#### **Fraud and Abuse Laws**



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(7-19)



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#### Holland & Hart Webinar Series

**Overview of Relevant Fraud and Abuse Laws** 

- June 27: Eliminating Kickbacks in Recovery Act ("EKRA")
- July 2: Fraud and Abuse Laws
  - Federal
  - State

Applying the Fraud and Abuse Laws

- July 18: Waiving Copays, Free or Discounted Items or Services, and Other Common Issues Involving Patients.
- August 8: Compensation Arrangements, Free or Discounted Items or Services, and other Common Issues Involving Referring Providers.

To sign up, contact Laura Squyres at <u>LDSquyres@hollandhart.com</u>.



#### **Written Materials**

- .Ppt slides
- OIG, Avoiding Fraud and Abuse
- OIG, Supplemental Compliance Program Guidance for Hospitals
- Stanger, *Fraud and Abuse in Healthcare Transactions*
- If you did not receive materials, contact Laura Squyres at <u>LDSquyres@hollandhart.com</u>.
- Additional resources at <a href="https://www.hollandhart.com/health">https://www.hollandhart.com/health</a> <a href="https://www.hollandhart.com/health">https://www.hollandhart.com/health</a>





#### **Fraud and Abuse**



#### If you fear reprisal:

Federal employees and employees of contractors, subcontractors, and grantees are protected by law from reprisal for reporting wrongdoing to a recipient authorized by law to receive such reports.



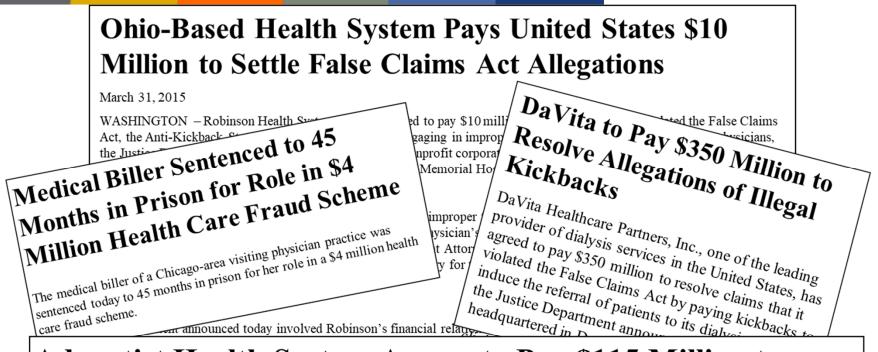
Contact the OIG Whistleblower Ombudsman to learn more about your rights:

OIGWPEAOmbuds@state.gov









#### Adventist Health System Agrees to Pay \$115 Million to Settle False Claims Act Allegations

Adventist Health System has agreed to pay the United States \$115 million to settle allegations that it violated the False Claims Act by maintaining improper compensation arrangements with referring physicians and by miscoding claims, the Justice Department announced today. Adventist is a non-profit healthcare organization that operates hospitals and other health care



#### **Increased Penalties**

	Old Penalty	New Penalty
False Claims Act	\$5,500 to \$11,000 / claim	\$10,781 to \$21,563* /claim
Failure to repay		\$20,000 per claim
Anti-Kickback Statute	\$25,000 criminal penalty 5 years in prison	\$100,000 criminal penalty 10 years in prison
	\$50,000	\$100,000 civil penalty
Ethics in Patient Referrals ("Stark")	\$15,000 per claim	\$24,748* per claim
Circumvention scheme	\$100,000	\$164,992*
<b>Civil Monetary Penalties Law</b>		\$20,000 to \$100,000
Induce beneficiaries	\$10,000	\$20,000
Induce physicians	\$2,000	\$5,000
• Excluded Provider	\$10,000	\$20,000
(See 45 CFR 102.3)		

#### **Fraud and Abuse Laws**



- False Claims Act
- Anti-Kickback Statute ("AKS")
- Eliminating Kickbacks in Recovery Act ("EKRA")
- Ethics in Physician Referrals Act ("Stark")
- Civil Monetary Penalties Law ("CMPL")
- Travel Act
- State Laws



#### **False Claims Act**

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

(31 USC 3729; 42 CFR 102.3; see also 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. (*See Universal Health Serv., Inc. v. U.S. ex rel. Escobar* (S.Ct. 2016))



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





• 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 <u>one</u> 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.



- Penalties
  - 10 years in prison
  - \$100,000 criminal fine
  - \$100,000 penalty
  - 3x damages
  - Exclusion from Medicare/Medicaid

(42 USC 1320a-7b(b); 42 CFR102.3)

- 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.





#### **Anytime you want to:**

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

- 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...



- *U.S. v. Anderson* (10<sup>th</sup> 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: 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)

- Transportation programs
- OB malpractice insurance subsidies
- Electronic health record items or services
- Referral services
- Referral arrangements for specialty services
- Warranties
- Discounts
- Others



### **Advisory Opinions**

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



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 Part of Substance Use-Disorder Prevention that
 Promotes Opioid Recovery
 and Treatment for Patients
 and Communities Act
 ("SUPPORT Act") (2018)



## **EKRA**

 Cannot solicit, receive, pay or offer any remuneration in return for referring a patient to a laboratory, recovery homes or clinical treatment facility <u>unless</u> arrangement fits within regulatory exception.

(18 USC 220)

**Penalties** 

- \$200,000 criminal fine
- **10 years in prison** (18 USC 220)
- Maybe Anti-Kickback Statute violation?
- Maybe False Claims Act violation?



