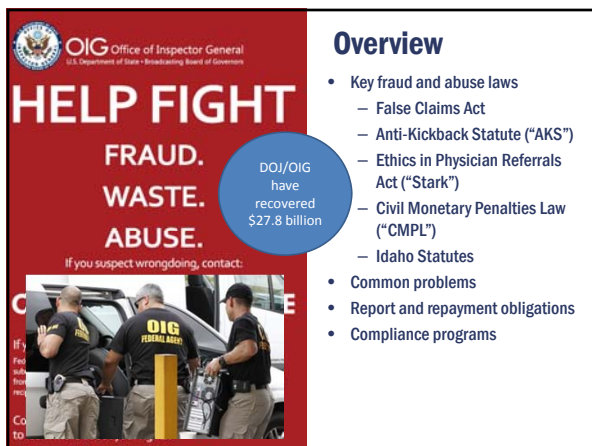




This presentation is similar to any other legal education materials designed to provide general information on pertinent legal topics. The statements made as part of the presentation are provided for educational purposes only. They do not constitute legal advice nor do they necessarily reflect the views 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.



HELP FIGHT FRAUD. WASTE. ABUSE.

DOJ/OIG have recovered \$27.8 billion

If you suspect wrongdoing, contact:

Overview

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

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

- *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).

Idaho False Claims Act

- **Cannot knowingly:**
 - **Submit claim that is incorrect.**
 - **Make false statement in any document submitted to state.**
 - **Submit a claim for medically unnecessary service.**
- **Penalties**
 - Exclusion from state health programs, e.g., Medicaid.
 - Civil penalty of up to \$1000 per violation.
 - Referral to Medicaid fraud unit.

(IC 56-209h(6))

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

- | | |
|---|--|
| <ul style="list-style-type: none"> • Penalties <ul style="list-style-type: none"> – 5 years in prison – \$25,000 criminal fine – \$50,000 penalty – 3x damages – Exclusion from Medicare/Medicaid <p>(42 USC 1320a-7b(b); 42 CFR 1003.102)</p> | <ul style="list-style-type: none"> • Anti-Kickback violation = False Claims Act violation <ul style="list-style-type: none"> – Lower standard of proof – Subject to False Claims Act penalties – Subject to qui tam suit. <p>(42 USC 1320a-7a(a)(7))</p> <ul style="list-style-type: none"> • 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.



Medical Equipment Company Will Pay \$6.46 Million for Making Illegal Payments to Doctors and Hospitals in United States and Latin America

Olympus Corp. of America, Nation's Largest Distributor of Endoscopes, Also Agrees to Reform and Subsidize Adults in Foreign Beryly

The United States' largest distributor of endoscopes and related equipment will pay \$6.46 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. Moore of the Justice Department's Civil Division announced today. U.S. Attorney Fishman and Principal Deputy Assistant Attorney General David Siskower of the Justice Department's Criminal Division also announced that a subsidiary of the distributor will pay \$1.8 million to resolve criminal charges relating to the Foreign Corrupt Practices Act (FCPA) in Latin America.

Anti-Kickback Statute Violations

Olympus Corp. of America (OCA) was charged in a criminal complaint filed today in Newark, New Jersey, federal court with conspiracy to violate the Anti-Kickback Statute (AKS), which prohibits payments to induce purchases paid for by federal health care programs. OCA has agreed to a three-year deferred prosecution agreement (DPA) that will allow it to avoid conviction if it complies with the notice and compliance requirements outlined in the agreement.

"For years, Olympus Corporation of America and Olympus Latin America dropped the compliance ball and failed to have in place policies and practices that would have prevented the substantial kickbacks and below their paid," said U.S. Attorney Fishman. "It is appropriate that they be penalized for that. At the same time, the deferred prosecution agreement takes into account the company's cooperation and commitment to fully financial corporate compliance."

As a result of the resolution outlined in the government's criminal complaint and DPA, OCA has agreed to pay a \$3.24 million criminal penalty and an additional \$3.2 million to settle civil claims under the federal and various state False Claims Acts, the largest total amount paid to U.S. Justice for violations involving the AKS to a medical device company.

