



HEALTHCARE FRAUD AND ABUSE:

APPLYING THE LAWS

Kim C. Stanger

(5-22)

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9/15/22	EMTALA
10/13/22	Nondiscrimination Rules
11/17/22	Creating, Managing, and Terminating Patient Relationships

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OVERVIEW



- Key Statutes
 - False Claims Act (“FCA”)
 - Anti-Kickback Statute (“AKS”)
 - Eliminating Kickbacks in Recovery Act (“EKRA”)
 - Ethics in Patient Referrals Act (“Stark”)
 - Civil Monetary Penalties Law (“CMPL”)
- Common Compliance Traps
- Report and Repayment Obligations

CAUTION

- This is a quick overview of the most relevant federal laws and regulations.
 - Beware other laws, including state laws
- Application may depend on—
 - Circumstances of your particular case
 - Payer involved (e.g., govt, insurer, patient)
 - Jurisdiction
- Be sure to confirm applicable laws and requirements when applying law to your facts.
- If you have questions,
 - Use chat feature, or
 - Email me at kcstanger@hollandhart.com


SUPPLEMENTAL RESOURCES

- .PPT slides
- *OIG, Avoiding Medicare and Medicaid Fraud and Abuse: A Roadmap for New Physicians*
<https://oig.hhs.gov/compliance/physician-education/>
- *OIG, OIG Supplemental Compliance Program Guidance for Hospitals*
<https://www.hhs.gov/guidance/document/oig-supplemental-compliance-program-guidance-hospitals>
- *OIG, OIG Compliance Program Guidance for Individuals and Small Physician Practices*
<https://oig.hhs.gov/documents/compliance-guidance/801/physician.pdf>
- *Stanger, Beware Laws Affecting Healthcare Transactions: <https://www.hollandhart.com/beware-laws-affecting-healthcare-transactions>*

SUPPLEMENTAL RESOURCES

- Stanger, *Patient Inducements: Gifts, Discounts, Waiving Co-Pays, Free Screening Exams, Etc.* <https://www.hollandhart.com/patient-inducements-gifts-discounts-waiving-co-pays-free-screening-exams-etc>
 - Stanger, *Fraud and Abuse in Private Payor Situations* <https://www.hollandhart.com/fraud-and-abuse-in-private-payor-situations>
 - Stanger, *Marketing Traps for Healthcare Providers* <https://www.hollandhart.com/marketing-traps-for-healthcare-providers>
 - Stanger, *Idaho Fraud and Abuse Statutes: Requirements, Penalties and Repayments* <https://www.hollandhart.com/idaho-fraud-and-abuse-statutes-requirements-penalties-and-repayments>
 - H&H, *CMS Issues Final Rule on Reporting and Returning Overpayments*, <https://www.hollandhart.com/CMS-Issues-Final-Rule-Overpayments>
- If you did not receive them, contact cecobbins@hollandhart.com.

KEY FRAUD AND ABUSE LAWS



**“I want my
money
back!”**

- False Claims Act
- Anti-Kickback Statute (“AKS”)
- Eliminating Kickbacks in Referrals Statute (“EKRA”)
- Ethics in Physician Referrals Act (“Stark”)
- Civil Monetary Penalties Law (“CMPL”)
- Healthcare criminal statutes





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FOR IMMEDIATE RELEASE

Tuesday, February 1, 2022

Justice Department's False Claims Act Settlements and Judgments Exceed \$5.6 Billion in Fiscal Year 2021

Second Largest Amount Recorded, Largest Since 2014

The Justice Department obtained more than \$5.6 billion in settlements and judgments from civil cases involving fraud and false claims against the government in the fiscal year ending Sept. 30, 2021, Acting Assistant Attorney General Brian M. Boynton of the Justice Department's Civil Division announced today. This is the second largest annual total in False Claims Act history, and the largest since 2014. Settlement and judgments since 1986, when Congress substantially strengthened the

FALSE CLAIMS ACT

- Cannot knowingly submit a false claim for payment to the federal govt, e.g.,
 - Not provided as claimed
 - Substandard care
 - Failure to comply with regulations
- Must report and repay an overpayment within the later of 60 days or date cost report is due.