## **EKRA**

- Applies to anyone involved in kickbacks.
- Applies to arrangements with:
  - Laboratories,
    - All clinical labs, not just toxicology labs
  - Recovery homes, or
  - Clinical treatment facilities
    - Not hospitals
- Applies to arrangements that would otherwise be protected by the AKS, e.g., productivity-based employment arrangements.
- Applies to items or services paid by private payers.
- Watch for regulations...





#### EKRA Safe Harbors

- Discount or other reduction in price under a health care benefit program.
- Payment by employer to employee or independent contractor
- Discounts by dug of a manufacturer under Medicare coverage gap discount program
- Compensation that satisfies AKS personal services and management contract safe harbor so long as compensation does not vary with referrals.
- Waiver or discount of copays that satisfies Stark safe harbor and certain other conditions met
- Subsidies to health centers
- Remuneration under alternative payment models
- Any other payment, remuneration, discount, or reduction as determined by the Attorney General, in consultation with the Secretary of Health and Human Services, by regulation

(18 USC 220(b))



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





- 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")
  - <u>unless</u> arrangement structured to fit within a regulatory exception.

(42 CFR 411.353)



- Penalties
  - No payment for services provided per improper referral.
  - Repayment of payments improperly received within 60 days.
  - Civil penalties.
    - \$24,748 per claim submitted
    - \$164,922 per circumvention scheme

(42 CFR 411.353, 1001.102(a)(5); 1001.103(b); and 102.3)

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





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

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

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



#### DEPARTMENT of JUSTICE ACTION CENTER

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Apply for a Grant

Submit a Complaint

Report Waste, Fraud, Abuse or Misconduct to the Inspector General

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

#### \$237,454,195 judgment

- Ultimately settled for \$72.4 million.
- Relator received \$18 million.





- Applies to referrals by <u>physician</u> to entities with which the physician (or their family member) has financial relationship.
  - Physician =
    - MDs
    - **DO**s
    - Oral surgeons
    - Dentists
    - Podiatrists
    - Optometrists
    - Chiropractors

(42 CFR 411.351)

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



- Applies to referrals by physician to entities with which physician (or their family member) has <u>financial</u> <u>relationship</u>.
  - 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)

- Applies to referrals for <u>designated health services</u> ("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: 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 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.



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

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	Current Law and	I Regulations	and commonly referred to as the "Stark Law":								
Seff-Referral	Code List for Ce	rtain Designated	<ol> <li>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.</li> <li>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.</li> <li>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.</li> <li>The following items or services are DHS:</li> </ol>								
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				6. Radiation therapy services and supplies.							
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### Civil Monetary Penalties Law (42 USC 1320a-7a)





# **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**

- Penalties vary based on conduct, but generally range from:
  - \$5,000 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
  - EKRA



### **Inducements to Govt Program Patients**

- Cannot offer or transfer remuneration to federal 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:
  - \$20,000 for each item or service.
  - 3x amount claimed.
  - Repayment of amounts paid.
  - Exclusion from Medicare and Medicaid.

(42 USC 1320a-7a(a)(5); 42 CFR 1003 and 102.3).

 Also a likely violation of the Anti-Kickback Statute



### **Inducements to Govt Program Patients**

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

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

• Govt will not prosecute based on item or service is 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))



### **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 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 <u>medically necessary</u> 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:
  - \$5,000 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) HOLLAND&HART

### **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").



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

- OIG maintains LEIE and updates monthly: <u>https://oig.hhs.gov/exclusions/exclusions\_list.asp</u>
  - 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**

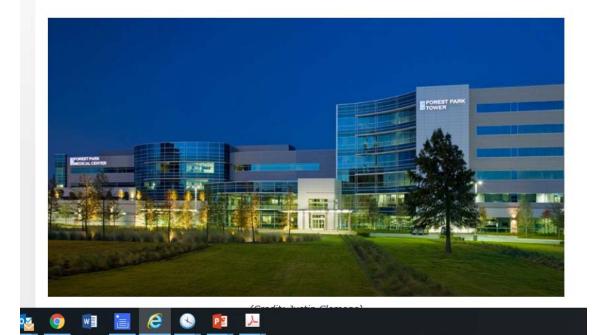
- OIG may issue advisory opinions.
  - Listed on OIG fraud and abuse website, www.oig.hhs.gov/fraud.
  - Not binding on anyone other than participants to the opinion.
  - But you are probably fairly safe if you act consistently with favorable advisory opinion.



### **Travel Act**

### Feds Allege Mass Forest Park Medical Center Kickback Scheme; 21 Indicted

12/1/2016 | by Matt Goodman | 15 Comments | 💽 Share Post





### **The Travel Act**

- Cannot use mail or interstate commerce to violate any state or federal law involving certain crimes, including bribery. (18 USC 1952)
- Penalties
  - Fines
  - Up to 20 years in prison.
- *US v. Beauchamp* (ND Tex. 8/18/18): applied Travel Act to kickback scheme involving physicians in violation of Texas law even though arrangement involved private payers.
- Beware state laws, especially those prohibiting commercial bribery...



### **State Laws**





## **Common State Laws**

- Fraud
- Bribery
- False claims acts
  - Medicaid
  - Others?
- Anti-kickback statutes
- Self-referral limitations
   "Mini-Stark" laws
- Fee splitting
- Others?

May apply to govt programs and/or private payers



### **Additional Resources**





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

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#### CONTACTS



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Partner Salt Lake City

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### **Questions?**



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