

# Fraud and Abuse Laws



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(1/16)

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# Overview

**“Medicare just got stronger.”**



Andy Griffith

**A stronger Medicare means:**

- New benefits for seniors
- New cost savings
- New fraud-fighting tools to protect taxpayer dollars

With the new health care law, there are new benefits available to people with Medicare, including lower prescription costs, wellness checkups and preventive care. But we don't want new opportunities for criminals to commit Medicare fraud, so the new law also provides better ways to protect us from fraud, making Medicare stronger for us and future generations. Now that's something we can all feel good about. Here are some easy things that folks like us can do to fight fraud.

- Tell your friends and neighbors to guard their Medicare and Social Security numbers.
- Don't ever let anyone borrow or pay to use your Medicare ID.
- Review your Medicare claims to make sure they are accurate. Check them early—the sooner you see and report errors, the sooner we can stop fraud.
- Check your “Medicare & You” handbook, coming soon.

If you see or think something might be Medicare fraud, call **1-800-MEDICARE** to report it.

Learn more about protecting yourself and spotting fraud at

**StopMedicareFraud.gov**



- Key fraud and abuse laws
  - False Claims Act
  - Anti-Kickback Statute
  - Ethics in Physician Referrals Act (“Stark”)
  - Civil Monetary Penalties Law
  - State Statutes
- Report and repayment obligations
- Compliance programs

# Preliminaries

- Written materials
  - Copy of .ppt slides
  - *Healthcare Transactions: Beware Stark, Anti-Kickback, and More*
  - *OIG Roadmap for New Physicians: Avoiding Medicare and Medicaid Fraud and Abuse*
  - *OIG Supplemental Compliance Program Guidance for Hospitals*
- Written materials are available per the webinar instructions or contact me at [kcstanger@hollandhart.com](mailto:kcstanger@hollandhart.com).
- The program will be recorded and available for download at [www.hhhealthlawblog.com](http://www.hhhealthlawblog.com).
- Submit questions per Web-Ex “chat” function or contact me at [kcstanger@hollandhart.com](mailto:kcstanger@hollandhart.com).

# Preliminaries

- This is an overview of some relevant federal laws.
- Additional laws may apply
  - State laws
  - Federal laws
  - Payer contracts
- Application may depend on specific facts.
- We're going to be moving fast.
  - Written materials will provide more detail.

# False Claims Act (18 USC 1347)



# False Claims Act

- **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 \$5,500 to \$11,000 per claim
  - 3x damages
  - Exclusion from Medicare/Medicaid

(18 USC 1347)

# False Claims Act

- ***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: 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).

# 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 even if there are other legitimate purposes. (*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

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

# 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.**



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## JUSTICE NEWS

### Department of Justice

Office of Public Affairs

FOR IMMEDIATE RELEASE

Wednesday, October 22, 2014

### DaVita to Pay \$350 Million to Resolve Allegations of Illegal Kickbacks

DaVita Healthcare Partners, Inc., one of the leading providers of dialysis services in the United States, has agreed to pay \$350 million to resolve claims that it violated the False Claims Act by paying kickbacks to induce the referral of patients to its dialysis clinics, the Justice Department announced today. DaVita is headquartered in Denver, Colorado and has dialysis clinics in 46 states and the District of Columbia.

The settlement today resolves allegations that, between March 1, 2005 and February 1, 2014, DaVita identified physicians or physician groups that had significant patient populations suffering renal disease and offered them lucrative opportunities to partner with DaVita by acquiring and/or selling an interest in dialysis clinics to which their patients would be referred for dialysis treatment. DaVita further ensured referrals of these patients to the clinics through a series of secondary agreements with the physicians, including entering into agreements in which the physician agreed not to compete with the DaVita clinic and non-disparagement agreements that would have prevented the physicians from referring their patients to other dialysis providers.



# 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**

- **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

- Exceptions and 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.

