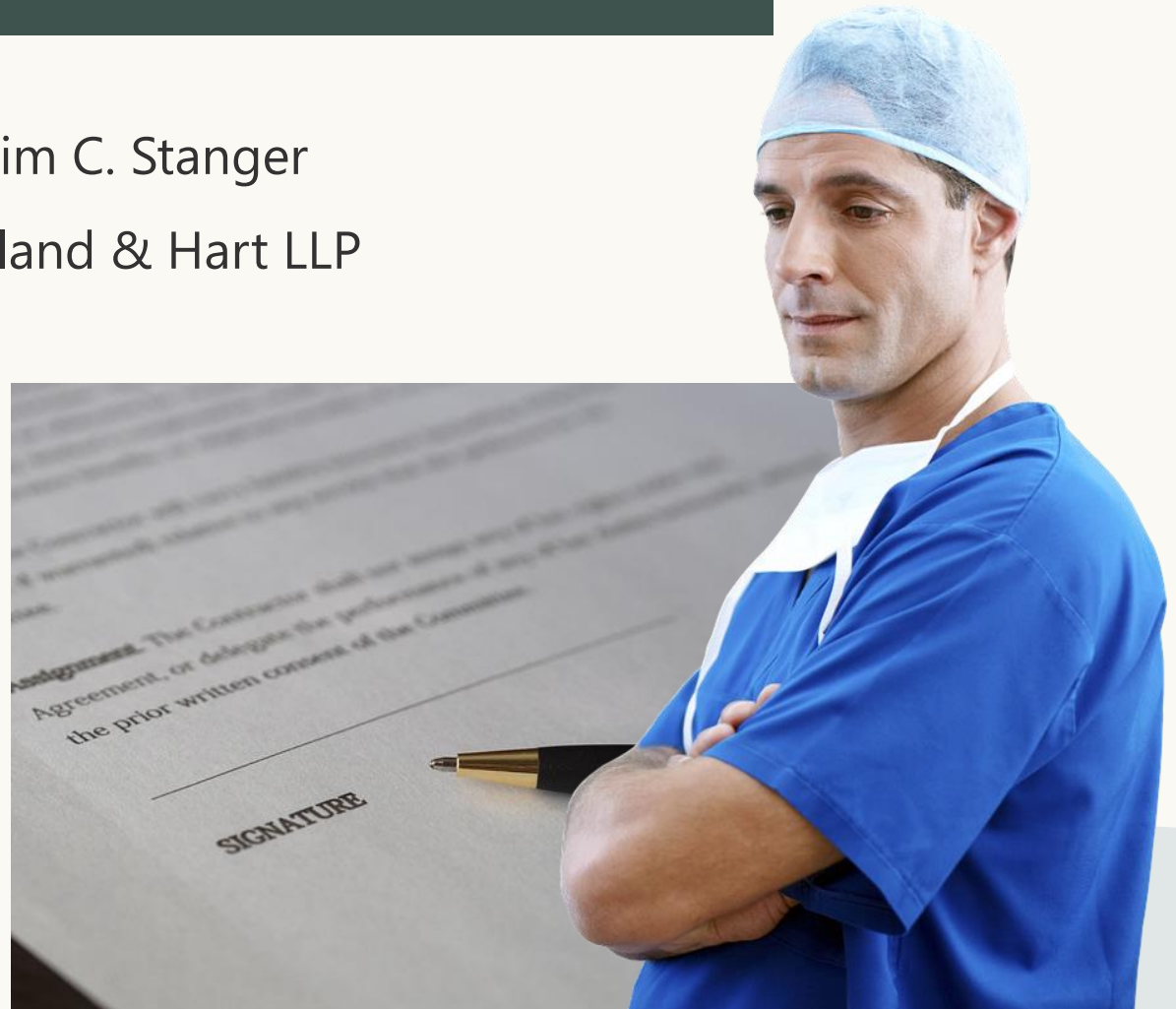


Provider Arrangements; Rules, Real Life, and Remedies

Kim C. Stanger
Holland & Hart LLP




Today's Presenter



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He is consistently named as one of the Best Lawyers in America® for Health Care Law by U.S. News and a Mountain States Super Lawyer. He has been repeatedly awarded the Best Lawyers® Health Care Law "Lawyer of the Year" for Boise. He is a member of the American Health Law, Past President of the Idaho Bar Association Health Law Section, and a frequent author and speaker on health law-related issues.



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Overview

- **Relevant laws**
- **Applying the law to common arrangements**
 - Services Contracts
 - Employment
 - Independent contractors
 - Recommended terms
 - Recruitment and retention
 - Nonmonetary compensation
 - Medical staff incidental benefits
 - Professional courtesies
 - Others
- **Managing physician arrangements**
- **Fixing problems**

Written Materials

- .ppt slides
- Anti-Kickback and Stark Safe Harbors
- Sample physician agreement
- Stanger, *Key Terms for Provider Contracts*, <https://www.hollandhart.com/key-terms-for-provider-contracts>
- Stanger, *Stark Requirements for Physician Contracts*, <https://www.hollandhart.com/stark-requirements-for-physician-contracts>
- Stanger, *Stark Requirements for Physician Leases*, <https://www.hollandhart.com/stark-requirements-for-physician-leases>
- Stanger, *Physician Timeshare Arrangements: New Stark Option for Sharing Space with Visiting Specialists and Others*, <https://www.hollandhart.com/physician-timeshare-arrangements-new-stark-option>

Laws and Regulations for Physician Arrangements



Employee v. Contractor

Employment

- Right of control
- Employer must withhold taxes
- Employer vicariously liable
- Employment laws apply, e.g., discrimination, wage/hour, etc.
- Easier to comply with regulations such as Stark and the Anti-Kickback Statute

Independent Contractor

- No right of control
 - See IRS test
- Employer does not withhold taxes; contractor must pay
 - Unless IRS disagrees with classification
- Employer not vicariously liable
 - But beware actual or apparent agency
- Not subject to employment laws
- Additional requirements to comply with Stark and Anti-Kickback Statute
- *May be liable for employment taxes if misclassify a contractor*

<https://www.irs.gov/businesses/small-businesses-self-employed/independent-contractor-self-employed-or-employee>



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Independent Contractor (Self-Employed) or Employee?

