 CFR 1003.101; *see also* Adv. Op. 12-16)

- Document factors such as local cost of living; patient's income, assets and expenses; patient's family size; scope and extent of bills.

# Waiving Copays or Deductibles

May waive or discount **govt** copays if satisfy AKS safe harbor.

- Hospital inpatient stay paid under PPS.
  - Waived amounts cannot be claimed as bad debt or shifted to any other payers.
  - Offered without regard to the reason for admission, length of stay, or DRG.
  - Waiver may not be made as part of any agreement with third party payer with limited exceptions.
- FQHC or other health care facility under any Public Health Services Grant.

(42 CFR 1001.952(k))

# Writing Off Bills



- Writing off entire debt safer than waiving copays.
  - No one gets billed.
- The key: document legitimate purpose, i.e., not intent to generate referrals!
  - Resolution of legitimate dispute or settlement of claim.
  - Unsuccessful attempts to collect.
  - Financial need.
  - Other

# Writing Off Bills

---

- Under CMPL, may waive or discount beneficiary's bills if:
  - 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.

(42 CFR 1320a-7a(i); 42 CFR 1003.101; *see also* OIG Bulletin, *Hospital Discounts Offered to Patients Who Cannot Afford to Pay Their Hospital Bills*)



# Writing Off Bills

---

- **OIG suggests that hospitals (and presumably other providers) should:**
  - **Have a reasonable set of financial guidelines based on objective criteria that documents real financial need.**
  - **Recheck patient's eligibility at reasonable intervals to ensure they still have financial need.**
  - **Document determination of financial need.**

*(OIG Bulletin, Hospital Discounts Offered to Patients Who Cannot Afford to Pay Their Hospital Bills)*

# Prompt Pay Discounts



- OIG has approved prompt pay discounts for **govt** beneficiaries if:
  - Amount of discount relates to avoided collection costs.
  - Offered to all patients for all services without regard to patient's reason for admission, length of stay, or DRG.
  - Not advertised so as to solicit business.
  - Notified private payers of program.
  - Costs not passed to Medicare, Medicaid or other payers.

(56 FR 35952; Adv. Op. 08-3)

# Prompt Pay Discounts

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- Private payer issues
  - Generally cannot discount copays and deductibles without violating managed care contracts unless payer agrees.
  - May adversely affect “usual and customary charges” and payer’s reimbursement under contract.
  - Payers may claim the benefit of the discount if the insurer pays within the relevant time.
- *Check your payer contract or contact your private payers.*

# Self-Pay Discounts



- Providers may generally charge different patients or payers different amounts.
  - Negotiated rates for payers.
  - Negotiated rates or discounts for self-pay patients.
- Limitations:
  - Illegal discrimination (e.g., race, sex, religion, etc.).
  - Perhaps hospitals that submit cost reports.
  - Perhaps FQHCs.
  - In some states, payer contracts may contain “most favored nation” clauses requiring providers to give their best rates.
  - Self-pay or other discounts may affect “usual and customary” charges.

# Medicare “Substantially in Excess” Rule

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- Provider may not charge Medicare “substantially in excess” of the provider’s usual charges.

(42 USC 1320a-7(b)(6); 42 CFR 1001.701(a)(1)).

- **Test: whether the provider charges more than half of its non-Medicare/Medicaid patients a rate that is lower than the rate it charges Medicare.**
- **OIG has stated that it would not use the rule to exclude or attempt to exclude any provider or supplier that provides discounts or free services to uninsured or underinsured patients.**

(See OIG Adv. Op. 15-04; OIG Letter dated 4/26/00, available at <http://oig.hhs.gov/fraud/docs/safeharborregulations/lab.html>)



# Paying Patient's Premiums

- If paying Medicare Part B, C or D premiums:
  - **OLG approved plan's payment of Part B premiums for ESRD patients where:**
    - Patients are already receiving the services, so unlikely to induce services that might not otherwise be received.
    - No inappropriate patient steering to particular providers.
    - Patients are not coerced into enrolling in Part B.
    - Certain protections built in to protect Medicare program from additional costs.
  - **OLG cautioned that it might reach different result in other circumstances.**

(Adv. Op. 13-16; *see also* Adv. Op. 01-15 and Adv. Op. 13-16))