(42 CFR 1001.952)

# Anti-Kickback Statute: Safe Harbors

- Exceptions and safe harbors (cont.)
  - OB malpractice insurance subsidies
  - Referral services
  - Referral arrangements for specialty services
  - Warranties
  - Discounts
  - Group purchasing organizations
  - Price reductions offered to health plans and MCOs
  - Ambulance replenishing
  - Health centers
  - Electronic health record items or services

(42 CFR 1001.952)

# Anti-Kickback Statute

- No *de minimus* safe harbor.
  - But not too much risk if remuneration is “nominal” (whatever that means...).
- 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

- **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.**



U.S. Department of Health & Human Services

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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)



- Regulations at 42 CFR 411.350-.389

# Stark

- **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 for such designated health services**unless arrangement structured to fit within a regulatory exception.**

(42 CFR 411.353)

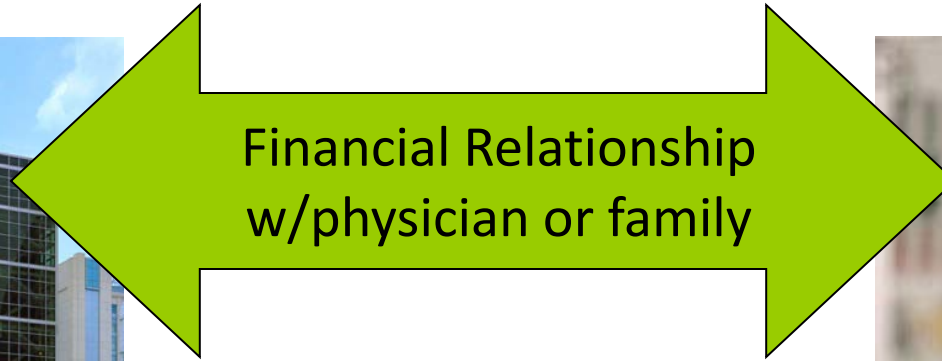


# Stark



St. Louis Children's Hospital

Photo by Alise O'Brien



Financial Relationship  
w/physician or family



Referrals for DHS



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



# 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))



## 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.

"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.

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 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.



Department of Justice Action Center with links: 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 a physician to entities with which the physician (or their family member) has a 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 the 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 since 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

- Stark does not require intent to violate statute.
  - No “good faith” compliance.
- To comply with Stark, transaction must either:
  - Fall outside statute, i.e., no “financial relationship” or “referral”, or
  - Fit within regulatory safe harbor.
- Exception: Entity may bill for prohibited services rendered per improper referral if entity did not know and did not act in reckless disregard or deliberate indifference concerning the identity of the referring physician.

(42 CFR 411.353)

# Stark: Safe Harbors

- 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

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 arrangements.\*
  - Physician recruitment.
  - Midlevel recruitment.\*
  - Physician retention.
  - 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.

\* Effective 1/1/16.

# Stark: Analysis

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?

# Stark: Common Problems

- Physician referrals to entities that the physician owns.
- Compensation arrangements which pay physicians based on their referrals to others (e.g., “eat what you kill” for ancillary services).
- Paying physicians more than fair market value.
- Paying physicians even though services are not provided or needed.
- Giving physicians discounts or freebies (e.g., professional courtesies).
- Subsidizing physician practices.
- Financial arrangements without a written contract.
- Performing after a written contract has expired.
- Amending contracts within one year.
- Leases that fail to satisfy lease safe harbors (e.g., “per click”, “on demand”, non-exclusive).

# 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

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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. Parenteral and enteral nutrients, equipment, and supplies.

- Advisory opinions
- FAQs
- DHS by CPT code
- Self-Referral Disclosure Protocol
- Recent settlements



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



# Civil Monetary Penalties Law

- Prohibits certain specified conduct:
  - Submitting false or fraudulent claims or misrepresenting facts relevant to services.
  - Offering, soliciting, giving or receiving remuneration to induce referrals (i.e., kickbacks).
  - **Offering inducements to program beneficiaries.**
  - **Offering inducements to physicians to limit services.**
  - **Submitting claims for services ordered by, or contracting with, an excluded entity.**
  - **Failing to report and repay an overpayment.**
  - **Failing to grant govt timely access.**

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

# Civil Monetary Penalties Law

- Penalties vary based on conduct, but generally range from:
  - \$2,000 to \$50,000 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 1003.102).