English | [Español](#) | [中文\(简体\)](#) | [中文\(繁體\)](#) | [한국어](#) | [Русский](#) | [Tiếng Việt](#) | [Kreyòl ayisyen](#)

Individuals

Businesses and Self-Employed

Business Tax Account

Small Business and Self-Employed

Employer ID Numbers

Business Taxes

Reporting Information
Returns

Self-Employed

Starting a Business

Operating a Business

Closing a Business

It is critical that business owners correctly determine whether the individuals providing services are employees or independent contractors.

Generally, you must withhold and deposit income taxes, social security taxes and Medicare taxes from the wages paid to an employee. Additionally, you must also pay the matching employer portion of social security and Medicare taxes as well as pay unemployment tax on wages paid to an employee. Generally, you do not have to withhold or pay any taxes on payments to independent contractors.

Select the Scenario that Applies to You:

• I am an independent contractor or in business for myself

If you are a business owner or contractor who provides services to other businesses, then you are generally considered self-employed. For more information on your tax obligations if you are self-employed (an independent contractor), see our [Self-Employed Individuals Tax Center](#).

• I hire or contract with individuals to provide services to my business

If you are a business owner hiring or contracting with other individuals to provide services, then you must determine whether the individuals providing services are employees or independent contractors. Follow the rest of this page to find out more about this topic and what your responsibilities are.

Related Topics

- [Businesses with Employees](#)
- [Hiring Employees](#)
- [Know Who You're Hiring Independent Contractor \(Self-employed\) vs Employee](#)
- [Voluntary Classification Settlement Program \(VCSP\) Frequently Asked Questions](#)
- [Topic No. 762, Independent Contractor vs. Employee](#)

Forms & Instructions

- [About Form SS-8, Determination of Worker Status for Purposes of Federal Employment Taxes and Income Tax Withholding](#)

art

IRS Factors for Determining Employee v. Contractor

- **Behavioral**

- Type and degree of instruction given
- Evaluate how work performed or just end result
- Instruction as to how work is performed

- **Financial**

- Wage/salary or payment of flat fee for job
- Investment in equipment used
- Unreimbursed expenses
- Opportunity for profit or loss
- Worker may perform services elsewhere in the market

- **Type of Relationship**

- Terms of written contract
- Payment of employee benefits
- Services provided as key activity of the business
- Permanency of relationship

**Right
of
Control**

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); 42 CFR 1003.300(d))

- “One purpose” test

(*US v. Greber*, 760 F.2d 68 (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)
- False Claims Act violation

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

- Must report and repay
- \$11,803 to \$23,607 per claim
- Qui tam lawsuits

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



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PRESS RELEASE

Covenant Healthcare System and Physicians Pay Over \$69 Million to Resolve False Claims Act Allegations Related to Improper Financial Relationships

Wednesday, March 29, 2023

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For Immediate Release

U.S. Attorney's Office, Eastern District of Michigan

DETROIT – A regional hospital system and two physicians have paid over \$69 million in three related civil settlements to resolve possible False Claims Act violations, United States Attorney Dawn N. Ison announced today.

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**

OIG Advisory Opinions



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Advisory Opinions

HHS-OIG issues advisory opinions about the application of certain fraud and abuse enforcement authorities to the requesting party's existing or proposed business arrangements.

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<https://oig.hhs.gov/compliance/advisory-opinions/>

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US v. Anderson (10th Cir. 2000)

Facts

- Baptist Medical Center contracted with physicians as Co-Directors of Gerontology Services and paid them \$75,000 per year.
- Physicians referred nursing home patients to Baptist.
- But...
 - Minimal services performed.
 - Services not really needed.
 - "I don't look good in stripes..."

Holding

- Physician 1: 6 years + \$75,000 fine + \$142,000 restitution
- Physician 2: 3 years + \$25,000 fine
- Hospital CEO: 4 years + \$75,000 fine
- Hospital COO: acquittal reversed
- Hospital attorney: acquitted

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 regulatory exception.

(18 USC 220(a))

- Applies to referrals paid by private or public payers.

Penalties

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

(18 USC 220(a))

Beware:

- *Few statutory safe harbors.*
- *No regulatory safe harbors.*
- *Limited case law*

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 DHSunless arrangement fits within a regulatory exception.

(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 submitted
 - \$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

Only applies if:

Physician

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



Financial

Referral

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

(42 CFR 411.351 and 411.353)

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



[Justice.gov](#) > [Office of Public Affairs](#) > [News](#) > [Press Releases](#) > United States Resolves \$237 Million False Claims Act Judgment Against South Carolina Hospital That Made Illegal Payments To Referring Physicians

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PRESS RELEASE

United States Resolves \$237 Million False Claims Act Judgment against South Carolina Hospital that Made Illegal Payments to Referring Physicians

Friday, October 16, 2015

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The Department of Justice announced today that it has resolved a \$237 million False Claims Act judgment against Tuomey Healthcare System for illegal payments to referring physicians with whom the hospital entered into long-term, part-time employment contracts to keep them from opening competing surgery centers.

US v. Tuomey Healthcare Sys.
Hospital entered long-term, part-time employment contracts with physicians to keep them from opening competing surgery centers.

