



Healthcare Fraud and Abuse: Applying The Laws

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Health Law Webinar Series

Date	Webinar
3/2/23	Fraud and Abuse I: The Laws
3/16/23	Fraud and Abuse II: Applying the Laws
3/30/23	Fraud and Abuse III: Responding to Noncompliance
4/13/23	Telehealth
4/27/23	EMTALA
5/11/23	Reproductive Rights
5/25/23	Nondiscrimination Rules
6/1/23	HIPAA and Patient Privacy

<https://www.hollandhart.com/events>

Supplemental Resources

- .PPT slides
- OIG, *Avoiding Medicare and Medicaid Fraud and Abuse: A Roadmap for New Physician*,
<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>

Supplemental Resources

- Stanger, *Beware Laws Affecting Healthcare Transactions*, <https://www.hollandhart.com/beware-laws-affecting-healthcare-transactions>
- 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, *Gifts to Patients and Referring Providers*, <https://www.hollandhart.com/gifts-to-patients-and-referring-providers>
- Stanger, *Stark Requirements for Physician Contracts*, <https://www.hollandhart.com/stark-requirements-for-physician-contracts>
- Stanger, *Paying Employees for Referring Healthcare Business*, <https://www.hollandhart.com/paying-employees-for-referring-healthcare-business>
- Stanger, *Directed Referrals: New Stark Rules*, <https://www.hollandhart.com/directed-referrals-new-stark-rules>

Supplemental Resources

- Stanger, *Common Stark Concerns for Hospitals*,
<https://www.hollandhart.com/common-stark-concerns-for-hospitals>
 - Stanger, *Group Compensation Arrangements: Stark Requirements*,
<https://www.hollandhart.com/group-compensation-arrangements-stark-requirements>
 - Stanger, *Stark Requirements for Physician Leases*,
<https://www.hollandhart.com/stark-requirements-for-physician-leases>
 - 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>
- See more at <https://www.hhhealthlawblog.com/>

Caution

- This is a quick overview of the most relevant federal laws and regulations and application to common situations.
 - 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

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
- State laws and regulations

False Claims Act ("FCA")

- Cannot knowingly submit a false claim for payment to the federal govt, e.g.,
 - Not provided as claimed
 - Substandard care
 - Failure to comply with applicable 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)
- Potential *qui tam* lawsuits

Anti-Kickback Statute ("AKS")

- 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 FCA violation
(42 USC 1320a-7a(a)(7))
- Minimum \$100,000 settlement

Eliminating Kickback in Recovery Act (“EKRA”)

- Cannot solicit, receive, pay or offer any remuneration in return for referring a patient to a laboratory, recovery home 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))
- Applies to private or public payors.

EKRA

Only applies to referrals to:

- **Lab** = facility for examination of materials derived from the human body for the purpose of providing info for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings.
- **Clinical treatment facility** = a medical setting, other than a hospital, that provides detox, risk reduction, outpatient treatment, residential treatment, or rehabilitation for substance use, pursuant to licensure or certification under State law.
- **Recovery home** = shared living environment that is free from alcohol and illicit drug use and centered on peer support and connection to services that promote sustained recovery from substance use disorders.

(18 USC 220)

Ethics in Patient Referrals Act ("Stark")

- If physician (or family member) has financial relationship with entity:
 - Physician may not refer patients to the 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 FCA violation
 - Likely AKS violation

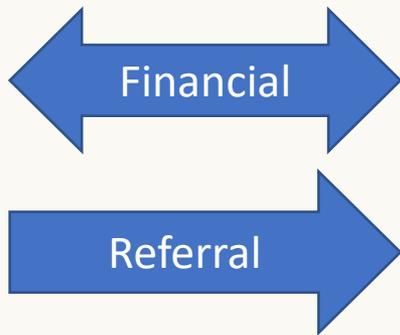
Stark

Only applies if:

Physician

- MD
- DO
- Dentist
- Oral surgeon
- Podiatrist
- Optometrist
- Chiropractor

(42 CFR 411.351 and
411.353)



Designated Health Service (“DHS”)

- Inpatient/outpatient hospital services
- Outpatient prescription drugs
- Radiology and certain imaging services
- Radiation therapy and supplies
- Clinical laboratory services
- Physical, occupational, or speech therapy
- Home health services
- Durable medical equipment and supplies
- Prosthetics and orthotics
- Parenteral and enteral nutrients, equipment, and supplies

Civil Monetary Penalties Law ("CMPL")

- 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

Civil Monetary Penalties Law ("CMPL")

- 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.