# Inducements to Govt Program Patients

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

(42 USC 1320a-7a(i); 42 CFR 1003.101; 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 delivery of preventative care.
  - 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 1003.101)

# Inducements to Govt Program Patients

- **OIG has approved the following in opinions or comments:**
  - Free or discounted item or service of low value, i.e.,
    - Each item or service is less than \$10, and
    - Aggregate is less than \$50 per patient per year.

(OIG Bulletin, *Offering Gifts and Inducements to Beneficiaries*(8/02); 66 FR 24410-11)
  - Free screenings not conditioned on or tied to additional services from any provider. (Adv. Op. 09-11)
  - Free transportation programs where transportation is reasonable and local, open to patients regardless of payor, and other transportation options are limited. (Adv. Op. 11-02; OIG Bulletin, *Offering Gifts and Inducements to Beneficiaries*(8/02)).

# 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 services provided to Medicare or Medicaid beneficiaries who are under the direct care of the physician.**
  - **Includes “gainsharing” programs.**
- **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)



# Payment to Limit Services

- **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.**

*(See, e.g., Adv. Op. 12-22)*
- **OIG advisory opinions do not apply to Stark.**
- **CMS/OIG have issued interim rule waiving CMPL and Stark for ACOs.**

# 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 1003.102; 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 .1003.102(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”).



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**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

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- Frequently Asked Questions
- Special Advisory Bulletin and Other Guidance



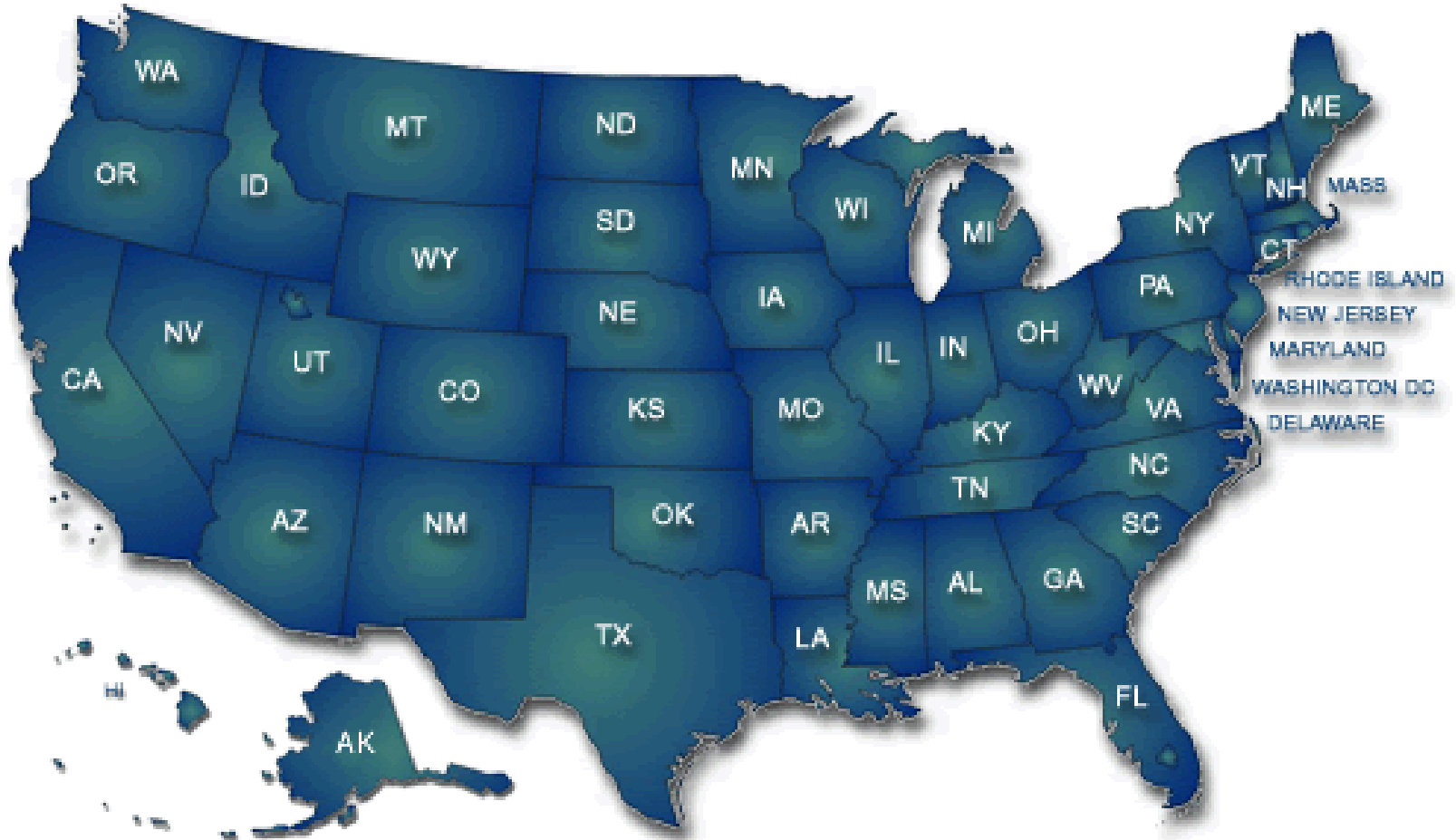
# List of Excluded Individuals and Entities (“LEIE”)