**Held: Stark and AKS violations;
\$237 million verdict
\$72.4 million settlement**



[Justice.gov](#) > [Office of Public Affairs](#) > [News](#) > [Press Releases](#) > Former Chief Executive of South Carolina Hospital Pays \$1 Million and Agrees To Exclusion To Settle Claims Related To Illegal Payments To Referring Physicians



PRESS RELEASE

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

Tuesday, September 27, 2016

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Tuomey CEO

- Paid \$1 million
- Excluded from Medicare/Medicaid for 4 years.

The Department of Justice announced today that it has reached a settlement with Ralph J. Cox III, the former chief executive officer of Sumner Medical Center, a South Carolina Healthcare System, for his involvement in the hospital's illegal Medicare and Medicaid billings.

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

☒ E-mail me when this page is updated.

Download the LEIE Database

ANNOUNCEMENT: As of the September 2013 update, only the LEIE files containing the NPI, Waiver, and Waiver States fields will be available.

[Instructions](#) and information [About the LEIE Files](#).

Below files updated: 05-08-2015

LEIE Database

[04-2015 Updated LEIE Database: EXE | ZIP](#)

Current Monthly Supplements

- [04-2015 Exclusions: EXE | ZIP](#)
- [04-2015 Reinstatements: EXE | ZIP](#)
- [Monthly Supplement Archive](#)

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[04-2015 Profile Corrections](#)

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**EXCLUSIONS
DATABASE**

501(c)(3) Tax Exempt Status: Private Inurement

- To qualify for tax exemption, no part of an organization's net earnings shall inure in whole or part to the benefit of private individuals.
 - Applies to "insiders", i.e., those with power exercise control or influence over the organization.
 - May extend to physicians employed by organization.

Penalties

- Loss of tax exempt status
- Intermediate sanctions for excess benefit transaction between disqualified person and 501(c)(3) entity.
 - 25% excise tax
 - 200% tax if fail to correct

(IRC 4958)

Corporate Practice of Medicine

- **Background**

- Some states prohibit corporate entities from employing physicians and perhaps other healthcare providers.
- Theory: corporations cannot practice medicine; interferes with professional judgment

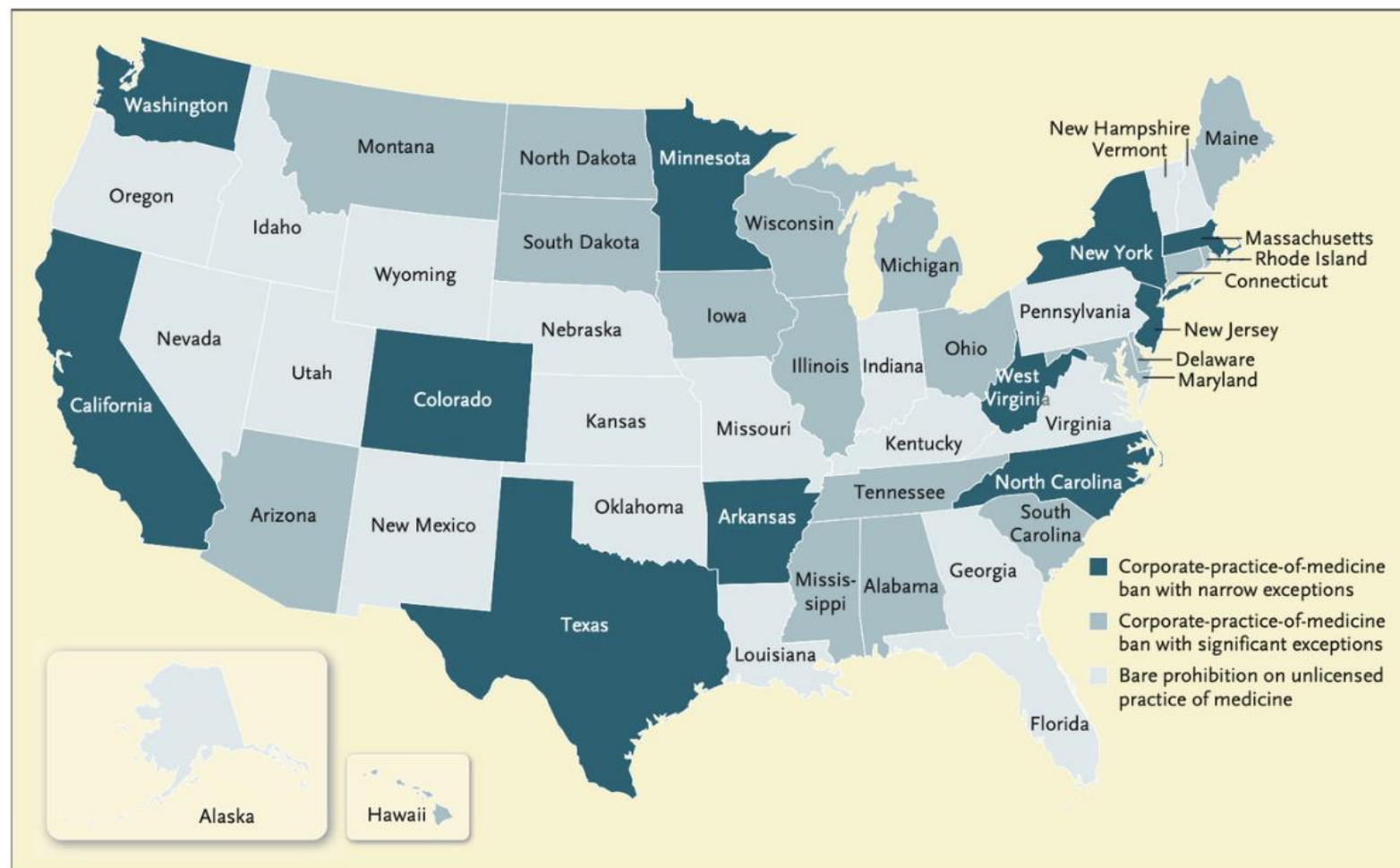
- **Common exceptions**

- Professional corporations, PLLCs, PLLPs, etc.
- Employment by hospitals, HMOs, networks, etc.
- Others?