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

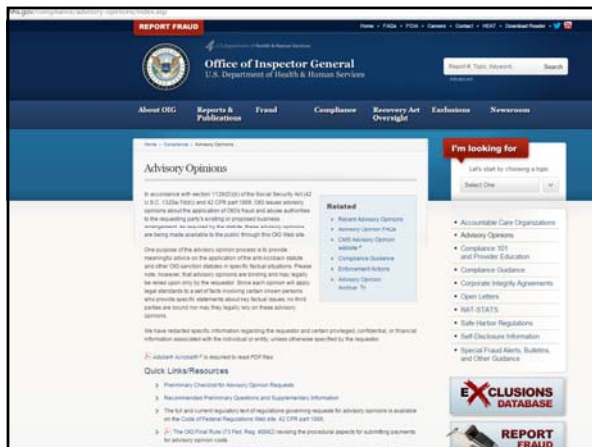
(42 CFR 1001.952)

Anti-Kickback Statute

- No *de minimus* safe harbor.
 - But not too much risk if remuneration is nominal.
- 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.



Idaho Anti-Kickback Statute

- Service provider (including providers of healthcare services) cannot:
 - Pay another person, or other person cannot accept payment, for a referral.
 - Provide services knowing the claimant was referred in exchange for payment.
 - Engage in regular practice of waiving, rebating, giving or paying claimant's deductible for health insurance.
 - Penalties
 - \$5000 fine by Department of Insurance
- (IC 41-348)

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




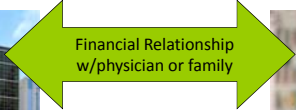
Stark

- 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 or Medicaid for such designated health services (“DHS”)

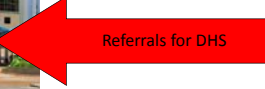
unless arrangement structured to fit within a regulatory exception.
- (42 CFR 411.353)

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

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

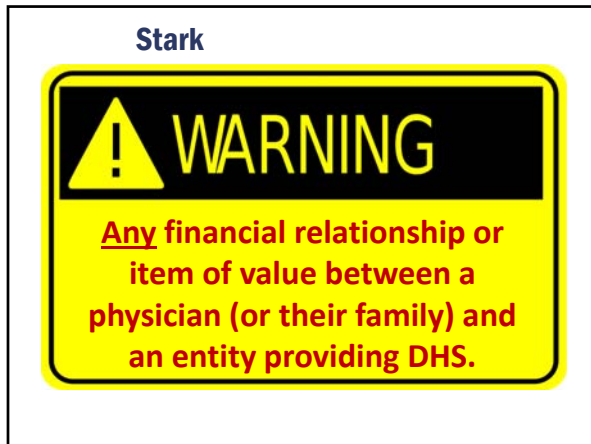
(42 CFR 411.353, 1001.102(a)(5), and 1001.103(b))

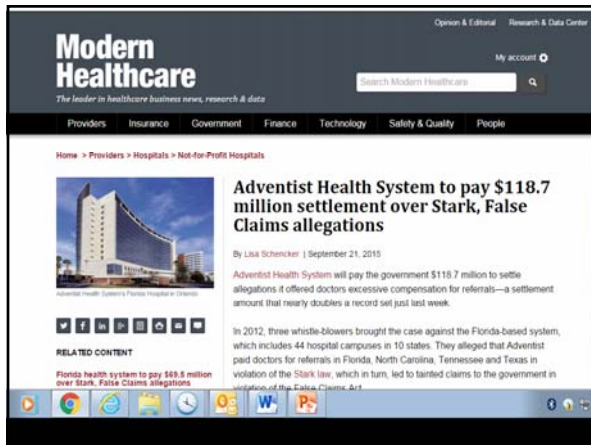
- May also constitute Anti-Kickback Statute violation
- May trigger False Claims Act.

Stark

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

(42 CFR 411.353(c)(1))







Stark

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 because they usually do not make “referrals”.