Common State Laws and Regulations

- False claims acts
- Anti-kickback statutes
- Self-referral prohibitions
- Fee splitting prohibition
- Disclosure of financial interests
- Insurance statutes
- Medicaid conditions
- Fraud or misrepresentation
- Consumer protection laws
- Bribery
 - May trigger Travel Act claims
- Others?

Penalties

- Civil penalties
- Criminal penalties
- Adverse licensure action
- Other

Beware:

- May apply to private payers in addition to govt programs.
- May not contain the same exceptions or safe harbors as federal statutes

Applying the Laws to Common Situations



Relationships
with referral
sources, e.g.,

- Patients
- Referring
providers

General Rule

- Usually safer if no federal program items, services or patients are involved.
- AKS, Stark, and CMPL only apply to arrangements that involve referrals for items or services covered by federal healthcare programs.

But beware:

- **“Carve out” programs.**
 - Pay to induce private pay may induce federal business .
(OIG Adv. Op. 12-06)
- **State laws**
 - May apply to govt and private programs.
- **EKRA**
 - Applies to govt and private pay programs.

Arrangements with Patients



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 screening exam or service
- Free equipment, supplies, or drugs
- Free meals or lodging
- Free transportation
- Reward or incentive to comply with treatment
- Parking reimbursement
- Waiver or discount of copay or deductible
- Write offs
- Paying patient premiums
- Anything else of value that does not reflect fair market value (“FMV”)

Potential violations of

- AKS
- EKRA
- CMPL
- State laws
- Others?

Free or Discounted Items or Services to Patients

May generally offer free or discounted items to govt patients if:

- Remuneration is not likely to influence the patient to order or receive items or services payable by govt healthcare program.
- Fit within an AKS safe harbor.

(42 USC 1320a-7a(a)(5); see also 42 USC 1320a-7b(b))

Free or Discounted Items or Services to Patients

May generally offer free or discounted items to govt patients if:

- 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))
- No similar rule AKS, but OIG has indicated that it would not challenge gifts of “nominal value.” (See, e.g., *OIG Special Fraud Alerts* dated 2/19/94)

Free or Discounted Items or Services to Patients

May generally offer free or discounted items to govt patients if:

- Demonstrated financial need
 - Either (i) good faith determination that beneficiary has financial need or (ii) 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 generally offer free or discounted items to govt patients if:

- Promotes access to items or services payable by Medicare/ Medicaid and does not:
 - Interfere with clinical decision making;
 - Increase costs to federal program or beneficiary; or
 - Raise patient care concerns.

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

- No similar AKS safe harbor, but risk is probably small if satisfy CMPL exception.

Free or Discounted Items or Services to Patients

May generally offer free or discounted items to govt patients if:

- 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.
- Certain other situations.
(42 USC 1320a-7a(i); 42 CFR 1003.110)
- No similar AKS safe harbor, but risk is probably small if fit within the CMPL exception.

Free Tests or Screening Exams

- OIG has approved free screening services (e.g., free blood pressure check) where:
 - Not conditioned on 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*)

- May use independent foundation 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 or Discounting Copays or Deductibles

May waive or discount govt copays or deductibles if:

- Good faith determination that (i) beneficiary is in financial need or (ii) 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.
- Periodically review evaluation.

Waiving or Discounting Copays or Deductibles

May waive or discount govt copays and deductibles 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 Public Health Services Grant.
- Pharmacy if certain conditions satisfied.
- Ambulance service if certain conditions satisfied.

(42 CFR 1001.952(k))

Waiving or Discounting Copays or Deductibles

- Generally, may not waive or discount copays and deductibles or engage in “insurance only” billing for private payers.
 - Likely violates private payor contracts.
 - May violate state laws, e.g., insurance statutes, state AKS, insurance fraud, etc.
- Payers may not complain if write off after failed collection efforts.
- Check your payor contract or contact your private payors.