(31 USC 3729; 42 USC 1320a-7a(a); 42 CFR 1003.200)

Penalties

- Repayment plus interest
- Civil monetary penalties of \$11,803* to \$23,607* per claim
- Admin penalty \$22,427* per claim failed to return
- 3x damages
- Exclusion from Medicare/Medicaid

(42 USC 1320a-7a(a); 42 CFR 1003.210; 45 CFR 102.3; 86 FR 70740)

➤ *Subject to qui tam claims*

FALSE CLAIMS ACT

Govt Priorities

- Pandemic-related payments
- Telehealth
- Cybersecurity
- Medical necessity
- Kickbacks and inducements

Methods

- OIG/DOJ analytics
- Qui tam whistleblowers
- Self-reports



ANTI-KICKBACK STATUTE

- Cannot knowingly and willfully offer, pay, solicit or receive remuneration to induce referrals for items or services covered by govt program unless transaction fits within a regulatory safe harbor.

(42 USC 1320a-7b(b); 42 CFR 1003.300(d))

- "One purpose" test
(*US v. Greber* (1985))

Penalties

- Felony
- 10 years in prison
- \$100,000 criminal fine
- \$112,131* civil penalty
- 3x damages
- Exclusion from Medicare/Medicaid

(42 USC 1320a-7b(b); 42 CFR 1003.310; 45 CFR 102.3)

➤ *Automatic False Claims Act violation*

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



ANTI-KICKBACK STATUTE

**Remuneration
+ Intent to induce
referrals for items
payable by federal
programs
AKS violation**

- ✓ **Safe Harbor, e.g.,**
 - **Employment**
 - **Personal services**
 - **Leases**
 - **Group practice**
 - **Others**
- ✓ **Advisory Opinion**



ANTI-KICKBACK STATUTE: SAFE HARBORS

- Bona fide employment
- Personal services contracts
- Leases for space or equipment
- Investments in group practice
- Investments in ASCs
- Sale of practice
- Recruitment
- Certain investment interests
- Waiver of beneficiary coinsurance and deductible amounts.
- Transportation programs
- OB malpractice insurance subsidies
- Electronic health record items or services
- Cybersecurity technology
- Warranties
- Discounts
- Value-based care arrangements
- Care coordination arrangements
- Patient engagement incentive

(42 CFR 1001.952)



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Advisory Opinions

In accordance with section 1128(D)(b) of the Social Security Act (42 U.S.C. 1320a-7d(b)) and 42 CFR part 1008, OIG issues advisory opinions about the application of OIG's fraud and abuse authorities to the requesting party's existing arrangement. As required, advisory opinions are being made available.

One purpose of the advisory opinions is to provide meaningful advice to the requesting party and other OIG sanctioned parties. Note, however, that advisory opinions should not be relied upon only as a guide to legal standards to which all parties are bound. Only the OIG's final advisory opinions are binding.

We have redacted information associated with the advisory opinions.

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Quick Links/F

- Preliminary
- Recommendation
- The full and current version of 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.
-  The OIG Interim Final Rule (73 Fed. Reg. 15927) revising the procedural aspects for submitting

Related

I'm looking for

Let's start by choosing a topic

Select One



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

**REPORT
FRAUD**

ELIMINATING KICKBACK IN RECOVERY ACT ("EKRA")

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

(18 USC 220(a))

Penalties

- \$200,000 criminal fine
- 10 years in prison

(18 USC 220(a))

- *Beware if you operate or deal with a lab.*
- *Applies to private or public payors.*

EKRA SAFE HARBORS

- Discount or other reduction in price under a health care benefit program
- Payment by employer to employee or independent contractor
- Discounts by drug manufacturer under Medicare coverage gap discount program
- Compensation that satisfies AKS personal services and management contract safe harbor
- Waiver or discount of copays
- Subsidies to health centers
- Remuneration under alternative payment models
- Any other payment, remuneration, discount, or reduction as determined by the Attorney General, in consultation with the Secretary of Health and Human Services, by regulation

(18 USC 220(b))

➤ *No implementing regulations yet...*

ETHICS IN PATIENT REFERRALS ACT ("STARK")

- If physician (or family member) has financial relationship with entity:
 - Physician may not refer patients to entity for designated health services ("DHS"), and
 - Entity may not bill Medicare or Medicaid for such DHS

unless arrangement fits within a regulatory exception (safe harbor).