(42 CFR 411.351)

Stark

- Applies to referrals for designated health services (“DHS”) payable in whole or part by Medicare.
 - Inpatient and outpatient hospital services
 - Outpatient prescription drugs
 - Clinical laboratory services
 - Physical, occupational, or speech therapy
 - Home health services
 - Radiology and certain imaging services
 - Radiation therapy and supplies
 - Durable medical equipment and supplies
 - Parenteral and enteral nutrients, equipment, and supplies
 - Prosthetics and orthotics
- CMS website lists some of the affected CPT codes.
(42 CFR 411.351)

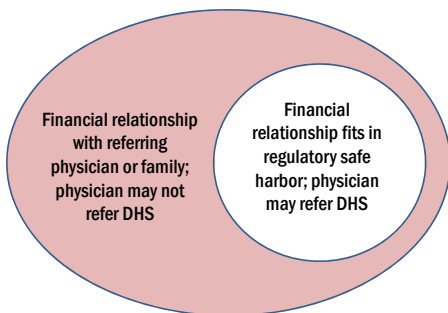
Stark

- 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 Analysis

Either:

- No financial relation with referring physician or family,
- or
- Physician does not refer DHS



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

Stark: Changes/Clarification

- “Writing” may be shown by series of documents, e.g., board minutes, e-mails, letters, invoices, time sheets, fee schedules, etc.
 - Test: do documents confirm compliance with Stark rules?
- Holdovers do not violate Stark so long as:
 - Original agreement satisfied Stark, and
 - Holdover on same terms.
- Have 90 days to obtain required signatures.
- Contracts comply with one year requirement if they remain in effect for one year regardless of terms.
- Arrangement whereby facility bills technical fee and physician bills pro fee do not constitute “remuneration”. (80 FR 71300 et seq.)

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?

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

The screenshot shows the CMS.gov website for Physician Self Referral. The left sidebar contains links for Advisory opinions, FAQs, DHS by CPT code, Self-Referral Disclosure Protocol, and Recent settlements. The main content area features a navigation menu with categories like Medicare, Medicaid, and Physician Self Referral. The 'Physician Self Referral' section is highlighted, with a sub-section for 'Physician Self Referral' containing a definition and a list of designated health services (DHS) such as Clinical laboratory services, Physical therapy services, and Occupational therapy services.

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

The illustration depicts a hand holding a stack of US dollar bills. The hand is positioned directly above a circular saw blade, which is shown in a cross-section view, suggesting the 'cutting' of costs or the enforcement of penalties. This visual metaphor represents the financial impact of the Civil Monetary Penalties Law.

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(f); 42 CFR 1003.101)

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)

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”).



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.

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.

Applying the Rules...





Free or Discounted Items or Services to Patients

For example:

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



Freebies to Patients

- Idaho Anti-Kickback Statute, if induce insured patient
- CMPL, if induce govt beneficiary
- AKS, if induce govt beneficiary
- Stark, if to physician or family who refers DHS
- IRS, if to employees and not part of benefit plan

Freebies to Patients

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

- Remuneration is not likely to influence the beneficiary to order or receive items or services payable by federal or state health care program.
(42 USC 1320a-7a(5))
- Item or service is of low value, i.e.,
 - Each item or service is less than \$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)

Freebies to Patients

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

- Financial need
 - Good faith determination that beneficiary has financial need or after reasonable collection efforts have failed;
 - Not offered as part of any advertisement or solicitation;
 - Not tied to provision of other federal program business; and
 - Reasonable connection between item or service and medical care of beneficiary.
(42 CFR 1320a-7a(i); 42 CFR 1003.101; see also OIG Bulletin, *Hospital Discounts Offered to Patients Who Cannot Afford to Pay Their Hospital Bills*)

Freebies to Patients

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

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

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



Free Tests or Screening

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

(Adv. Op. 09-11)

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

Free Transportation



- OIG has approved free transport if:
 - Program open to all eligible patients; not selectively limited to targeted beneficiary populations.
 - Type of transportation is reasonable (i.e., no limousine).
 - Travel is local to physicians' offices.
 - Public transportation and parking is limited.
 - Cost of program would not be claimed on cost report or shifted to a federal program.

(Adv. Op. 11-02; see also OIG Bulletin, *Gifts to Beneficiaries*)

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

Waiving Copays or Deductibles



What's the big deal?