# Paying Patient's Premiums

- If paying premiums for health insurance exchange:
    - “HHS has significant concerns with this practice because it could skew the insurance risk pool and create an unlevel playing field in the Marketplaces. HHS discourages this practice and encourages issuers to reject such third party payments. HHS intends to monitor this practice and to take appropriate action, if necessary.” (HHS Letter dated 11/4/13).
    - Letter does not apply to:
      - Indian tribes and govt grant programs.
      - Payments made by private non-profit foundation based on defined criteria based on financial status that does not consider health status and payment covers entire year.
- (HHS Letter dated 2/7/14; 79 FR 15240)

# Paying Patient's Premiums

- If paying private insurance premiums (e.g., COBRA or other coverage):
  - Probably does not implicate AKS or CMPL unless it is tied to or induces referrals for services payable by govt programs.
  - May implicate Idaho AKS, but not tested.
  - COBRA regulations contemplate that COBRA premiums may be paid by third party.
  - Check payer contracts.
- *But stay tuned—this is a developing area of the law.*

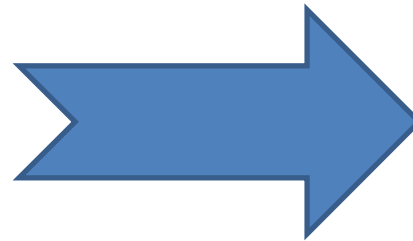


# Contracts with Referring Providers



# Contracts with Referring Providers

- Employment
- Independent contractor or other services agreement
- Group compensation arrangement
- Lease for space or equipment
- Recruitment agreement
- Management or support services



**Stark  
Anti-Kickback  
Statute**

# Contracts with Referring Providers

- Employees, especially physicians or their family members.
  - Identifiable services
  - Fair market value
  - Not based on the volume or value of referrals
    - Not based on referrals for ancillary services or services performed by others
    - May pay based on services the provider personally performs
  - Commercially reasonable

(42 CFR 411.357(d); 42 CFR 1001.952(i))

# Contracts with Referring Providers

- Independent contractors or other services agreements.
  - Written agreement signed by parties.
  - Specifies services provided.
  - Terms remain in effect for at least one year.
  - Compensation:
    - Set in advance
    - Consistent with fair market value
    - Not based on volume or value of referrals.
      - May pay based on personally performed services.
      - May not pay based on referrals for ancillary services or services by others.
  - Commercially reasonable.

(42 CFR 411.357(c), (l); 42 CFR 1001.952(d))

# Contracts with Referring Providers

- Group Practice compensation for physicians.
  - Distribution of overhead expenses and income based on formula set prospectively.
  - Compensation not based on volume or value of referrals for designated health services.
    - May pay based on personal productivity and “incident to” services, but not ancillary services or services performed by other employees that are not “incident to”.
    - May pay based on share of overall profits so long as subgroups have at least 5 physicians.
    - May pay based on other methods that do not reflect volume or value of designated health services.

(42 CFR 411.352(e), (g), (i))

# Contracts with Referring Providers

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- Leases for space and equipment
  - Written lease signed by the parties.
  - Specifies the premises covered.
  - Term is for at least one year; may not modify within 1 year term.
  - Space leased does not exceed that which is needed and is commercially reasonable.
  - Tenant has exclusive use of space or equipment.
  - Rent is set in advance, consistent with FMV, and not based on:
    - % of business generated in space or by equipment, or
    - Per-unit of service if includes services referred by landlord.

(42 CFR 411.357(a)-(b); 42 CFR 1001.952(b))

# Ownership Interests

- Physician generally may not refer designated health services to an entity in which physician has ownership interest.
- Exceptions:
  - Group practice if satisfies definition of “group practice”.
  - Ownership interest in a hospital if certain conditions met.
  - Ownership of a rural provider, i.e., furnishes not less than 75% of DHS to residents of a rural area.

(42 CFR 411.355 and .356)

# Gifts or Perks to Providers or Other Referral Sources





# Gifts or Perks to Providers or Other Referral Sources

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E.g., soliciting, giving or receiving:

- Gifts, e.g., “thank you” or appreciation gifts.
- Free items or services, e.g., meals, CME, travel, space, equipment, perks, insurance, etc.
- Discounted items or services, i.e., less than fair market value, professional courtesies, etc.
- Payments for services not performed.
- Payments for unnecessary services.
- Overpayments for items or services.
- Practice or expense subsidies.
- Business opportunities without investment.
- Failure to recoup money owed.

# Gifts or Perks to Providers

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- Lower risk if entity receiving gift does not refer items or services payable by federal healthcare programs.
  - Stark, AKS and CMPL generally apply to referrals for items or services payable by govt programs.
- But no guarantee...
  - OIG has cautioned that carving out federal programs from specific transaction may not protect the parties if there are other referrals for federal programs between parties.
  - Still violates Idaho AKS and fee splitting statute.