- **Addressing CPOM**

- Independent contractor agreements
- Management services organizations
- Foundation model
- Others?

Corporate Practice of Medicine



Scope of State Corporate-Practice-of-Medicine Laws in the United States.

Information is based on the authors' analysis of primary documents and summaries of legal texts as of April 2023.

Applying the Laws



Applying the Laws

- **“One size does not fit all.”**
 - Consider specific circumstances and needs.
 - Requirements vary based on type of provider.
 - Check applicable laws and regulations.
 - Contracting with individual or group
 - Parties may have personal preferences.
- **Draft the agreement so there is no misunderstanding.**
 - Just because you know what you mean does not mean that others will, including other party, court, and/or regulatory agencies
- **Terms will vary between**
 - Employment
 - Independent contractor
- **My comments favor employer.**

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.

(42 CFR 1001.952(i))

- Safe harbor may not apply to excess payments for referrals instead of “furnishing items or services”.

(OIG Letter dated 12/22/92 fn.2)

- But these comments have been rejected in more recent cases.

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

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))

Group Practices

Stark

- Group practices can compensate physicians differently than hospitals, e.g.,
 - Groups may pay share of profits subject to certain limits.
 - Groups may pay physicians for services performed “incident to” the physician services.

(42 CFR 411.352 and .355)

- Contracts between the hospital and group may create additional issues, particularly for the group, e.g.,
 - “Under arrangement” contracts may prevent the group from relying on the group practice exceptions.

Payment for Services \leq \$5000

Stark

- May pay physician for services provided by physician if:
 - Compensation
 - \leq \$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.

Key Contract Terms



Parties

- **Contracting with individual?**
- **Contracting with group?**
 - Reserve right to approve of persons rendering services and/or identify persons authorized to render services.
 - Require physicians providing services to comply with terms of the agreement.
- For group practices, to satisfy in-office ancillary services exception:
 - Contract must be with individual, not group.
 - Contractor must perform services in the group's facilities.

(See 42 CFR 411.354, definition of "physician in the group practice").

Effective Date

- **Effective and binding immediately?**
 - Must terminate per contract terms.
 - Parties breach or fail to perform per the agreement.
- **Effective at some future date?**
 - May allow termination prior to effective date.
 - Include outside date when services must be provided or else agreement terminates.

Services

- Person or entity providing services
 - If group,* approve person providing services
- Employment v. independent contractor
- Confirm services
 - Clinical
 - Administrative
 - Call
 - Supervision
 - Others?
- Schedule (fulltime, part-time, as-needed)
 - Reserve right to modify schedule.

* Group services raise additional issues under Stark.

Qualifications

Condition contract on satisfaction of qualifications

- Successfully pass pre-employment screening.
- Required vaccinations and immunizations.
- Licensure without restriction.
- DEA and state board of pharmacy authorization.
- Able to participate in Medicare, Medicaid, and other payer programs.
- Medical staff membership and privileges without restriction.
- Insurable under hospital's policies or maintain own insurance, depending on whether employed or contractor.
- Board certification or board eligible.
- Able to perform services.
- Other?

Performance Standards

- Comply with laws and regulations; standard of care; hospital bylaws, and policies; payer requirements; third party contracts.
- Act in professional, cooperative, non-disruptive manner.
- Timely complete records per hospital policy.
 - Consider penalties for failure to complete records.
- Promote service line.
- Support quality assurance, compliance and other programs.
- Attend required meetings and participate in assigned committees.
- Immediately notify hospital of circumstances giving rise to potential claims.
- Adhere to such other performance standards as reasonably established by employer.
- Others?

Exclusivity

- If contract is not intended to be exclusive:
 - Confirm same.
 - Require cooperation with other providers.
- If contract is intended to be exclusive:
 - Define scope of exclusivity carefully.
 - Allow for appropriate exceptions.
 - Condition contract and privileges on continuance of exclusive arrangement.
 - Terminate contract and privileges if provider is no longer a part of the group that has the exclusive arrangement.

Outside Activities

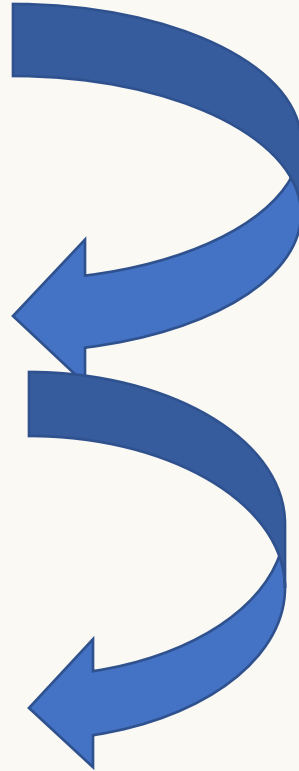
- Limit performance of professional services outside agreement during the term without employer's consent.
 - May specify permissible services, e.g., teaching, writing, performing expert testimony, etc.
 - Reserve right to revoke consent at anytime.
- Ownership of fees generated from outside activities.
- Obligation to secure insurance coverage.
- Coordinate with non-compete.
- Prohibit outside activities that:
 - Interfere with performance of services per agreement.
 - Compete with employer's services.
 - Increase employer's liability.
- Reserve right to withdraw consent.

Compensation



Compensation

- **Set salary**
- **Time-based**
 - Per hour, shift, day, or month
- **Productivity-based**
 - wRVUs
 - Net charges
 - Net collections
 - Net income
- **Value-based**



Many/most entities have moved to production-based compensation to avoid losses.

