Fraud and Abuse Laws: Understanding, Applying and Avoiding Liability

Kim C. Stanger

(1/17)

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

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.

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.
- The program will be recorded and available for download at www.hhhealthlawblog.com.
- Submit questions per Web-Ex "chat" function or contact me at kcstanger@hollandhart.com.

OIG Office of Inspector General
U.S. Department of State • Broadcasting Board of Governors

HELP FIGHT

FRAUD.

WASTE.

ABUSE.

If you suspect wrongdoing, contact:

DOJ/OIG recovered $30 billion since 2009; $2.5 billion in 2016

Govt Enforcement

- Govt actively enforcing fraud and abuse statutes.
- Enforcement likely to continue under new administration.
- Per 2015 study, for every $1 spent in enforcement, govt recovers $7.70.

HOLLAND&HART

Recent Cases

Facts	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	$32,700,00
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

The Yates Memo

- In September 2015, DOJ Deputy AG Sally Yates released a Memorandum focusing on individual accountability for corporate wrongdoing.

The Yates Memo – 6 Key Factors

1

Companies will have to turn over information on involved individuals in order to get cooperation credit.

2

All investigations—both criminal and civil—will start with a focus on individual actors within the company.

3

Criminal and civil attorneys will work in lockstep on corporate cases, sharing information freely.

4

Line prosecutors need written approval from a senior DOJ attorney before offering protection to individuals.

5

Individual actions have to be resolved (or have a resolution plan) before corporate actions can be resolved.

6

Civil actions will be pursued against culpable individuals, even if they can't pay a substantial fine.

FOR MORE LIKE THIS, CHECK OUT **THEBROADCAT.COM**

HOLLAND&HART

JUSTICE NEWS

Department of Justice

Office of Public Affairs

SHARE

FOR IMMEDIATE RELEASE

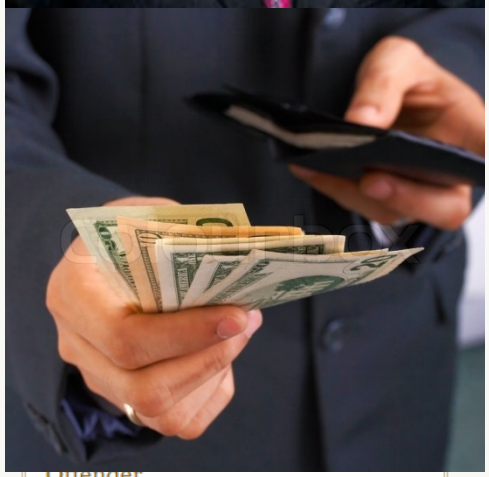
Tuesday, September 27, 2016

Former Chief Executive of South Carolina Hospital Pays $1 Million and Agrees to Exclusion to Settle Claims Related to Illegal Payments to Referring Physicians

The Department of Justice announced today that it has reached a $1 million settlement with Ralph J. Cox III, the former chief executive officer of Sumter, South Carolina-based Tuomey Healthcare System, for his involvement in the hospital's illegal Medicare and Medicaid billings for services referred by physicians with whom the hospital had improper financial relationships.

Under the terms of the settlement agreement, Cox will also be excluded for four years from participating in federal health care programs, including providing management or administrative services paid for by federal health care programs. The illegal physician arrangements resulted in a $237.4 million judgment against Tuomey following a jury verdict. On Oct.16, 2015, the United States resolved its judgment against Tuomey for payments totaling $72.4 million, and the hospital was sold to Palmetto Health, a multi-hospital healthcare system based in Columbia, South Carolina.

"Sweetheart deals between hospitals and referring physicians distort medical decision making and drive up the cost of healthcare for patients and insurers alike," said Principal Deputy Assistant Attorney General Benjamin C. Mizer, head of the Justice Department's Civil Division. "Patients have a right to be confident that a physician who orders a procedure or test does so because that service is in the patient's best interest, and not because the physician stands to gain financially from the referral. Today's settlement demonstrates that the Justice Department and its law enforcement partners will hold individual decision makers accountable for their involvement in causing the companies and facilities they run to engage in unlawful activities."