(42 USC 1395nn; 42 CFR 411.353 and 1003.300)

Penalties

- No payment for services provided per improper referral.
- Repayment w/in 60 days.
- Civil penalties.
 - \$27,750* per claim
 - \$174,172* per scheme

(42 CFR 411.353, 1003.310; 45 CFR 102.3)

- *Likely False Claims Act violation*
- *Likely Anti-Kickback Statute violation*

STARK

- Applies to referrals by physician to entities with which the physician (or their family member) has financial relationship.
- Physician = as defined in 42 USC 1395x(r), i.e.,
 - 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 for designated health services (“DHS”) payable in whole or part by Medicare or Medicaid.
 - 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
- Check definitions to confirm scope and exceptions.
- CMS website lists some of the affected CPT codes, e.g., radiology.

(42 CFR 411.351)

**Financial arrangement
with physician or
family member
+ Referrals for DHS
Stark violation**

- ✓ **Safe Harbor, e.g.,**
 - **Employment**
 - **Personal services**
 - **Leases**
 - **Group practice**
 - **Others**
- ✓ **Advisory Opinion**

STARK SAFE HARBORS: OWNERSHIP

Ownership + Compensation Arrangements

- Physician services
- In-office ancillary services
- Prepaid health plans
- Academic medical centers
- Implants by an ASC
- EPO and dialysis drugs
- Preventive screening tests, immunizations and vaccines
- Eyeglasses and contact lenses following surgery

(42 CFR 411.355)

Ownership Arrangements

- Publicly traded securities
- Mutual funds
- Rural providers
- Whole hospital
- Publicly traded securities
- Intra-family rural referrals
- Others

(42 CFR 411.356)

➤ *Must satisfy all the requirements to receive safe harbor protection*

STARK SAFE HARBORS COMPENSATION

Compensation

- Employment
- Personal services contracts
- Remuneration to physician < \$5000 per year
- Fair market value
- Space or equipment leases
- Timeshare arrangements
- Recruitment and retention
- Non-monetary compensation up to \$429
- Medical staff incidental benefits
- Professional courtesy
- OB malpractice subsidies
- Isolated transactions
- Payments by a physician
- Charitable donations by a physician
- Compliance training
- Indirect compensation arrangements
- Referral services
- Health information technology and support
- Cybersecurity technology
- Valued based compensation arrangements

(42 CFR 411.357)

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Physician Self Referral

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Physician Self Referral

Section 1877 of the Social Security Act (the Act) (42 U.S.C. 1395nn), also known as the physician self-referral law and commonly referred to as the "Stark Law":

1. Prohibits a physician from making referrals for certain designated health services (DHS) to an entity with which he or she (or an immediate family member) has a financial relationship (investment, or compensation), unless an exception applies.
2. Prohibits the entity from presenting or causing to be presented claims to Medicare (or billable individual, entity, or third party payer) for those referred services.
3. Establishes a number of specific exceptions and grants the Secretary the authority to create additional exceptions for financial relationships that do not pose a risk of program or patient abuse.

The following items or services are DHS:

1. Clinical laboratory services.
2. Physical therapy services.
3. Occupational therapy services.
4. Outpatient speech-language pathology services.
5. Radiology and certain other imaging services.
6. Radiation therapy services and supplies.
7. Durable medical equipment and supplies.
8. Parenteral and enteral nutrients, equipment, and supplies.

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

CIVIL MONETARY PENALTIES LAW

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

- Prohibits offering remuneration to a Medicare/Medicaid beneficiary if know or should know that it is likely to influence such beneficiary to order or receive services from a particular provider or supplier.