- **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

- **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.**

# Remember State Laws



# Common State Laws

- State false claims acts.
- State anti-kickback statutes.
- State self-referral (“mini-Stark”) laws.
- Fee splitting statutes.
- Healthcare fraud statutes.
- Others?



# Common State Laws

## Federal Fraud and Abuse Laws

- Generally limited to claims for federal healthcare programs, e.g.,
  - Medicare
  - Medicaid
  - TriCare
  - Others?

## State Fraud and Abuse Laws

- May be broader than federal statutes, e.g.,
  - State healthcare programs
  - Private payer arrangements
  - Others?

*Don't forget to check state laws or private contacts.*

# Better to comply in the first place!

An Ounce of Prevention is  
Worth a Pound of Cure  
- Benjamin Franklin -

# Compliance Plans



# Why have a compliance plan?

- **ACA will require providers to have compliance plan as condition to enrollment in Medicare, Medicaid, SCHIP. (ACA 6401)**
  - **HHS to develop “core elements” of required compliance plans.**
  - **HHS has not issued implementing regulations for physicians yet.**
  - **Regulations issued for other providers suggests that HHS will track elements from earlier Compliance Program Guidance.**

# Why have a compliance plan?

- Even if not mandated, compliance plan is still a good idea.
  - May facilitate compliance and avoid repayments and penalties.
  - May help avoid fraud charges.
  - May mitigate penalties.
  - May improve performance.
    - facilitates prompt claims submissions
    - identifies undercoding as well as upcoding
    - reduces claim denials
    - improves medical record documentation
    - may identify and prevent patient care problems
- Compliance plan = preventative medicine



U.S. Department of Health & Human Services

# Office of Inspector General

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## 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.

### Related

← Compliance Resource Material

The compliance program guidance documents are listed below.

#### 09-30-2008

- ✦ [Supplemental Compliance Program Guidance for Nursing Facilities \(73 Fed. Reg. 56832; September 30, 2008\)](#)
  - ✦ [Compliance Program Guidance for Nursing Facilities \(65 Fed. Reg. 14289; March 16, 2000\)](#)

#### 11-28-2005

- ✦ [Draft Compliance Program Guidance for Recipients of PHS Research Awards \(70 Fed. Reg. 71312; November 28, 2005\)](#)
  - ✦ [NSTC Launches Government-Wide Initiative Based on OIG Draft Guidance for HHS Research Grants \(June 7, 2006\)](#)

#### 01-31-2005

- ✦ [Supplemental Compliance Program Guidance for Hospitals \(70 Fed. Reg. 4858; January 31, 2005\)](#)
  - ✦ [Compliance Program Guidance for Hospitals \(63 Fed. Reg. 8987; February 23, 1998\)](#)

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# OIG Compliance Program Guidance

- Not mandatory.
- Not a compliance plan itself.
- Provides a guide or outline for a compliance plan.
- Feds will give some deference if plan addresses the elements and standards in the OIG guidance.
  - 7 elements are based on Federal Sentencing Guidelines.
- Unlike other similar programs, OIG is very flexible and does not expect small practices to formally implement all 7 elements.