- Medicare typically pays 80% of reasonable charge, which is based on provider's customary and actual charges. "A provider ... who routinely waives Medicare copayments or deductibles is misstating its actual charges..."
 - "[I]f patients are required to pay [a] portion of their care, they will be better health care consumers, and select items or services because they are medically needed, rather than simply because they are free. Ultimately, if Medicare pays more for an item or service than it should, or if it pays for unnecessary items or services, there are less Medicare funds available to pay for truly needed services."
- (OIG Fraud Alert, *Routine Waiver of Copayments or Deductibles*)
- Same considerations apply to private insurers.

Waiving Copays or Deductibles



- Private insurance contracts
- Idaho Anti-Kickback Statute, if "regular practice" of waiving deductibles or to induce referrals
- CMPL, if induce govt beneficiary
- AKS, if induce govt beneficiary
- Stark, if to physician or family who refers DHS
- IRS, if to employees and not part of benefit plan

Waiving Copays or Deductibles

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

- Not offered as part of any advertisement or solicitation;
 - Do not routinely waive copays or deductibles; and
 - Waive or discount after
 - good faith determination that the beneficiary is in financial need, or
 - unable to collect after reasonable collection efforts.
- (42 USC 1320a-7a(f)(6); 42 CFR 1003.101; *see also* Adv. Op. 12-16)
- Document factors such as local cost of living; patient's income, assets and expenses; patient's family size; scope and extent of bills.

Waiving Copays or Deductibles

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

- Hospital inpatient stay paid under PPS.
 - Waived amounts cannot be claimed as bad debt or shifted to any other payers.
 - Offered without regard to the reason for admission, length of stay, or DRG.
 - Waiver may not be made as part of any agreement with third party payer with limited exceptions.
- FQHC or other health care facility under any Public Health Services Grant.
(42 CFR 1001.952(k))

Writing Off Bills



- Writing off entire debt safer than waiving copays.
 - No one gets billed.
- Beware:
 - AKS, Idaho AKS, and CMPL if intend to induce referrals
 - Stark, if referring physician or family member
 - IRS, if employee

Writing Off Bills

- The key: document legitimate purpose, i.e., not intent to generate referrals!
 - Resolution of legitimate dispute or settlement of claim.
 - Unsuccessful attempts to collect.
 - Financial need.
 - Other



Writing Off Bills

- Under CMPL, may waive or discount beneficiary's bills if:
 - Good faith determination that beneficiary has financial need or after reasonable collection efforts have failed;
 - Not offered as part of any advertisement or solicitation;
 - Not tied to provision of other federal program business; and
 - Reasonable connection between item or service and medical care of beneficiary.

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

Writing Off Bills

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

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

Prompt Pay Discounts



- Discounted items or services =
 - Remuneration.
 - May induce patient to receive future services.
- Beware:
 - AKS, Idaho AKS, and CMPL if induce referrals.
 - Idaho AKS, if regularly waive deductibles.
 - Private payor contracts
 - Stark, if offered to referring physicians or family members.

Prompt Pay Discounts

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

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

Prompt Pay Discounts

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

Self-Pay Discounts



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

Medicare “Substantially in Excess” Rule

- Provider may not charge Medicare “substantially in excess” of the provider’s usual charges.
(42 USC 1320a-7(b)(6); 42 CFR 1001.701(a)(1)).
 - Test: whether the provider charges more than half of its non-Medicare/Medicaid patients a rate that is lower than the rate it charges Medicare.
 - OIG has stated that it would not use the rule to exclude or attempt to exclude any provider or supplier that provides discounts or free services to uninsured or underinsured patients.

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



Paying Patient’s Insurance Premiums

Beware

- AKS, Idaho AKS, and CMPL, if induce patients to receive services
- Stark, if paid for referring physicians or family members.
- Tax exempt status laws.
- Payer contracts.