Offender

To make matters worse…

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 (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 or date cost report is due.
- 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

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

    $237,454,195 judgment
  - Ultimately settled for $72.4 million.
  - Relator will receive $18 million.

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).
- Failure to timely report and repay overpayment.

Department of Justice

U.S. Attorney's Office

Southern District of New York

FOR IMMEDIATE RELEASE

Wednesday, August 24, 2016

Manhattan U.S. Attorney Announces $2.95 Million Settlement With Hospital Group For Improperly Delaying Repayment Of Medicaid Funds

Continuum Admits That It Did Not Fully Reimburse Medicaid For Erroneously Billed Claims For Over Two Years

Preet Bharara, the United States Attorney for the Southern District of New York, Scott J. Lampert, Special Agent in Charge of the New York Field Office of the U.S. Department of Health and Human Services

JUSTICE NEWS

Department of Justice

Office of Public Affairs

SHARE

FOR IMMEDIATE RELEASE

Wednesday, December 14, 2016

Justice Department Recovers Over $4.7 Billion From False Claims Act Cases in Fiscal Year 2016

Third Highest Annual Recovery in FCA History

The Department of Justice obtained more than $4.7 billion in settlements and judgments from civil cases involving fraud and false claims against the government in fiscal year 2016 ending Sept. 30, Principal Deputy Assistant Attorney General Benjamin C. Mizer, head of the Justice Department's Civil Division, announced today. This is the third highest annual recovery in False Claims Act history, bringing the fiscal year average to nearly $4 billion since fiscal year 2009, and the total recovery during that period to $31.3 billion.

"Congress amended the False Claims Act 30 years ago to give the government a more effective tool against false and fraudulent claims against federal programs," said Mizer. "An astonishing 60 percent of those recoveries were obtained in the last eight years. The beneficiaries of these efforts include veterans, the elderly, and low-income families who are insured by federal health care programs; families and students who are able to afford homes and go to college thanks to federally insured loans; and all of us who are protected by the government's investment in national security and defense. In short,

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

JUSTICE NEWS

Department of Justice

Office of Public Affairs

SHARE

FOR IMMEDIATE RELEASE

Tuesday, March 1, 2016

Medical Equipment Company Will Pay $646 Million for Making Illegal Payments to Doctors and Hospitals in United States and Latin America

Olympus Corp. of the Americas, Nation's Largest Distributor of Endoscopes, Also Agrees to Reforms and Subsidiary Admits to Foreign Bribery

The United States' largest distributor of endoscopes and related equipment will pay $623.2 million to resolve criminal charges and civil claims relating to a scheme to pay kickbacks to doctors and hospitals, U.S. Attorney Paul J. Fishman of the District of New Jersey and Principal Deputy Assistant Attorney General Benjamin C. Mizer of the Justice Department's Civil Division announced today. U.S. Attorney Fishman and Principal Deputy Assistant Attorney General David Bitkower of the Justice Department's Criminal Division also announced that a subsidiary of the distributor will pay $22.8 million to resolve criminal charges relating to the Foreign Corrupt Practices Act (FCPA) in Latin America.

Anti-Kickback Statute Violations

Olympus Corp. of the Americas (OCA) was charged in a criminal complaint filed today in Newark, New Jersey, federal court

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
  - Transportation programs

(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.
- Not binding on anyone other than participants to the opinion.
- But you are probably fairly safe if you act consistently with favorable advisory opinion.

.hhs.gov/compliance/advisory-opinions/index.asp

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.

Related

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

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.

I'm looking for

Let's start by choosing a topic

Select One

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

EXCLUSIONS DATABASE

REPORT FRAUD

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

- 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.

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 deal ians, like the ones in this case, undermine patient confidence and drive up healthcare cost rogram and its beneficiaries," said Principal Deputy Assistant Attorney Gener rtment's Civil Division. "This case demonstrates the United States' comm beneficiaries to hospitals for procedures, tests and other health serv patient's best interest, and not because the physician stands to tice is determined to prevent the kind of abuses uncovered in this ca he integrity of the Medicare program."

The judg a statute that prohibits hospitals from billing Medicare for certa) that have been referred by physicians with whom the hospital l cludes exceptions for many common hospital-physician arrangeme pital makes to a referring physician be at fair market value for the phys volume or value of the physician's referrals to the hospital.