Writing Off Entire Bill

- Writing off entire bill for service is safer than waiving copays.
 - Payors usually don't complain if not billed.
- 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, etc.
 - 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 should:
 - Have a reasonable set of financial guidelines based on objective criteria that document 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*)

- Other providers may want to adopt similar measures.

Professional Courtesy

Beware professional courtesies to govt patients.

- No AKS or CMPL safe harbor.
- Consider whether intent is to induce referrals.
- Don't waive copays or deductibles or engage in “insurance only” billing.
- Consider whether other exceptions or safe harbors apply.

Professional Courtesy

- Professional courtesy to physicians, their family members, or their staff implicates Stark if the physician refers DHS payable by Medicare/Medicaid.
- Stark safe harbor requires:
 - Provider has formal medical staff.
 - Courtesy offered to all physicians on medical staff or in the service area regardless of referrals.
 - Services are of a type routinely provided by the entity.
 - Written policy approved in advance by governing body.
 - Not offered to govt patients unless good faith showing of financial need.

(42 CFR 411.357(s); 72 FR 51064)

Free or Discounted Items to Employees

If govt payers or private insurance is involved:

- Offering free or discounted services to your own employees likely does not violate AKS, EKRA, or Stark if not tied to referrals.
 - Fits within bona fide employee safe harbor.
- Waiving copays or other cost-sharing or “insurance only” billing likely violates CMPL and private payor contracts.
 - 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

Govt patients

- OIG has approved prompt pay discounts for govt patients if:
 - Amount of discount reflects avoided collection costs, not an incentive to obtain services.
 - 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 payors

- Generally, may not 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 charge different amounts to patients and payers, i.e., not required to charge all persons the same amounts.
 - Payment is a matter of contract between provider and patient or payor.
 - Providers often negotiate different rates for different payors.
 - Provider may negotiate different rates or discounts for self-pay patients.
- But beware limitations....

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) (“Patient charges must be uniform.”).
- 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 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>)

Patient Paying 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 and HIPAA prohibit 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.

(78 FR 5628)

Paying Patient's Premiums

- If paying Medicare Part B, C or D premiums:
 - OIG approved 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 state laws.
 - COBRA regulations contemplate that COBRA premiums may be paid by third party.
 - Check payor contracts.
- Stay tuned—this is a developing area of the law.

Arrangements with Referring Providers



Remuneration to/from Referring Providers

- Employment
- Services agreements
- Ownership interests
- Group compensation
- Leases
- Recruitment
- Joint Ventures
- Free or discounted items
- Space, equipment, support
- Professional courtesies
- Incidental benefits
- Insurance
- Over/under payments
- Any other remuneration, i.e., something of value.



- Stark
- AKS
- CMPL
- EKRA
- State laws
 - AKS
 - Mini-Stark laws
 - Fee splitting
 - Others?

Don't forget if:

- Labs
- Tx Facilities
- Recovery Home

Arrangements with Physicians or Their Family

Stark Safe Harbors

- Employment
- Independent contractor
- Compensation < \$5000
- Group practice compensation
- Recruitment and retention
- Leases for space or equipment
- Ownership
- Non-monetary stuff up to \$489
- Medical staff incidental benefits
- Professional courtesy
- EHR support
- Isolated transactions
- Value-based care
- Others

(42 CFR 411.355-.357)

AKS Safe Harbors

- Employment
- Independent contractor
- Leases for space/equipment
- Group practice compensation
- Sale of practice
- Recruitment
- OB malpractice subsidy
- Investments in other entities
- ASCs
- EHR support
- Value based care arrangements
- Others

(42 CFR 1001.952)

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

Arrangements with Non-Physicians

Stark does not apply to referral sources who are not:

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

➤ **But don't forget about—**

- ✓ **State laws**
- ✓ **EKRA**

AKS Safe Harbors

- Employment
- Independent contractor
- Leases for space/equipment
- Group practice compensation
- Sale of practice
- Recruitment
- OB malpractice subsidy
- Investments in other entities
- ASCs
- EHR support
- Value based care arrangements
(42 CFR 1001.952)
- ✓ One purpose to induce referrals?
- ✓ Favorable advisory opinion?