Paying Patient’s Premiums

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

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

Paying Patient's Premiums

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

Paying Patient's Premiums

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

Gifts or Perks to Providers or Other Referral Sources



**Gifts or Perks to Providers
or Other Referral Sources**

E.g., soliciting, giving or receiving:

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




**Gifts or Perks to
Referring Providers**

- Idaho AKS, if induce referrals
- CMPL, if induce reduction in services
- AKS, if induce govt beneficiary
 - Best if structure to fit safe harbor
- Stark, if to physician or family who refers DHS
 - Must structure to fit safe harbor
- IRS, if to employees and not part of benefit plan

Gifts or Perks to Providers

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




Professional Courtesy

- Stark safe harbor applies if:
 - Practice has formal medical staff.
 - Written policy approved in advance.
 - Offered to all physicians in service area regardless of referrals.
 - Not offered to govt beneficiaries unless showing of financial need.
 - Does not violate AKS.
(42 CFR 411.357(s); 72 FR 51064)
- *But beware AKS, Idaho AKS, and private payer contracts.*

Professional Courtesy

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

Gainsharing or Cost Saving Program



What's the big deal?

- When govt changed to prospective payment system (DRGs),
 - Payment for hospital episode of care was capped despite costs involved in care.
 - Govt concerned that hospitals would create incentives to reduce costs by reducing or limiting services.
- Congress: “We must not tolerate hospitals paying physicians to reduce or limit services to the elderly.”
(OIG Bulletin, Gainsharing Arrangements)

Gainsharing Programs

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

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

Gainsharing Programs

- OIG has periodically approved gainsharing in advisory opinions if certain safeguards included, e.g.,
 - Proposed plan does not adversely affect patient care.
 - Quality evaluated by third party.
 - Low risk that incentive will lead physicians to provide medically inappropriate care.
 - Payments limited in duration and amount.
 - Payments not tied to referrals or other suspect actions.
- (See, e.g., Adv. Op. 12-22)
- OIG advisory opinions do not apply to Stark.
 - CMS proposed Stark exception, but was not finalized.
- CMS/OIG have issued interim rule waiving CMPL and Stark for ACOs.

Repay Overpayments
(18 USC 1347; 42 CFR 401.301 et seq.)



Repaying Overpayments

- If provider has received an “overpayment”, provider must:
 - Return the overpayment to federal agency, state, intermediary, or carrier, and
 - Notify the entity of the reason for the overpayment.
 - Must report and repay within the later of:
 - 60 days after overpayment is identified, or
 - date corresponding cost report is due.
- (42 USC 1320a-7k(d); 42 CFR 401.305)
- No “finders keepers”
 - Separate rules for Medicare Parts A and B, C and D, Medicaid

Overpayments: Penalty

- “Knowing” failure to report and repay by deadline =
 - False Claims Act violation
 - \$5,500 to \$11,000 per violation
 - 3x damages
 - Qui tam lawsuit
(31 USC 3729)
 - Civil Monetary Penalty Law violation
 - \$10,000 penalty
 - 3x damages
 - Exclusion from Medicare or Medicaid
(42 USC 1320a-7a(a)(10))



Overpayments

- “Overpayment” = funds a person receives or retains to which the person, after applicable reconciliation, is not entitled, e.g.,
 - Payments for non-covered services
 - Payments in excess of the allowable amount
 - Errors and non-reimbursable expenses in cost reports
 - Duplicate payments
 - Receipt of Medicare payment when another payor is primary
 - Payments received in violation of:
 - Stark
 - Anti-Kickback Statute
 - Exclusion Statute

Repaying Overpayments

Condition of payment from govt program

- Requires repayment, e.g.,
 - Billing or claim requirements
 - Anti-Kickback Statute
 - Stark
 - Civil Monetary Penalties re excluded individuals

Condition of participation in govt program other regulation

- Does not necessarily require repayment, e.g.,
 - Conditions of Participation
 - Conditions of Coverage
 - Licensure requirements
 - HIPAA
 - EMTALA
 - OSHA

Overpayments: Identified

- Identify overpayment = person has or should have, through exercise of reasonable diligence, determined that they received overpayment.
 - Actual knowledge
 - Reckless disregard or intentional ignorance
- Have duty to investigate if receive info re potential overpayment, e.g.,
 - Significant and unexplained increase in Medicare revenue
 - Review of bills shows incorrect codes
 - Discover services rendered by unlicensed provider
 - Internal or external audit discloses overpayments
 - Discover AKS, Stark or CMPL violation
- “Reasonable diligence” =
 - Proactive monitoring
 - Reactive investigations

(81 FR 7659-61)