# **OIG Compliance Guidance: Elements**

- 1. Internal monitoring and auditing.**
- 2. Written standards, policies and procedures.**
- 3. Compliance officer or contacts.**
- 4. Education and training.**
- 5. Investigation of alleged violations and appropriate disclosures to government agencies.**
- 6. Open lines of communication, e.g., open discussions at staff meetings or bulletin board notices.**
- 7. Enforcement of disciplinary standards.**

**Implementation depends on size and resources of group.**



# Action Items



# Action Items

- **Identify remuneration to referral sources (e.g., providers, facilities, vendors, govt program patients).**
  - **Contracts (employment, independent contractors, etc.).**
  - **Group compensation structures.**
  - **Leases (space, equipment, etc.).**
  - **Subsidies or loans.**
  - **Joint ventures or partnerships.**
  - **Free or discounted items or services (e.g., use of space, equipment, personnel or resources; professional courtesies; gifts; etc.).**
  - **Marketing programs.**
  - **Financial policies.**

# Action Items

- Review relationships for compliance with statute or exception, e.g.,
  - No intent to induce referrals for government program business.
  - Written contract that is current and signed by parties.
  - Compliance with terms of contract.
    - Parties providing required services.
    - Documentation confirming that services provided.
  - Fair market value.
  - Compensation not based on volume or value of referrals.
  - Arrangement is commercially reasonable and serves legitimate business purpose.

# Action Items

- **Implement method to track and monitor relationships with referral sources for compliance.**
  - Central repository for contracts or deals.
  - Method to track contract termination dates.
  - Process for confirming compliance before payment.
  - Require review and approval by compliance officer, attorney or other qualified individual.
    - Contracts.
    - Joint transactions with referral sources.
    - Benefits or perks to referral sources.
    - Marketing or advertising.

# Action Items

- Ensure your compliance policies address fraud and abuse laws.
- Train key personnel regarding compliance.
  - Administration.
  - Compliance officers and committees.
  - Human resources.
  - Physician relations and medical staff officers.
  - Marketing / public relations.
  - Governing board members.
  - Purchasing.
  - Accounts payable.
- Document training.

# If you think you have a problem

- Don't do this!



# 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 repayment per applicable law.
  - Self-disclosure program.
    - To OIG, if there was knowing violation of False Claims Act, Anti-Kickback Statute or Civil Monetary Penalties Law.
    - To CMS, if there was violation of Stark.

# Additional Resources





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

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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
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- Compliance 101 and Provider Education
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- Corporate Integrity Agreements
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## Healthcare

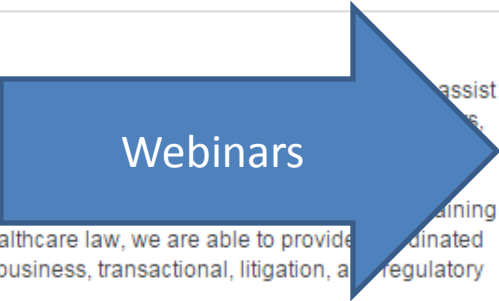
### Overview

Holland & Hart provides legal assistance to our clients in navigating the complex regulatory environment that healthcare has experienced in recent years. With our competition, and increasing number of attorneys and staff skilled in this area, on the forefront of healthcare law, we are able to provide coordinated services to meet the business, transactional, litigation, and regulatory needs of our clients.

Our healthcare clients include hospitals, individual medical providers, medical groups, managed care organizations (MCOs), third-party administrators (TPAs), health information exchanges (HIEs), practice managers and administrators, independent practice associations (IPAs), owners of healthcare assets, imaging centers, ambulatory surgery centers, medical device and life science companies, rehabilitation centers, and extended and eldercare facilities. We have also assisted clients with the significant changes enacted by the Affordable Care Act, including advice regarding employer and health plan compliance, health insurance exchanges, accountable care organizations, and nonprofit cooperative health plans.

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### Contact



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2/4 HIPAA Privacy and Security Rules

2/11 HIPAA for Business Associates

2/18 Responding to HIPAA Breaches

- To receive notices or client alerts, contact me at [kcstanger@hollandhart.com](mailto:kcstanger@hollandhart.com).

# Questions?



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