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

Penalties

- \$22,427* per violation.
- Exclusion from Medicare and Medicaid

(42 CFR 1003.1010(a); 45 CFR 102.3)

➤ *Likely also an Anti-Kickback Statute violation*

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; and
 - 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:
 - Waivers or co-pays based on financial need or after failed collection efforts if certain conditions met.
 - Items or services if financial need and certain conditions met.
 - Incentives to promote delivery of preventative care if certain conditions met.
 - Payments meeting Anti-Kickback Statute safe harbor.
 - Retailer coupons, rebates or rewards offered to public.
 - Any other remuneration that promotes access to care and poses a low risk of harm to patients and federal health care programs.
 - Certain other situations.

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

CIVIL MONETARY PENALTIES LAW

- 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.

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

Penalties

- \$5,606* per violation.
- Exclusion from Medicare and Medicaid

(42 CFR 1003.1010(a); 45 CFR 102.3)

➤ *Beware gainsharing arrangements.*

CIVIL MONETARY PENALTIES LAW

- Excluded person cannot order or prescribe items payable by federal healthcare program.
- Cannot submit claim for item ordered or furnished by an excluded person.
- Excluded owners cannot retain ownership interest in entity that participates in Medicare.
- Cannot hire or contract with excluded entity to provide items payable by federal programs.

(42 USC 1320a-7a(a)(8); 42 CFR 1003.200(a)(3), (b)(3)-(6))

Penalties

- \$22,427* per item or service ordered.
- 3x amount claimed.
- Repayment of amounts paid.
- Exclusion from Medicare and Medicaid

(42 USC 1320a-7a(a)(8); 42 CFR 1003.210; 45 CFR 102.3; OIG Bulletin, *Effect of Exclusion*)





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LEIE Downloadable Databases

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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

Current Record Layout

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Let's start by choosing a topic

Select One

Check the
LEIE on
regular basis!

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



OTHER STATUTES

- Health Care Fraud, 18 USC 1347
- False Statements Relating to Health Care Matters, 18 USC 1035
- Mail and Wire Fraud, 18 USC 1341 and 1343
- Theft or Embezzlement in Connection with Health Care, 18 USC 669
- Racketeer Influenced and Corrupt Organizations Act (“RICO”), 18 USC 1961-1968
- Travel Act, 18 USC 1952
- Others?

(See OIG Compliance Program for Individual and Small Group Physician Practices, 65 FR 49448 et seq.)



PRIVATE PAYORS

Statutes

- Federal
 - Healthcare fraud
 - EKRA
 - Travel Act
- State statutes
 - Anti-kickbacks
 - Self-referrals
 - Fee-splitting
 - Insurance fraud
 - Consumer protection
- Others?

Private lawsuit

- Breach of contract
 - Conditions of payment
 - Repayment
- Common law fraud or misrepresentation
- Unjust enrichment
- Restitution
- Interference with contract
- Others?

APPLYING THE LAWS TO COMMON SITUATIONS



- Relationships with referral sources, e.g.,
 - Patients
 - Referring providers

FREE OR DISCOUNTED ITEMS OR SERVICES TO PATIENTS

- Gifts to patients (e.g., gift basket, gift card, basket of products for new mothers, etc.)
 - “Refer a friend” incentive
 - Free exam or service
 - Free equipment, supplies or drugs
 - Free meals
 - Free transportation
 - Parking reimbursement
 - Waiver of copay or deductible
 - Write offs
 - “Refer a friend” incentive
 - Paying premiums
 - Anything else of value that does not reflect fair market value (“FMV”)
- Potential violations of
- Anti-Kickback Statute
 - Civil Monetary Penalties Law
 - State Laws
 - Others?



FREE OR DISCOUNTED ITEMS OR SERVICES 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(a)(5))

- Item or service is of low value, i.e.,
 - Each item or service is less than \$15, and
 - Aggregate is less than \$75 per patient per year.