The governmen t it could lose lucrative outpatient procedure referrals to a new freestanding surge 9 specialist physicians that required the physicians to refer their outpatient procedures to 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."

Stark = False Claim; 3x damages under FCA

DEPARTMENT OF JUSTICE ACCOMPLISHMENTS

OPEN GOVERNMENT AT THE DEPARTMENT of JUSTICE

SMART ON CRIME

DEPARTMENT of JUSTICE ACTION CENTER

Report a Crime

Get a Job

Locate a Prison, Inmate, or Sex Offender

Apply for a Grant

Submit a Complaint

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

Stark


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

Stark

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

- 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

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

(42 CFR 411.351)

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

Stark

Applies to referrals by physician to entities with which physician (or their family member) has a direct or indirect financial relationship.

Ownership Interest

- Equity interest
- Partnership
- Investment
- Joint venture
- Indirect ownership

Compensation = Anything of Value

- Contract
- Free or discounted space, items, or services
- Professional courtesy
- Subsidies or support
- Above or below FMV
- Loan

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.
  - Beware multiple relationships in same transaction.

(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.

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?

Common Stark Problems

- No written contract for services.
  - Exception: employed physicians.
- No lease for space or equipment.
- Compensation > fair market value.
  - No documented services for compensation.
  - Contract not updated to cover change in services.
- Compensation takes into account referrals, e.g.,
  - % of revenues generated by others, profit sharing, gainsharing, etc.
  - Exception: personally performed services.
- Compensation changes within 1 year for contracted physicians.
- Free or discounted items, services or subsidies for physicians.
  - Professional courtesies.
  - Incidental staff benefits.
  - Practice subsidies, support or staff

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

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

Civil Monetary Penalties Law (42 USC 1320a-7a; 42 CFR 1003)

Civil Monetary Penalties Law

- New regulations issued 12/7/16
- Restructured CMPL regulations to make more user-friendly.
  - Standards for determining amount of penalties.
  - Subparts grouped according to violations with associated penalties.
- Modified aspects of regs.
  - Bases for penalties.
  - Standards for determining amount of penalties.
  - Definition of "remuneration".

(81 FR 88334, 81 FR 88368)

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:
  - $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.

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

- 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*)

Inducements to Govt Program Patients

- "Remuneration" does not include:
  - Items or services if financial need and certain conditions met.
  - Waivers or co-pays if:
    - Not offered as part of advertisement or solicitation;
    - Not routine;
    - After good faith determination of financial need or failed collection efforts.
  - Payments meeting Anti-Kickback Statute safe harbor.

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

Inducements to Govt Program Patients

- "Remuneration" does not include:
  - Incentives to promote delivery of preventative care if:
    - Not tied to Medicare or state services;
    - Not cash or instrument convertible to cash; and
    - Value not disproportionately high in relation to preventive value.
  - Items or services that improve beneficiary's ability to obtain items or services payable by Medicare or Medicaid and pose low risk of harm.
  - Retailer coupons, rebates or rewards offered to public.
  - Certain other situations.

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

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 $15, and
    - Aggregate is less than $75 per patient per year.

    (OIG Bulletin, *Gifts of Nominal Value to Beneficiaries* (12/7/16); OIG Bulletins, *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 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)

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 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.
- Cannot retain more than 5% interest in entity that participates in federal healthcare 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").

ov/exclusions/exclusions_list.asp

REPORT FRAUD

Home • FAQs • FOIA • Careers • Contact • HEAT • Download Reader •

U.S. Department of Health & Human Services

Office of Inspector General
U.S. Department of Health & Human Services

Report #, Topic, Keyword.. Search
Advanced

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

Home > 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

Related Information

- Waiver Info
- Search the Online LEIE Database

How To Use These Files

View a video tutorial on using the downloadable files.

I'm looking for

Let's start by choosing a topic

Select One

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

EXCLUSIONS DATABASE

List of Excluded Individuals and Entities ("LEIE")

- OIG maintains LEIE and updates monthly: 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.