Many entities will need to move toward value-based compensation to align with changing payer arrangements.

Compensation

- **Base salary, per hour, per day, per month, per shift, per service**
 - Define what you are paying for, e.g.,
 - Clinical v. administrative services
 - Adjustment for partial shifts, partial years, etc.
 - APPs: consider wage/hour laws.
- **Productivity = personally performed services.**
 - wRVUs + appropriate modifiers for multiple procedures, surgical assists, contractual adjustments, no assigned wRVU, etc.
 - Allow for adjustment if cannot bill for services due to conduct of physician.
 - Billing or collections.
 - Include example of calculation to avoid misunderstanding.
 - Consider advance + true up at end of period with necessary repayment.
 - Not share of overall profits, services performed by others (including "incident to"), ancillaries, cost savings, etc.



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PRESS RELEASE

Florida Hospital System Agrees to Pay the Government \$85 Million to Settle Allegations of Improper Financial Relationships with Referring Physicians

Tuesday, March 14, 2017

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US v. Halifax Hospital

- 15% of operating margin for Oncology Program put in incentive compensation pool. Employed oncologists paid based on their personal performed services.
- Qui tam suit by Director of Physician Services
- Stark violation; hospital pays \$85 million

Value-Based Compensation

Stark

New safe harbors for:

- Arrangements that facilitate a value-based health delivery and payment—full financial risk.
- Value-based arrangements with meaningful downside financial risk to physician.
- Value-based arrangements.

(42 CFR 411.357(aa))

AKS

New safe harbors for:

- Outcomes-based payments
(42 CFR 1001.952(d)(2))
- Care coordination arrangements to improve quality, outcomes and efficiency.
- Value-based arrangements with substantial financial risk.
- Value-based arrangements with full financial risks.

(42 CFR 1001.952(d))

Value-Based Compensation

- “Nothing in [Stark] bars payments based on quality measures, as long as the overall compensation is fair market value and not based directly or indirectly on the volume or value of DHS referrals, and the other conditions of the exception are satisfied. For example, nothing in [Stark] would prohibit payments based on achieving certain benchmarks related to the provision of appropriate preventative health care services or patient satisfaction.”

(69 FR 16088)

Compensation

May use existing metrics, e.g.,

- Healthcare Effectiveness Data and Information Set (HEDIS)
- Physician Quality Reporting System (PQRS)

- Value-based compensation
 - Patient management compensation
 - 5%-20% of compensation based on achieving quality metrics, e.g.,
 - Clinical quality/patient safety/outcomes (e.g., patients with diabetes achieved certain standards)
 - Patient satisfaction
 - Access to care
 - Efficiency
 - Use of health IT
 - Citizenship (e.g., participation in committees, meetings, etc.)
- * Beware “take back” or “penalty” provisions.

Compensation

Additional compensation

- Supervision of others
 - Actual time spent
- Signing bonus
- Retention bonus
- Relocation assistance
- Student loan repayment
- Deferred compensation
 - Check with tax advisor
- Malpractice tail insurance from prior employer
- Others?

- ✓ Include when calculating FMV
- ✓ Must remain through entire bonus period to get bonus
- ✓ Consider repayment if provider leaves within certain period of time
 - Repay all
 - Prorate over time
- ✓ Payments as forgivable loans
 - Promissory note + security interest
 - Beware limits for govt entities
- ✓ Beware tax ramifications
 - Withholdings
 - Provider liability

Benefits

- Health and dental insurance
- Life insurance
- Disability insurance
- Workers compensation
- Retirement
- Time off
- CME or professional education
- Licensure, professional fees, and costs
- Reimbursement of business expenses
- Others

- ✓ Consider simply referring to existing employee benefit plans
 - Allows modification
 - Avoids complex contracts
- ✓ Confirm benefits are subject to existing plans and may be changed at anytime
- ✓ Beware discrimination in favor of highly paid employees
- ✓ Consider whether benefits payable to part-time or PRN
- ✓ Beware paying to contractor

Compensation

- Beware stacking compensation:

Base salary

+ Production bonus

+ Quality bonus

+ Call coverage

+ Medical directorship

+ Midlevel supervision

+ Resident supervision

Total compensation

Cumulative compensation may exceed FMV, especially when provider is paid for separate services performed at same time, or cumulative time exceeds reasonably available hours (e.g., physician who is paid for 40 hours of clinical services should only receive additional compensation for services in excess of 40 hours).

- To mitigate, ensure that separate compensation is for separate services and distinct time requirements.
- Consider cap on compensation.

Call Coverage

- OIG has approved paying for call coverage if, e.g.,
 - Lack of specialty services otherwise available, and/or
 - Physicians won't take call w/out pay because of practice demands, time commitment, or uncompensated care. (See, e.g., OIG Adv. Op. 12-15)
- Ensure payments satisfy applicable safe harbor, e.g.,
 - Written arrangement, if independent contractor
 - Fair market value
 - Commercially reasonable
- Document need for call coverage and services provided

Call Coverage

Common methods

- Daily or hourly rate, with or without right to bill.
- Paying lower hourly/daily, but higher rate if provider is called in.
- Paying for excess call over certain number of shifts per month.
- Paying for professional fees for uninsured patients, perhaps based on Medicare rates.
- Income guarantee for services performed while on call coverage.
- Paying physician's malpractice insurance for call.
- Joint arrangement with other hospitals to share call coverage and payment for same.
 - Consider antitrust implications.
- Deferred compensation plan.

Penalties

- “Penalty” or adjustment provisions.
 - Failure to timely complete records.
 - Failure to comply with billing rules.
 - Contractual adjustments.
 - Other.
- Many states prohibit imposing monetary “penalty” on employee wages.
 - Pay as bonus for compliance.
 - Include factors in determination of bonus amount.
 - Reserve right to recover damages.
 - Include indemnification provision.