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

FREE OR DISCOUNTED ITEMS OR SERVICES 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 1003.110; see also OIG Bulletin, Hospital Discounts Offered to Patients Who Cannot Afford to Pay Their Hospital Bills)

FREE OR DISCOUNTED ITEMS OR SERVICES TO PATIENTS

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

- Fit within Anti-Kickback Statute safe harbor.
- Promotes delivery of preventative care, i.e.,
 - Pre-natal or post-natal well-baby service, or listed in *Guide to Clinical Preventive Services*;
 - No cash or instruments convertible to cash; and
 - Not tied to other Medicare services.
- Promotes access to items or services payable by Medicare and Medicaid and does not:
 - Interfere with clinical decision making;
 - Increase costs to federal program or beneficiary; or
 - Raise patient care concerns.
- Certain other situations.

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

FREE TESTS OR SCREENING

- OIG has approved free screening services (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 on follow-up services; and
 - If test shows abnormal results, visitor is advised to see his or her own health care professional.

(Adv. Op. 09-11, but note that *Advisory Opinions are not binding*)

- Some services may fit within CMPL exception for:
 - Certain preventative services.
 - Services that promote care and pose low risk of fraud or abuse.
- Independent foundation or entity may be able to provide such services but be careful.

FREE TRANSPORTATION

Local Transportation

- Set forth in policy applied uniformly
- Not determined based on volume or value of referrals
- Not air, luxury, or ambulance-level transport
- Not publicly marketed or advertised
- Drivers not paid per beneficiary
- Only for established patients within 25 miles or, in rural area, 75 miles
- Costs not shifted to payors or individuals

Shuttle on Set Schedule

- Not air, luxury, or ambulance-level transport
- Not publicly marketed or advertised
- Drivers not paid per beneficiary
- Only within provider's local area, i.e., within 25 miles or, in rural area, 75 miles
- Costs not shifted to payors or individuals

(42 CFR 1001.952(bb))

WAIVING COPAYS OR DEDUCTIBLES

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

- Good faith determination that beneficiary is in financial need or you are unable to collect after reasonable collection efforts.
- Not offered as part of any advertisement or solicitation; and
- Not offered routinely.

(42 USC 1320a-7a(i)(6); 42 CFR 1003.110; IC 41-348; *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; etc.

WAIVING COPAYS OR DEDUCTIBLES

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

- Hospital inpatient stay paid under PPS, and
 - Waived amounts cannot be claimed as bad debt or shifted to any other payors;
 - Offered without regard to the reason for admission, length of stay, or DRG; and
 - Waiver may not be made as part of any agreement with third party payor with limited exceptions.
- FQHC or other health care facility under any Public Health Services Grant.
- Pharmacy if certain conditions satisfied.
- Ambulance service if certain conditions satisfied.

(42 CFR 1001.952(k))

WAIVING COPAYS OR DEDUCTIBLES

Beware waiving copays and deductibles required by **private payors**.

- Likely violates private payor contracts.
 - Breach of contract
 - Maybe insurance fraud
 - May violate Idaho Anti-Kickback Statute if offered routinely. (IC 41-348)
- *Check your payor contract or contact your private payors.*

WRITING OFF ENTIRE BILL

- Writing off entire bill for service is safer than waiving copays.
 - No payor is billed so payor is happy.
 - Not an inducement for services related to the bill.
- Document legitimate purpose, i.e., not intended to generate referrals, e.g.,
 - Unable to properly bill, e.g., not medically necessary, substandard care, no documentation, failure to satisfy conditions for payment.
 - Resolution of legitimate dispute or claim.
 - Financial need or unsuccessful attempts to collect.
(See 42 CFR 1320a-7a(i); 42 CFR 1003.110; 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; and
 - Document determination of financial need.

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

PROFESSIONAL COURTESY

- Beware professional courtesies to **govt beneficiaries**.
 - No AKS or CMPL safe harbor.
 - Consider whether intent is to induce referrals.
 - \$15/\$75 aggregate may apply.
 - Don't waive copays or deductibles.
- Stark contains safe harbor for courtesies to physicians or their family members 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)

FREE OR DISCOUNTED ITEMS TO EMPLOYEES

- Beware waiving copays or other cost-sharing amounts if adversely affects payors.
 - 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 ensure compliance with ERISA or similar laws.