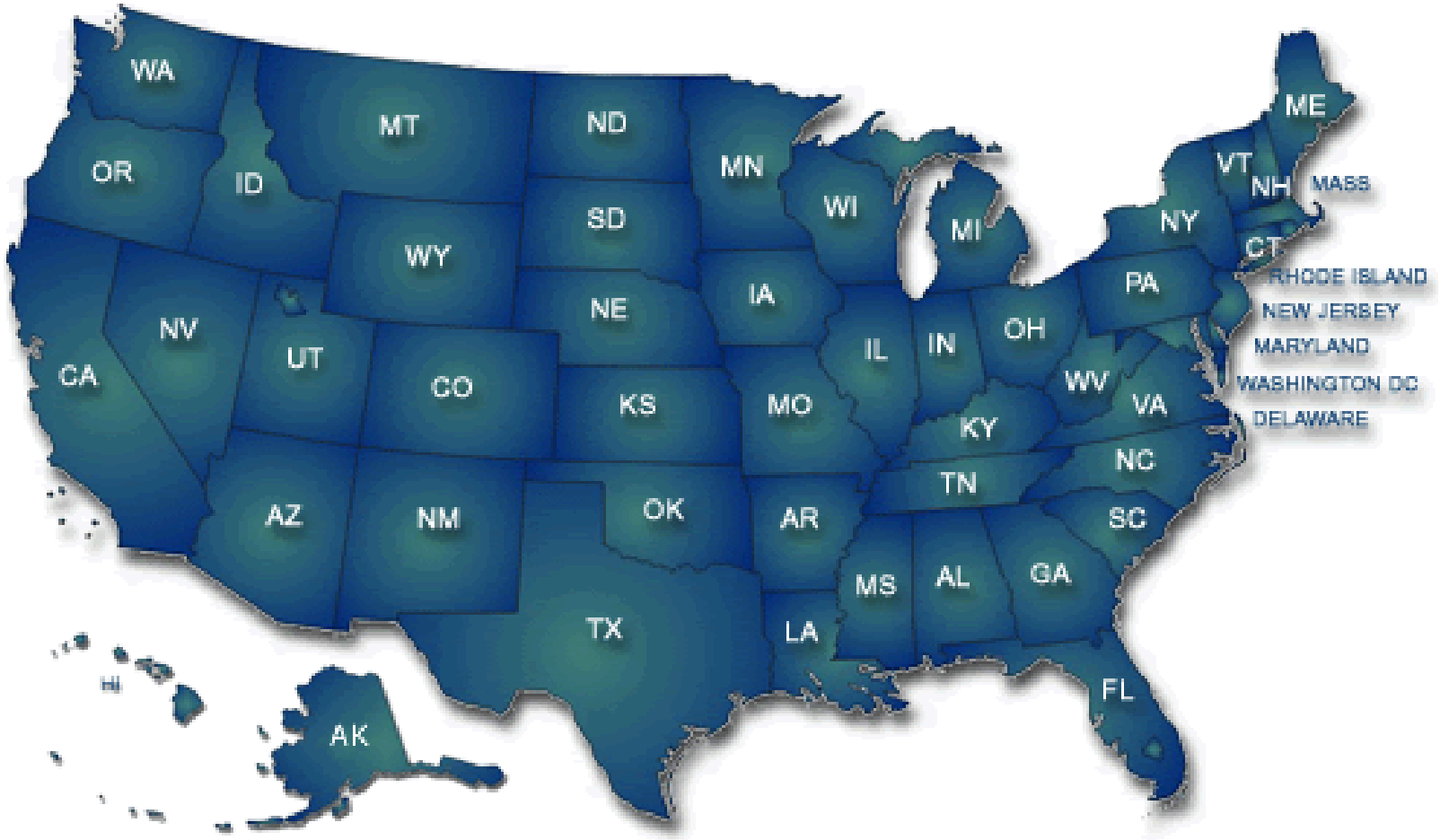
Common CMPL Problems

- Freebies to patients, e.g.,
  - Marketing program that offers freebies
  - Free services to induce others
  - Free screening
  - Free transportation
  - Gifts or "thank you" items > $15 or $75 aggregate
  - Discounts tied to other services
- Waive or discount copays or deductibles, or "insurance only" billing unless
  - Demonstrated financial need
  - Failed collection efforts
- Physician gainsharing arrangements.
- Employing or contracting with excluded entities.
- Failing to repay overpayment.