# Professional Courtesy

- Stark safe harbor applies if:
  - Practice has formal medical staff.
  - Written policy approved in advance.
  - Offered to all physicians in service area regardless of referrals.
  - Not offered to govt beneficiaries unless showing of financial need.
  - Does not violate AKS.

(42 CFR 411.357(s); 72 FR 51064)

- But beware AKS, state laws, and private payer contracts.

# Professional Courtesy

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- Especially beware waiving copays, deductibles or engaging in “insurance only” billing.
  - See prior discussion.
- Offering free items or services to employees may implicate tax or employee benefit laws.
  - Benefits to employees are usually taxable.
  - May be structured to fit within employee benefit plan, but may be subject to ERISA or similar laws.

# Gainsharing or Cost Saving Programs



- 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.
  - Includes “gainsharing” programs.
- Physician cannot knowingly accept such a payment.
- Penalties:
  - \$2000 for each individual with respect to whom payment made.
  - Any other penalty allowed by law.

(42 USC 1320a-7a(b)(1); 42 CFR 1003.102)

# Gainsharing Programs

- **OIG has periodically approved gainsharing in advisory opinions if certain safeguards included, e.g.,**
  - **Proposed plan does not adversely affect patient care.**
  - **Quality evaluated by third party.**
  - **Low risk that incentive will lead physicians to provide medically inappropriate care.**
  - **Payments limited in duration and amount.**
  - **Payments not tied to referrals or other suspect actions.**

*(See, e.g., Adv. Op. 12-22)*

- **OIG advisory opinions do not apply to Stark.**
  - **CMS proposed Stark exception, but was not finalized.**
- **CMS/OIG have issued interim rule waiving CMPL and Stark for ACOs.**

# Additional Resources

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# https://oig.hhs.gov/compliance/

The screenshot shows a Windows Internet Explorer browser window displaying the 'Compliance' page of the Office of Inspector General (OIG) website. The address bar shows the URL 'https://oig.hhs.gov/compliance/'. The browser's Favorites bar includes links to 'AHLA Lists', 'AKS', 'CMS home', 'CMS Stark', 'eCFR', 'EMTALA guidelines', 'Gmail', 'HIPAA', 'Hotmail', 'Idaho Statutes', 'IDAPA DHW', 'IDSOS Search', 'MapQuest', 'Nursing Facilities', 'OCR HIPAA', 'OIG', and 'Stark'. The website header features a 'REPORT FRAUD' button, navigation links for 'Home', 'FAQs', 'FOIA', 'Careers', 'HEAT', and 'Contact Us', and social media icons for YouTube and Twitter. The main content area is titled 'Compliance' and includes a search bar with the text 'Report #, Topic, Keyword..'. Below the search bar is a navigation menu with links for 'About OIG', 'Reports & Publications', 'Fraud', 'Compliance', 'Recovery Act Oversight', 'Exclusions', and 'Newsroom'. The 'Compliance' section is highlighted, and the page content includes a breadcrumb 'Home > Compliance', a 'Compliance' heading, and two main sections: 'Accountable Care Organizations' and 'Advisory Opinions'. Each section has a brief description and a 'Read More' button. On the right side, there is a red callout box that says 'I'm looking for' with a dropdown menu containing a list of topics: 'Accountable Care Organizations', 'Advisory Opinions', 'Compliance 101 and Provider Education', 'Compliance Guidance', 'Corporate Integrity Agreements', 'Open Letters', 'RAT-STATS', and 'Safe Harbor Regulations'. The browser's status bar at the bottom shows 'Done', 'Internet | Protected Mode: Off', and the system clock indicating 7:43 PM on 2/19/2013.

Compliance | Office of Inspector General | U.S. Department of Health and Human Services - Windows Internet Explorer provided by

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

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## Compliance

### Accountable Care Organizations

The Affordable Care Act contains several provisions that support the development of Accountable Care Organizations to manage and coordinate care for beneficiaries.

Read More

### Advisory Opinions

The OIG issues advisory opinions about the application of OIG's fraud and abuse authorities to the requesting party's existing or proposed business arrangement.

Read More

**I'm looking for**

Let's start by choosing a topic

Select One

- Accountable Care Organizations
- Advisory Opinions
- Compliance 101 and Provider Education
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- Corporate Integrity Agreements
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<https://www.hollandhart.com/healthcare#overview>



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- Imaging centers
- Ambulatory surgery centers
- Medical device and life science companies



# Questions?

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