Employment

Stark (Physicians or Family)

- Identifiable services.
- Compensation is:
 - Consistent with FMV;
 - Does not vary with volume or value of referrals for DHS.
 - Commercially reasonable absent referrals.
- Personally performed services do not vary with referrals.

(42 CFR 411.357(c))

AKS

- Compensation paid to bona fide employees for furnishing items or services payable by Medicare/Medicaid.
- Safe harbor may not apply to excess payments for referrals instead of “furnishing items or services”.

(42 CFR 1001.952(i))
(OIG Letter dated 12/22/92 fn.2)

Employment

EKRA (Labs, Tx Facilities, Recovery Homes)

- Bona fide employment
- Compensation does not vary by:
 - Number of individuals referred to lab, tx facility, or recovery home;
 - Number of tests or procedures performed; or
 - Amount billed or received from a health care benefit from individuals referred to the lab, tx facility or recovery home.

(18 USC 220(b)(2))

Independent Contractors

For example,

- Professional services agreements
- Call coverage agreements
- Medical directorships
- Medical staff leadership
- Management services
- Administrative services
- Marketing
- Consulting
- Other situations in which a provider:
 - contracts with or pays a non-employee for services and
 - the contractor refers or generates business for provider.

Independent Contractors

Stark (Physicians or Family)

- Writing signed by parties covering identifiable services.
- Compensation formula is:
 - Set in advance.
 - Consistent with FMV.
 - Does not take into account the volume or value of services or other business generated by physician.
- Arrangement is commercially reasonable even if no referrals.
(42 CFR 411.357(d) or (l))
- May modify compensation prospectively if other conditions met.
(42 CFR 411.354(d)(1); 85 FR 77595)

AKS

- Writing signed by parties for specified services.
- Term not less than 1 year.
- Compensation methodology is:
 - Set in advance.
 - Consistent with FMV.
 - Does not take into account the volume or value of referrals for federal program business.
- Aggregate services not more than reasonably necessary to accomplish commercially reasonable purpose.
(42 CFR 1001.952(d))

Independent Contractors

EKRA (Labs, Tx Facilities, Recovery Homes)

Option 1

- Compensation does not vary by:
 - Number of individuals referred to lab, treatment facility, or recovery home;
 - Number of tests or procedures performed; or
 - Amount billed or received from a health care benefit from individuals referred to the lab, treatment facility or recovery home.

(18 USC 220(b)(2))

Option 2

- Satisfy AKS safe harbor for independent contractors at 42 CFR 1001.952(d)
(18 USC 220(b)(4))

Payment for Services ≤ \$5000

Stark: may pay physician for services provided by physician if:

- Compensation
 - ≤ \$5000* aggregate per calendar year if:
 - Does not take into account volume or value of referrals or other business generated by the physician.
 - Does not exceed FMV.
- Arrangement is commercially reasonable even if no referrals.
- If compensation is for use of space or equipment, compensation formula:
 - Not based on % of revenue, or
 - Per-unit (other than time-based) that depends on referrals by lessor.

(42 CFR 411.357(z))

- ✓ Allows entities to avoid *de minimus* violations.
- ✓ May be used with other safe harbors to establish compliance.

Requiring Referrals

Stark: may require physician to refer DHS to a particular provider if:

- Referral requirement is set out in writing signed by parties.
- Compensation set prospectively for duration of agreement.
- Compensation satisfies other safe harbor requirements (e.g., FMV and not based on volume or value of referrals).
- Referrals relate solely to physician's services under the contract and are necessary to effectuate legitimate purpose of the arrangement.
- Referral requirement does not apply if:
 - Patient prefers to go to a different provider;
 - Insurer determines the provider; or
 - Physician determines not in patient's best medical interests.
- Cannot condition on number or value of referrals but may require % of referrals.