Requiring Referrals

- Under 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; any changes are prospective only.
 - 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))

Term and Termination

- Proper termination provisions minimize risks of any arrangement!



Term

- Set term
 - Contractors: cannot terminate and enter new agreement within 1 year.
 - May terminate early.
 - May modify within term.
- Auto-renewal
 - e.g., for x years but renews unless prior notice is given or contract is terminated per agreement.
 - Avoids unintended expiration.
 - Less important now that Stark allows for holdover agreements.
- Continue until terminated per agreement

Termination

- **Termination without cause** on x days prior notice.
 - Allow immediate termination if pay comp for unexpired portion of notice period.
 - Damages if provider fails to give required notice.
- **Termination with cause** on x days notice + chance to cure.
- **Immediate termination** for certain conduct.
 - Death or disability.
 - Failure to satisfy qualifications.
 - Violation of law or regulation.
 - Commit, charged with, plea to, or convicted of crime.
 - Misrepresentation or dishonest conduct.
 - Substance abuse that adversely affects work.
 - Beware ADA issues.
 - Repeated violation of performance standards.
 - Performance is disruptive, jeopardizes patients, or may subject hospital to liability.
 - Others?

Post-Termination Obligations

- Terminates right to receive compensation.
 - Ensure consistent with compensation formula.
- Return all property, keys, documents, etc.
- Complete records before or within x days of termination.
 - Consider damages or penalties.
- Cooperate in transferring care and duties.
- Cooperate in responding to investigations or claims.
- Surrender of medical staff membership and privileges unless waived by hospital.
- Others?

Non-Competes

- Providing services, contracting with, owning or investing in competitor, or providing services in competition with employer during or after the agreement
- Check state law requirements, e.g.,
 - Reasonable in time and scope.
 - Supported by consideration.
 - Others.
- May violate public policy if limits necessary services.
- Court may “blue pencil” to limit scope.
- Remedies.
 - Injunction without bond.
 - Liquidated damages.
 - Loss of severance.

Non-Solicitation

- **Soliciting, inducing, diverting, contracting with, or interfering with patients, employees, contractors, key vendors, contract partners, etc.**
- **Limitation may be subject to reasonable limits**
 - Time
 - Scope of services
 - Geography
- **Remedies**
 - Injunction without bond.
 - Liquidated damages.
 - Loss of severance.

Confidentiality

- Require provider to maintain confidentiality of certain records, “including but not limited to”:
 - Patient info, including patient lists
 - Personnel info
 - Business plans and strategies
 - Pricing and financial info
 - Risk management, credentialing, and quality assurance
 - Litigation
 - Trade secrets or competitively sensitive info
 - Agreement
- Remedies
 - Liquidated damages
 - Injunction with fees and without bond.

HIPAA Compliance

- Not necessary because providers already have obligation to comply with applicable laws and regulations
- Business associate agreements (“BAA”)
 - Employees
 - No BAA needed for members of workforce
 - Independent contractors
 - Probably not required because—
 - Providers are not business associates while providing treatment
 - Provider may be member of workforce
 - Provider is part of organized healthcare arrangement (OHCA)
 - May be required if perform administrative services (e.g., medical director services) outside organized healthcare arrangement

Indemnification

- May not be necessary under common law rules
 - May generally sue for breach of contract or tort damages
- Unilateral v. mutual
 - Including clause may prompt demand for mutuality
- Indemnification for:
 - Breaches of agreement
 - Violations of law, regulations, or policies
 - Intentional, grossly negligent, or negligent acts or omissions, e.g., malpractice, billing errors, misrepresentations, etc.
- Coordinate with available insurance
 - Limit to extent not covered by insurance
 - Ensure it does not nullify insurance

Additional Terms to Consider

- Liability insurance
 - Who provides?
 - Consider tail insurance
- Use of hospital resources for personal business
- Intellectual property rights
- Ownership and access to records
 - **Contractors: include Medicare access clause.**
- Notice
- Governing law and venue
- Alternative dispute resolution
- Assignment
- Integration, i.e., confirm it is entire agreement
- Coordinate with other agreements and bylaws
- Survival of terms
- Interpretation and construction

Other Arrangements



Recruiting Providers

- **May compensate recruited provider under:**

- Employee safe harbor
- Independent contractor safe harbor
- Group practice safe harbor
- Recruitment safe harbor
 - Allows hospital or FQHC to pay physician or midlevel to relocate to service area.
 - Compensation not limited to FMV.
 - Subject to many conditions.
(42 CFR 411.357(e) and (x);
1001.952(n))

Limited to FMV

Recruitment Agreement

Stark

- Payments by hospital to recruit.
- Written agreement signed by parties.
- Physician relocates from at least 25 miles into hospital's service area.
- Not conditioned on referrals.
- If recruit into existing group:
 - Cannot subsidize group.
 - Hospital payments must be:
 - Directly passed on to recruited physician.
 - Reimburse group for recruitment expenses.
 - Income guaranty limited to additional incremental expenses attributable to adding physician.

• See other conditions

(42 CFR 411.357(e))

➤ See separate safe harbor for APPs.

AKS

- Payment to induce practitioner to relocate to HPSA.
- Written agreement signed by parties.
- 75% of revenues from new practice.
- Benefits provided < 3 years.
- Terms not renegotiated during the 3 years.
- No required referrals.
- Amount of benefits not based on referrals.
- No restriction on staff privileges elsewhere.
- Cannot discriminate against federal program beneficiaries.
- Cannot benefit any entity in a position to generate referrals.