Overpayments: Deadline

- 60-day deadline begins to run when either:
 - Person completes reasonably diligent investigation which confirms:
 - Received overpayment, and
 - Quantified amount of overpayment.
 - If no investigation, the day the person received credible information that should have triggered reasonable investigation.
 - “Reasonable diligence” = timely, good faith investigation
 - At most 6 months to conclude diligence
 - 2 months to report and repay
 - Deadline suspended by:
 - OIG Self-Disclosure Protocol
 - CMS Stark Self-Referral Disclosure Protocol (“SRDP”)
 - Person requests extended repayment schedule
- (42 CFR 401.305(a); 81 FR 7661-63)

Overpayments: Reporting

- May either:
- Use Medicare contractor process for reporting overpayments, e.g.,
 - claims adjustment
 - credit balance
 - self-reported refund
 - Use OIG or CMS self-disclosure protocol that results in settlement.
- (42 CFR 401.305(d))

<https://med.noridianmedicare.com/web/jfb/topics/overpayment-recoupment>

Overpayment: Lookback Period

- Not required to self-report if identified overpayment more than 6 years of the date the overpayment was received.

(42 CFR 401.305(f))

Overpayment: Reporting

- Repayment per Repayment Rule does not resolve violations or penalties under other laws, e.g.,
 - Anti-Kickback Statute, Civil Monetary Penalties Law, or False Claims Act, which are resolved by OIG or DOJ.
 - Stark, which is resolved by CMS.
- If Medicare contractor believes repayment involves violation of federal law, contractor may report repayment to the OIG, CMS, or other federal agency.
 - Be careful how and what you disclose.
- May want to consider other disclosure protocols.
 - OIG Self-Disclosure Protocol
 - Stark Self-Referral Disclosure Protocol

Idaho Medicaid: Duty to Repay

- **Provider must repay overpayments or claims previously found to have been obtained contrary to statute, rule regulation or provider agreement.**
 - **Penalties**
 - Exclusion from state health programs, e.g., Medicaid
 - Civil penalty of up to \$1000 per violation
 - Referral to Medicaid fraud unit
- (IC 56-209h(6)(h))
- **Provider agreement requires providers to immediately repay overpayments.**

Idaho Medicaid: Duty to Repay

- Medicaid ostensibly requires immediate repayment.
 - Notice requires response within 15 days.
 - May have up to 60 days interest free.
- May enter repayment agreement, which is typically no longer than 12 months.

OIG Self-Disclosure Protocol



OIG SDP: Benefits

- Voluntary program
- Benefits
 - OIG may use reduced multiplier if fully disclose and cooperate.
 - 1.5x damages instead of 3x damages
 - Probably no corporate integrity agreement or permissive exclusion.
 - May preclude *qui tam* lawsuits.
 - Suspends repayment under Repayment Rule.

OIG SDP: Risks

- But be careful!



OIG SDP: Risks

- No guarantee that OIG will reduce penalties.
- Minimum penalties:
 - \$50,000 for Anti-Kickback Statute violation
 - \$10,000 for others
 - \$1.5x damages
- OIG may broaden investigation
- New matters discovered by OIG are outside protocol.
- Failure to fully disclose or cooperate may result in more penalties.
- OIG may report to other govt agencies.
- Participation is burdensome.
- Likely will waive of privilege.
- Info may become public.
- Tolls statute of limitations.

OIG SDP Settlements (2016)

Conduct	Settlement
Care center employed excluded individual.	\$162,171
Hospital paid physicians in excess of FMV for services not performed	\$79,167
Hospital paid submitted claims to Medicaid without preauthorization	\$196,013
Hospital received services by home health agency to induce referrals	\$1,923,993
Health care company employed two excluded individuals	\$359,388
Hospital submitted unsupported claims for home health services	\$3,757,615
Hospital submitted claims for services that were not provided as claimed	\$872,925
Physician group upcoded claimes	\$259,746
Physician group submitted claims for services that were not provided as claimed, used wrong CPT codes to increase reimbursement	\$422,741