(42 CFR 411.354(d)(4))

Group Practice Compensation

Stark (Physicians)

- Owners
 - Rural providers.
 - **Physician services.***
 - **In-office ancillary services exception.***

(42 CFR 411.355)

*** Must qualify as a “group practice” under 42 CFR 411.352.**
- Non-owners
 - Employee safe harbor
 - Contractor safe harbor

(42 CFR 411.357)

 - Group practice safe harbors

(42 CFR 411.355)

AKS

- Equity interests held by licensed providers who practice in the group.
 - Equity in group itself, not some subdivision of the group.
 - In case of a group practice, qualify as a **“group practice”** under Stark.
 - Unified business with centralized decision-making, pooling of expenses and revenues, and no satellite offices operating as separate profit centers.
 - Ancillary services satisfy the **“in-office ancillary services”** exception under Stark.
- (42 CFR 1001.952(p))

“Group Practice”

Stark

- Operate as single legal entity.
- 2+ physicians.
- Physicians provide services through shared office space, facilities, equipment and personnel.
- At least 75% of services performed by and billed through the group.
- Physicians in group perform at least 75% of physician encounters.
- Distribution of overhead expenses and income determined prospectively before receipt of payment.
- Operate as unified business with centralized decision-making, consolidated billing, accounting, financial reporting.
- Compensation is not based on the volume or value of referrals except as permitted in 42 CFR 411.352(i).

(42 CFR 411.352)

“Group Practice” Compensation

Stark: Paying Based on Overall Profits

- May pay group members share of overall profits that is not directly related to volume or value of referrals for DHS.
 - > 5 physicians: must have at least 5 physicians in profit pool.
 - ≤ 5 physicians: all are included in profit pool.
- Profits deemed not to be based on referrals if:
 - Overall profits divided per capita.
 - Overall profits distributed based on distribution of non-DHS.
 - DHS revenues < 5% of total revenue, and portion of DHS Revenue distributed to physician ≤ 5% of total compensation.

(42 CFR 411.352(i)(1))

“Group Practice” Compensation

Stark: Paying Based on Productivity

- May pay group members based on services they personally perform and “incident to” the physician’s services.
- Productivity compensation deemed not to be based on referrals if:
 - Productivity based on physician’s total patient encounters or RVUs personally performed by the physician.
 - Services on which productivity bonus is based are not DHS.
 - DHS revenues < 5% of total revenue, and portion of DHS Revenue distributed to physician \leq 5% of total compensation.

(42 CFR 411.352(i)(2))

In-Office Ancillary Services Exception

Stark: physician may refer in-office ancillary services to others in the group if:

- Services furnished by referring physician, member of the group, or individual supervised by group member.
 - For contracted physicians, must contract directly with provider and provide services in group's facilities.
- Services performed in “same building” as group or “centralized building” owned or leased fulltime by the group.
- Services billed by the performing/supervising physician or group practice under number assigned to the physician or the group.
- For MRI, CT, and PETs, must provide written notice of other entities from which the patient may obtain the services.

(42 CFR 411.355(b); 411.351)

Lease Space or Equipment

Stark (Physicians or Family)

- Written agreement signed by parties.
 - Specifies space, equipment, etc.
 - Term for at least one year.*
 - Legitimate need, no more than necessary, and commercially reasonable.
 - Exclusive use by lessee
 - Rental charges are:
 - Set in advance and FMV.*
 - Not based on referrals.
 - Not % of revenue.
 - Not per unit of service referred by lessor.
 - Holdover okay if based on same terms.
- (42 CFR 411.357(a)-(b); see also .357(l))

AKS

- Written agreement signed by parties.
- Specifies space, equipment, etc.
- Specifies schedule of use.
- Term for at least 1 year.
- Space is reasonably necessary to accomplish commercially reasonable business purpose.
- Aggregate rental charge is:
 - Set in advance and FMV.
 - Not based on referrals.

(42 CFR 1001.952(b))

Timeshare for Space or Equipment

Stark (Physicians or Family)

- Between physician/group and hospital or another group.
- Written agreement signed by parties specifying space, equipment, personnel, supplies, etc.
- Used predominantly for evaluation and management (“E&M”)
- Not conditioned on referrals.
- Compensation is
 - Set in advance and FMV.
 - Does not vary with volume or value of referrals.
 - Not based on a % of revenue or unit of service referred by licensor
- Commercially reasonable even if there were no referrals.
- Does not convey leasehold.
- See other conditions

(42 CFR 411.357(y))

Use of Space or Equipment

Stark (Physician or Family)

- Perhaps no financial relationship if:
 - No direct financial relationship with physician/family, and
 - Physician's compensation does not vary with referrals.
(42 CFR 411.354(d)(2))
- CMS indicates no “remuneration” if:
 - Physician bills professional fees.
 - Owner of space/equipment (e.g., hospital or clinic) bills technical/facility fees.
 - Neither bill globally.
(80 FR 71321-22)
- Make sure physician is using appropriate site of service modifier.
- Beware AKS, EKRA, and state laws.