(42 CFR 1001.952(n))

Retention Agreement

Stark

- Hospital or FQHC payments to retain physician in HPSA or MUA.
- Physician has either:
 - Bona fide offer elsewhere, or
 - Certifies in writing s/he has bona fide opportunity elsewhere.
- Retention payment submit to limits.
- 75% of patients in MUA or MUP.
- Only one retention agreement per 5 years.
- Terms not altered based on referrals.
- Arrangement does not violate Anti-Kickback Statute.
- See additional requirements.

(42 CFR 411.357(t))

Use of Space, Equipment or Personnel

- **Use of space, equipment, supplies or personnel**

- Medical staff members
- Visiting specialists
- Full or part-time lease
- Professional courtesy
- Etc., etc., etc.

- ✓ **Stark**

- ✓ **Anti-Kickback Statute**

- ✓ **501(c) tax issues**

- ✓ **Impermissible sharing of hospital space**

- See recent guidance on sharing of hospital space

- ✓ **Provider-based rules**

- Must be held out to public as the hospital-owned

- ✓ **Others?**

Lease Space or Equipment

Stark

- Written lease signed by parties.
- Specifies space, equipment, etc.
- No changes within 1 year.
- Legitimate need, no more than necessary, and commercially reasonable.
- **Exclusive use by lessee.**
- Rent is
 - Fair market value.*
 - 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))

Anti-Kickback Statute

- Written lease signed by parties.
- Specifies space, equipment, etc.
- Specifies schedule of use.
- Term < 1 year.
- Aggregate rent is:
 - Fair market value.*
 - Not based on referrals.
- Reasonably necessary to accomplish commercially reasonable business purpose.

(42 CFR 1001.952(b))

Timeshare

Stark

- Between physician/group and hospital.
- Written agreement signed by parties specifying space, equipment, personnel, etc.
- Used predominantly for evaluation and management ("E&M")
- Not conditioned on referrals.
- Does not violate Anti-Kickback Statute.
- Does not convey leasehold.

• **Compensation is**

- Set in advance
- Fair market value
- Not based on:
 - % of revenue
 - Per unit of service referred by licensor
- Commercially reasonable.

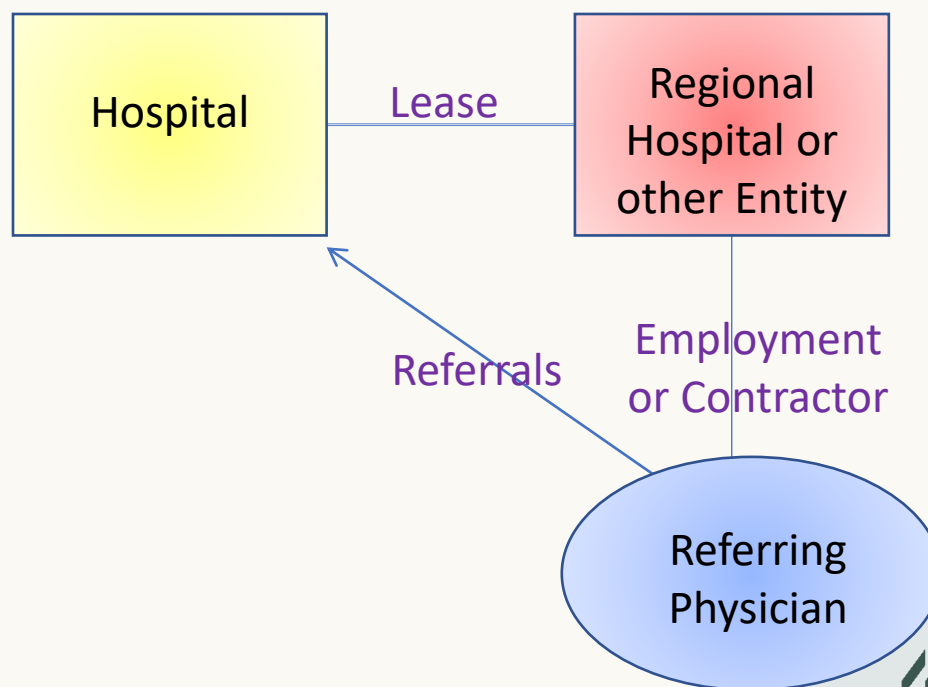
• **See other conditions.**

(42 CFR 411.357(y))

Indirect Financial Relationships

- Under Stark, no “financial relationship” exists if closest compensation relationship with physician does not vary with volume or value of referrals.
- Beware physician owners who “stand in the shoes” of their group.

(42 CFR 411.354(c))



Indirect Financial Relationship

Stark

- Indirect compensation arrangement.
- Compensation is
 - Fair market value for services provided, and
 - Not determined based on referrals.
- Additional rules for leases.
- Compensation arrangement:
 - Set out in written agreement signed by parties (except employment agreement);
 - For identifiable services; and
 - Commercially reasonable.
 - Does not violate Anti-Kickback Statute or other law governing billing submissions.

(42 CFR 411.357(p))

Use of Space/Equipment

- **CMS recently indicated no “remuneration” if:**
 - Physician bills professional fees.
 - Hospital/clinic bill technical/facility fees.
 - Neither bill globally.

(80 FR 71321-22)

- **Make sure physician is using appropriate site of service modifier.**
- **May potentially be AKS issues.**

Non-Monetary Compensation Less than \$489*+/Year

- Items or services (not cash or cash equivalents) that do not exceed \$489*/year, as adjusted per CPI.
- Not based on volume or value of referrals or other business generated between the parties.
- Not solicited by physician or physician's practice.
- If there is violation, physician may repay excess if certain conditions met.
- Entity with formal staff may provide one medical staff appreciation event annually.