OIG SDP: Application

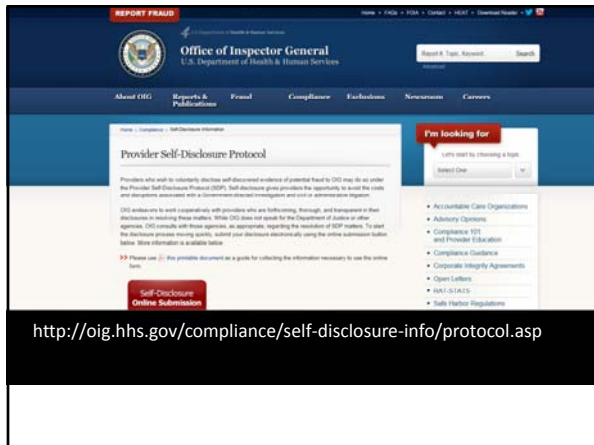
Applies to:

- Matters which, “in the disclosing party’s reasonable assessment, potentially violate Federal criminal, civil, or administrative laws for which CMPs are authorized”, e.g., anti-kickback violations, excluded entities, fraudulent claims, etc.

(SDP at 3-4)

Does not apply to:

- Matters that involve overpayments or errors.
- Stark violations.
- Requests for advisory opinions.



<http://oig.hhs.gov/compliance/self-disclosure-info/protocol.asp>

OIG Self-Disclosure Problem



If you think you have an
OIG compliance issue,

- Contact the compliance officer
- Consider contacting knowledgeable attorney

Stark Self-Referral Disclosure Protocol (OMB # 0938-1106)



Stark SRDP: Benefits

- Voluntary program
- Benefits
 - CMS may reduce penalties if fully disclose and cooperate.
 - May preclude *qui tam* lawsuits.
 - Suspends repayment under Proposed Repayment Rule.
 - Allows for some finality.

Reported SRDP Settlements

- Have limited information re SRDP settlements

Violation	Exposure	SRDP Settlement
Failed regulatory requirements applicable to service contracts with physicians	\$14,500,000*	\$579,000 Approximately 4% of potential exposure

* Based on news accounts

Reported SRDP Settlements

Conduct	Settlements
Exceeded annual total for non-monetary compensation exception	\$4500
	\$6700
	\$6800
Failed lease requirements	\$42,000
Failed employment requirements	\$74,000
Failed independent contractor requirements (e.g., expired contract)	\$22,000
	\$22,000
	\$59,000
	\$125,000
	\$130,000
	\$208,000

Stark SRDP: Risks

- No guarantee that CMS will reduce penalties.
- CMS may broaden investigation.
- Failure to fully disclose or cooperate may result in additional penalties.
- CMS may report to other govt agencies.
- Participation is fairly burdensome, but not as bad as OIG SDP.
- Reopening periods run from date of initial disclosure.
- Waiver of appeal rights concerning any overpayment.
- Likely will waive privileges.
- Info may become public.

Stark SRDP

Applies to:

- Confirmed Stark violations.
 - You are going to pay; only question is how much.




Does not apply to:

- Non-Stark violations, e.g., Anti-Kickback Statute, Civil Monetary Penalties Law
- Advisory opinions
 - CMS Advisory Opinion process at 42 CFR 411.370 et seq.
 - CMS Stark Frequently Asked Questions.



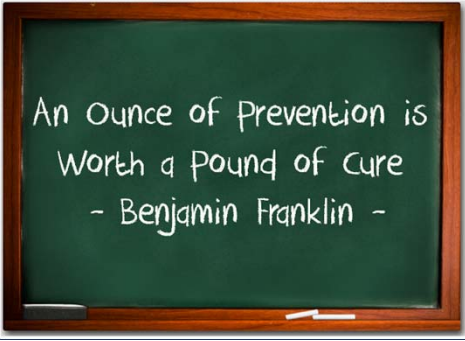
Stark SRDP



If you think you have a Stark problem,

- Contact compliance officer,
- Consider contacting knowledgeable attorney,
- Self-report, if appropriate.

Better to comply in the first place!





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 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**
- 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!

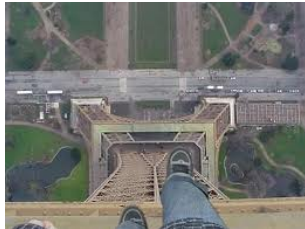


If you think you have a problem

- 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