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 payors of program.
 - Costs not passed to Medicare, Medicaid or other payors.

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

PROMPT PAY DISCOUNTS

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

SELF-PAY DISCOUNTS

- In most states, providers may generally charge different patients or payors different amounts.
 - Payment is a matter of contract between provider and patient or payor.
 - Negotiated rates for payors.
 - Negotiated rates or discounts for self-pay patients.
- But beware limitations....

SELF-PAY DISCOUNTS

Limits on ability to offer self-pay discounts:

- Some states limit ability to charge different rates.
 - Charging insurers more than self-pay patients.
 - Charging self-pay patients more than insurers.
- Maybe facilities that submit cost reports.
 - See Provider Reimbursement Manual 15.1 at § 2203 (charge structure should be “applied uniformly”).
 - Check with entity that prepares cost reports.
- FQHCs.
 - See MLN, *Federally Qualified Health Centers*, ICN 006397 (1/18) (“Charges must be uniform for all patients”).
- In some states, payor 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

- OIG may exclude provider who charges 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.
 - Presumably applies to specific charge or service.
- 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>)

CASH INSTEAD OF BILLING PAYORS

- Medicare, maybe Medicaid, and private payors generally prohibit billing patients for covered services except for copays or deductibles.

But...

- HITECH Act prohibits provider from using or disclosing PHI if the patient (or other person) pays for the episode of care and instructs provider not to submit to payor unless law requires disclosure.

(42 CFR 164.522(a)(1)(vi))

- Exception to Medicare payment rule.
- Overrules contrary payer contract language.
- Does not apply where state law requires the disclosure, e.g., Medicaid or private payers.

(78 FR 5628)

REMUNERATION TO/FROM REFERRING PROVIDERS

■ Contracts

- Employment
- Services agreements
- Ownership interests
- Group compensation
- Leases
- Recruitment
- Joint Ventures

■ Free or discounted items

- Gifts
- Space, equipment, support
- Professional courtesies
- Incidental benefits
- Insurance
- Over/under payments
- Others?



Beware!

- ✓ Stark
- ✓ Anti-Kickback Statute
- ✓ CMPL
- ✓ EKRA
- ✓ State laws
 - ✓ Mini-Stark laws
 - ✓ AKS
 - ✓ Fee splitting
 - ✓ Others?

PHYSICIANS OR THEIR FAMILY MEMBERS

Stark Safe Harbors

- Employment
- Independent contractor
- Compensation < \$5000
- Group practice compensation
- Recruitment
- Leases
- Ownership
- Non-monetary compensation up to \$429
- Medical staff incidental benefits
- Professional courtesy
- EHR support
- Isolated transactions
- Value-based care
- Others

(42 CFR 411.355-.357)

Anti-Kickback Statute Safe Harbors

- Employment
- Independent contractor
- Group practice
- Recruitment
- Leases
- Sale of practice
- Investments in other entities
- EHR support
- Others

(42 CFR 1001.952)

- One purpose to induce referrals?
- Favorable advisory opinion?



NON-PHYSICIAN PROVIDERS

Stark does not apply to providers who are not:

- MDs
- DOs
- Oral surgeons
- Dentists
- Podiatrists
- Optometrists
- Chiropractors

➤ *Beware state laws*

Anti-Kickback Statute

- Employment
- Independent contractor
- Group practice
- Recruitment
- Leases
- Sale of practice
- Investments in other entities
- EHR support
- Others

(42 CFR 1001.952)

EMPLOYMENT CONTRACTS

- AKS: generally does not apply to bona fide employment relationships
- Stark: employment agreement with physicians or their family members:
 - Identifiable services
 - Fair market value
 - Not based on the volume or value of referrals
 - Not based on referrals for ancillary services or services performed by others
 - May pay based on services the provider personally performs
 - Commercially reasonable