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.

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.

Compliance Plans

The best defense is a good offense.

Proverbs

QuoteAddicts

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


oig.hhs.gov/compliance/compliance-guidance/
REPORT FRAUD
Home • FAQs • FOIA • Careers • Contact
U.S. Department of Health & Human Services
Office of Inspector General
U.S. Department of Health & Human Services
Report #,
Advanced
About OIG
Reports & Publications
Fraud
Compliance
Recovery Act Oversight
Exclusions
Home › Compliance › Compliance Guidance
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)

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.

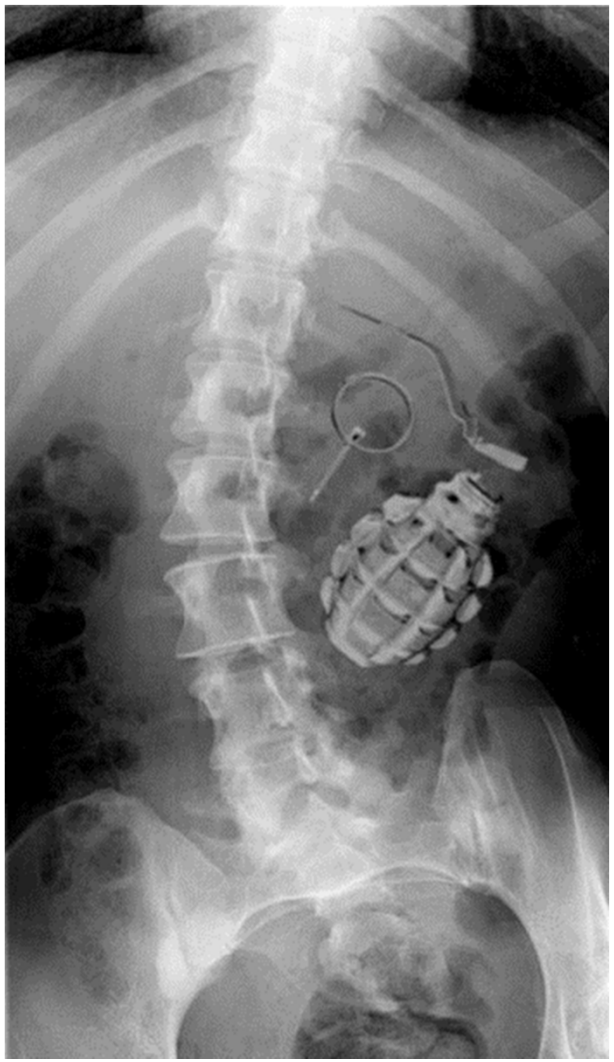
OIG Compliance Guidance: Elements

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



Review your internal policies and practices...

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.

Responding to Non-Compliance

- Just remember, once you take the step to self-report, there is no turning back…

Additional Resources

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

HOLLAND&HART

HOLLAND&HART

search this site

people
practices
firm
locations
news & resources
careers
diversity & inclusion
community

Contact
Disclaimer
Site Map

Healthcare

Overview

Holland & Hart provi… assist clients in navigating t… s. healthcare has expe… competition, and incr… attorneys and staff sk… ining on the forefront of healthcare law, we are able to provide… dinated services to meet the business, transactional, litigation, a… regulatory needs of our clients.

View our webinar recordings that cover HIPAA, antitrust, compliance, and more!

Webinars

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.

+ Read More

+ Expand All

+ News
+ Publications
+ Speaking Engagements and Events

Publications

Contact

Blaine J. Benard

Kim C. Stanger

Professionals ▸

– Related Practices

Business/Commercial Litigation
Compliance Systems, Audits, and Disclosures

Upcoming Holland & Hart Webinars

1/19 Responding to Noncompliance: Self-Reporting and Repaying

1/26 New Long Term Care Facility Rules

2/4 HIPAA Privacy Rule

2/7 HIPAA Security Rule

2/9 HIPAA and Business Associates

2/23 Responding to HIPAA Breaches

- To receive notices or client alerts, contact me at kcstanger@hollandhart.com.

Questions?

Kim C. Stanger

(208) 383-3913

kcstanger@hollandhart.com