Reconciling Payments

Stark: may submit claim for DHS if:

- Not later than 90 days after termination of arrangement, reconcile discrepancies in payments so that, after reconciliation, entire amount of remuneration has been paid as required by the terms of the arrangement, and
- The compensation arrangement otherwise fully complies with Stark.

(42 CFR 411.353(h))

Ownership Interest in Entity to Which You Refer

Stark (Physician or Family)

- ✓ Don't refer DHS to owned entity.
- ✓ Group practice if satisfy definition of “group practice” and satisfy:
 - In-office ancillary services.
 - Physician services.
- ✓ Ownership in a rural provider, i.e., furnishes not less than 75% of DHS to residents of a rural area.
- ✓ Ownership in the whole hospital.
- ✓ Indirect ownership if physician compensation does not vary with referrals.
- ✓ Entity is paid on composite rate.

(42 CFR 411.351, .354, .355 and .356)

AKS

- ✓ Don't refer federal program business to owned entity.
 - ✓ Fit within AKS safe harbor
 - Small investment
 - Group practice
 - ASC
- (42 CFR 1001.952(a), (p), (r))
- ✓ Advisory opinion
 - ✓ Consider risk mitigation factors

Ownership Interest in Entity to Which You Refer

AKS: OIG has often cited the following factors as mitigating risk:

- Investors pay FMV for their investment; no loans for investment.
- Investment opportunities are not based on referrals.
- Compensation to owners is based on their capital investment, not referrals.
- Compensation to owners is consistent with FMV in an arms length transaction.
- Referrals are not tracked.
- Owners do not require or encourage other investors, employees or contractors to make referrals.
- Owners periodically remind referring providers of the limits.
- Patients are advised concerning the ownership interest.
- Overall, the venture promotes effective, efficient healthcare.
- Overall, the arrangement generally poses a low risk of fraud or abuse.

(See, e.g., 42 CFR 1001.952(a)(2); OIG Adv. Ops. 21-02, 10-15, 01-17, 01-21; 09-09, 03-02, 08-08, 22-07)

Other Safe Harbors

Stark Safe Harbors (Physicians)

- Fair market value compensation
- Indirect compensation arrangements
- Isolated transactions, including settlements of bona fide dispute
- Payments by a physician
- Recruitment and retention
- Non-monetary stuff up to \$489
- Medical staff incidental benefits
- Professional courtesy
- Compliance training.
- OB malpractice subsidies
- EHR support
- Value-based care arrangements
- Intra-family referrals

(42 CFR 411.355-.357)

AKS Safe Harbors

- Sale of practice
- Recruitment
- OB malpractice subsidy
- Investments in other entities
- ASCs
- EHR support
- Managed care arrangements
- Value based care arrangements
- Others

(42 CFR 1001.952)

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

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
 - FMV
 - Compensation not based on referrals
 - Services actually provided
- Visiting specialists
- Overpayments or payment for items not provided
- Joint ventures
- Practice support
- Professional courtesies
- Others?

Health Law Webinar Series

Date	Webinar
3/2/23	Fraud and Abuse I: The Laws
3/16/23	Fraud and Abuse II: Applying the Laws
3/30/23	Fraud and Abuse III: Responding to Noncompliance
4/13/23	Telehealth
4/27/23	EMTALA
5/11/23	Reproductive Rights
5/25/23	Nondiscrimination Rules
6/1/23	HIPAA and Patient Privacy

<https://www.hollandhart.com/events>

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](#)



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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/>



[Submit a Complaint](#)

- Compliance
- Accountable Care Organizations
- Advisory Opinions
- Compliance Guidance**
- Corporate Integrity Agreements
- Open Letters
- RAT-STATS
- Safe Harbor Regulations
- Self-Disclosure

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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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.

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Clients We Serve

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- 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?

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