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

INDEPENDENT CONTRACTOR ARRANGEMENTS

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

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

GROUP PRACTICES

- To rely on Stark safe harbors, must qualify as a “group practice”:
 - Operate as single legal entity.
 - Must have at least 2 physicians who are members.
 - At least 75% of patient services furnished by and billed through group.
 - Overhead expenses and income distributed per method that is determined before receipt of payment for services.
 - Unified business with centralized management and consolidated billing, accounting and financial reporting.
 - Members of the group conduct at least 75% of the physician-patient encounters.
 - Compensation cannot vary directly based on referrals.

(42 CFR 411.352)

GROUP PRACTICES

Productivity bonuses

- May pay group physician based on:
 - Services physician personally performed, and/or
 - “Incident to” services.
- Productivity formula deemed not to be based on referrals if:
 - Bonus is based on total patient encounters or RVUs.
 - Bonus based on allocation of compensation attributable to services that are not DHS payable by fed program or private payer.
 - Revenues from DHS < 5% of group’s total revenues, and allocated portion of DHS revenues < 5% of physician’s total compensation.

(42 CFR 411.352(i))

GROUP PRACTICES

Share of Profits

- May pay group physician based on share of overall profits from DHS of group or component of at least 5 physicians ("Rule of 5"), provided that share is not determined in a manner that directly relates to volume or value of DHS by the physician.
- Share of profits deemed not to be based on referrals if:
 - Profits divided per capita.
 - Revenues from DHS distributed based on distribution of revenues from services that are not DHS payable by fed program or private payer.
 - Revenues from DHS < 5% of group's total revenues, and allocated portion of DHS revenues < 5% of physician's total compensation.

(42 CFR 411.352(i))

OWNERSHIP INTERESTS

Stark safe harbors

- Group practice if satisfy definition of “group practice” and fit within:
 - In-office ancillary services safe harbor, or
 - Physician services safe harbor.
- Ownership interest in a whole hospital if certain conditions met.
- Ownership of a rural provider, i.e., furnishes not less than 75% of DHS to residents of a rural area.

(42 CFR 411.355 and .356)

Anti-kickback safe harbors

- Small investment
- Group practice
 - Must qualify as a “group practice” under Stark
- If fail to qualify for AKS safe harbor, consider:
 - Advisory opinions
 - Risk of Medicare/Medicaid fraud and abuse
 - Factors to minimize exposure
 - Prohibit Medicare/Medicaid referrals.



REMEMBER OTHER SAFE HARBORS

Stark Safe Harbors

- Compensation < \$5000
- Recruitment
- Leases
- Ownership
- Non-monetary compensation up to \$429
- Medical staff incidental benefits
- Professional courtesy
- EHR support
- Isolated transactions
- Value-based care
- Others

(42 CFR 411.355-.357)

Anti-Kickback Statute Safe Harbors

- Recruitment
- Leases
- Sale of practice
- Investments in other entities
- EHR support
- Others

(42 CFR 1001.952)

- One purpose to induce referrals?
- Favorable advisory opinion?

REPAYING OVERPAYMENTS



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.
 - date corresponding cost report is due.

(42 USC 1320a-7k(d); 42 CFR 401.305).

OVERPAYMENTS: PENALTY

- “Knowing” failure to report and repay by deadline =
 - False Claims Act violation
 - \$11,803* to \$23,607* per violation
 - *Qui tam* lawsuit(31 USC 3729)
 - Civil Monetary Penalty Law violation
 - \$22,427* 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, etc.
- 6-year lookback period.
(42 CFR 401.305(f))

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))

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.

OVERPAYMENT: REPORTING

May want to consider other disclosure protocols.

- OIG Self-Disclosure Protocol, <https://oig.hhs.gov/compliance/self-disclosure-info/index.asp>
- Stark Self-Referral Disclosure Protocol, https://www.cms.gov/medicare/fraud-and-abuse/physiciansselfreferral/self_referral_disclosure_protocol.html

ACTION ITEMS



CHECK YOUR RELATIONSHIPS

With patients

- Billing policies
 - Waiving copays
 - Write offs
 - Prompt pay or self-pay discounts
 - Free or discounted items
- Marketing /advertising
 - Thank you gifts
 - Loss leaders
 - Free screening programs
 - “Refer a friend” programs
 - Others?