(42 CFR 411.357(k))

Medical Staff Incidental Benefits

- Items or services (not cash or cash equivalents) by hospital to medical staff .
- Used on hospital campus.
- Offered to all medical staff members in same specialty.
- Not based on the volume or value of referrals or other business generated between the parties.
- Provided while physician is making rounds or engaged in services benefiting hospital or patients.
- Reasonably related to patient care at hospital.
- Low value, i.e., less than \$25.

(42 CFR 411.357(m))

Professional Courtesy

- Practice has formal medical staff.
- Written policy approved in advance.
- Offered to all physicians in service area regardless of volume or value of referrals or other business generated between parties.
- Health care items or services are of type routinely provided by entity.
- Not offered to government beneficiaries unless showing of financial need.
- Does not violate Anti-Kickback Statute.

(42 CFR 411.357(s))

Additional Safe Harbors

Stark

- Isolated transactions, e.g.,
 - Sale of practice.
 - Settlements.
- Payments by a physician.
- Compliance training.
- OB malpractice subsidies.
- Certain EHR donations.
- Cybersecurity technology and related services.

(42 CFR 411.357(a)-(b))

AKS

- Sale of practice.
- Investments in group practices.
- Investment interests.
- ASCs.
- OB malpractice subsidies.
- Certain EHR donations.
- Cybersecurity technology and related services.

(42 CFR 1001.952(b))

Managing Physician Arrangements

- Develop process so that arrangements with physicians are reviewed and approved by qualified compliance officer or other appropriate person.
- Train staff, e.g., c-suite, medical staff, medical staff services, HR, marketing, accounts payable/receivable, other?
- Maintain good document management system.
- Periodically review and audit compliance.
- Monitor risk areas, e.g., missed payments, changed performance, different space, etc.
- Don't allow physician to get behind.
- Others?

Correcting Problems



No Written Agreement

Stark

- “Written arrangement” may be satisfied by a collection of documents, including contemporaneous documents evidencing the course of conduct between the parties.

(42 CFR 411.354(e)(2))

- For example, “board meeting minutes or other documents authorizing payments for specified services; written communication between the parties, including hard copy and electronic communication; fee schedules for specified services; check requests or invoices identifying items or services provided, relevant dates, and/or rate of compensation; time sheets documenting services performed; call coverage schedules or similar documents providing dates of services to be provided; accounts payable or receivable records documenting the date and rate of payment and the reason for payment; and checks issued for items, services, or rent. This list of examples is not exhaustive....”

(80 FR 71315-16)

Failure to Obtain Signatures

Stark

- Under Stark, the writing requirement or the signature requirement is satisfied if—
 - The compensation arrangement between the entity and the physician fully complies with an applicable Stark exception with respect to the writing or signature requirement of the exception; and
 - The parties obtain the required writing(s) or signature(s) within 90 consecutive calendar days immediately following the date on which the compensation arrangement became noncompliant with the requirements of the applicable exception (that is, the date on which the writing(s) or signature(s) were required under the applicable exception but the parties had not yet obtained them).

(42 CFR 411.354(e)(4))

Amendments

Stark

- Compensation formulas may be modified at any time during the course of the arrangement and satisfy the requirement that it is “set in advance” if all of the following conditions are met:
 - All requirements of an applicable Stark exception are met on the effective date of the modified compensation;
 - The modified compensation is determined before the furnishing of the items, services, office space, or equipment for which the modified compensation is to be paid; and
 - Before the furnishing of the items, services, office space, or equipment for which the modified compensation is to be paid, the formula for the modified compensation is set forth in writing in sufficient detail so that it can be objectively verified.

(42 CFR 411.354(d)(1))

Temporary Noncompliance

Stark

- May continue to submit a claim or bill and payment may be made to an entity that submits a claim or bill for DHS if
 - The financial relationship between the entity and the referring physician fully complied with an applicable Stark exception for at least 180 consecutive calendar days immediately preceding the date on which the financial relationship became noncompliant; and
 - The financial relationship has fallen out of compliance with the exception for reasons beyond the control of the entity, and the entity promptly takes steps to rectify the noncompliance.
 - Only applies to DHS furnished during the period of time it takes the entity to rectify the noncompliance, which must not exceed 90 consecutive calendar days following the date on which the financial relationship became noncompliant with an exception.
- May only use this exception once every 3 years with respect to the same referring physician.

(42 CFR 411.353(f))

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))

Report and Repay 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 411.353 and 401.305)

- For FCA repayments, report and repay to contractor.
- For Stark violations, see CMS Self-Referral Disclosure Protocol at <https://www.cms.gov/medicare/regulations-guidance/physician-self-referral/self-referral-disclosure-protocol>.
- For AKS violations, see OIG Self-Disclosure Protocol at <https://oig.hhs.gov/compliance/self-disclosure-info/>.

Additional Resources



<https://oig.hhs.gov/compliance/compliance-resource-portal/>

Compliance Resource Portal | Off x +

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Email your suggestions for new OIG compliance resources



This is not intended to be a formal agency solicitation. OIG welcomes ideas for new compliance resources that would be helpful to the health care community and that are consistent with OIG's mission, in any format. The receipt of a suggestion does not obligate OIG to take action, including responding to the suggestion, making suggestions public, or issuing public guidance. Members of the public are

<https://www.cms.gov/medicare/regulations-guidance/physician-self-referral>

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Physician Self Referral

Spotlight

Advisory Opinions (AOs)

Call Center

List of CPT/HCPCS Codes

CPI-U Updates

Current Law and Regulations

Definition of Entity

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) payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship (ownership, investment, or compensation), unless an exception applies.
2. Prohibits the entity from presenting or causing to be presented claims to Medicare (or billing another individual, entity, or third party payer) for those referred services.
3. Establishes a number of specific exceptions and grants the Secretary the authority to create regulatory exceptions for financial relationships that do not pose a risk of program or patient abuse.

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.

Questions?



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