With referral sources

- Contracts and leases
 - Fair market value
 - Compensation not based on referrals
 - Services actually provided
- Visiting specialists
- Overpayments or payment for items not provided
- Gainsharing
- Joint ventures
- Practice support
- Professional courtesies
- Others?



REVIEW AND UPDATE COMPLIANCE PLAN

- Ensure it has required elements
 - Policies, procedures and standards of conduct
 - Designated compliance officer and committee
 - Conduct effective training and education
 - Develop effective lines of communication, e.g., complaint hotline
 - Conduct internal monitoring and auditing
 - Enforce through publicized disciplinary guidelines
 - Respond promptly to offenses and implement corrective action.

See OIG Supplemental Compliance Program Guidance for Hospitals, 70 FR 4858, available at <https://oig.hhs.gov/fraud/docs/complianceguidance/012705HospSupplementalGuidance.pdf>



TRAIN KEY PERSONNEL

- Include following people:
 - Administration.
 - Compliance officers and committees.
 - Human resources.
 - Physician relations and medical staff officers.
 - Marketing / public relations.
 - Governing board members.
 - Purchasing.
 - Accounts payable.
- Document training.
- Review and repeat.

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 repay per applicable law.
 - Self-disclosure program.
 - To OIG, if there was knowing violation of FCA, AKS, or CMPL.
 - To CMS, if there was violation of Stark.

ADDITIONAL RESOURCES



HTTPS://OIG.HHS.GOV/COMPLIANCE/

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

An official website of the United States government [Here's how you know](#)



U.S. Department of Health and Human Services
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Compliance

To help healthcare providers such as hospitals and physicians comply with relevant Federal health care laws and regulations, OIG creates compliance resources, which are often tailored to particular providers.

OIG's compliance documents include special fraud alerts, advisory bulletins, podcasts, videos, brochures, and papers providing guidance on compliance with Federal health care program standards. OIG also issues advisory opinions, which cover the application of the Federal anti-kickback statute and OIG's other fraud and abuse authorities to the requesting party's existing or proposed business arrangement.

[HTTPS://OIG.HHS.GOV/COMPLIANCE/COMPLIANCE-GUIDANCE/](https://oig.hhs.gov/compliance/compliance-guidance/)

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Compliance Guidance

OIG has developed a series of voluntary compliance program guidance documents directed at various segments of the health care industry, such as hospitals, nursing homes, third-party billers, and durable medical equipment suppliers, to encourage the development and use of internal controls to monitor adherence to applicable statutes, regulations, and program requirements.

The compliance program guidance documents are listed below.

09-30-2008

- [Supplemental Compliance Program Guidance for Nursing](#)

Related

[Compliance Resources for Health Care Boards](#)

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Kim Stanger
Partner
Boise



Blaine Benard
Partner
Salt Lake City



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The Healthcare Industry is poised to continue its rapid evolution. With this sector now making up close to 20 percent of GDP, our lawyers stand ready to help as changes unfold.

Issues such as rising healthcare costs, healthcare reform, data and privacy security, and innovations in healthcare delivery, device and pharmaceutical designs are forefront in the minds of many of our clients. We are here to guide our clients through the challenges and opportunities that arise in this dynamic industry.

Clients We Serve

- Hospitals
- Individual medical providers
- Medical groups
- Managed care organizations (MCOs)
- Third-party administrators (TPAs)
- Health information exchanges (HIEs)
- Administrators and facilities
- Independent practice associations (IPAs)
- Owners of healthcare assets
- Imaging centers
- Ambulatory surgery centers



QUESTIONS?

Kim C. Stanger
Holland & Hart LLP
Office: (208) 383-3913
Cell: (208) 409-7907
kcstanger@hollandhart.com