Stark Law
Making the Confusion Understandable

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Learning Objectives

- Recognize when the Stark Act is implicated
- Comply with the components for exceptions for a physician practice
Stark Act
42 U.S.C. 1395nn

- The Stark II Act prohibits a physician from making a **Referral**
  - to an **Entity**
  - for the furnishing of a **Designated Health Service**
  - for which payment may be made under Medicare
  - if the physician (or an immediate family member)
  - has a **Financial Relationship** with the entity
Stark II Act

Proof of Intent is *Not* Required
Penalty

Denial of payment or refund; civil money penalties (up to $100,000) and exclusions from federal and state programs for improper claims or schemes
Examples

Simple Example:

Dr. X Practice

Referral

Lab Owned by Dr. X
Examples

Simple Example:

Dr. X Practice \[\rightarrow\] Referral \[\rightarrow\] Lab Owned by Dr. X

How Stark II has been applied:

Dr. X Practice \[\leftarrow\] Medical Directorship Payments \[\rightarrow\] Hospital V

Medical Suite Rent Payments \[\rightarrow\] Referral

In both examples, the referrals violate Stark unless an exception applies.
What is a Referral?

A referral includes:

- Request for an item or a service by a physician
- Request by physician for consultation with another physician, and any tests or procedures the other physician orders, performs or supervises
- Request for or of plan of care that includes provision of designated health services
What is a Referral?

- A referral is not a DHS personally performed by a physician.
- A referral does not include a request by:
  - Pathologists for clinical diagnostic laboratory tests and pathological examination services
  - Radiologists for diagnostic radiology services
  - Radiation Oncologists for Radiation Therapy
- If the request for such additional services results from a consultation initiated by another physician.
Designated Health Services

- **Designated Health Services** include:
  - Clinical laboratory services;
  - Physical therapy and occupational therapy services;
  - Radiology or other diagnostic services (including MRI, CAT scans);
  - Radiation therapy services;
  - Durable medical equipment;
  - Parental and enteral nutrients, equipment and supplies;
  - Prosthetics, orthotics and prosthetic devices;
  - Home health services;
  - Outpatient prescription drugs; and
  - Inpatient and outpatient hospital services (encompassing almost every type of medical procedure).

- **Note:** *Ambulatory Surgery Centers services are not DHS!*
What is a DHS Entity?

- Entity that bills for DHS service
- Entity that performs DHS service
  - “Perform” is given common meaning
What Is a Financial Relationship?

A *Financial Relationship* includes:

- **Ownership interests**
  - Through equity, debt, compensation or other means; and
- **Compensation arrangements**
  - Includes virtually any form of direct or indirect *remuneration* (i.e., personal service contracts, medical directorships, lease agreements, consulting arrangements, medical service provider arrangements)
What Is a Financial Relationship?

Remuneration is defined (42 CFR§ 411.351) as “any payment or other benefit made directly or indirectly, overtly or covertly, in cash or in kind …”
What Is a Financial Relationship?

Benefits:
- Payments for services rendered
- Use of space
- Use of personnel
- CME
- Dinners
- Trinkets
- Parking
Nature of Exceptions

If Financial Relationship exists with an Entity, and patients are being Referred for Designated Health Service, then activity must either comply with an exception or the activity is illegal.
Exceptions

- Permitted **Ownership** and Compensation Arrangements:
  - Physician Services
  - In-office Ancillary Services
  - Services to Members of Prepaid Health Plans
  - Academic Medical Centers
  - Implants Furnished by ASC
  - Dialysis-related Drugs Furnished by End Stage Renal Disease Facility
  - Preventative Screening Tests, Immunizations and Vaccines
  - Eyeglasses and Contact Lenses Following Cataract Surgery
  - Intra-family Rural Referrals*

*New Phase II (7/26/04 effective date)*
Exceptions

- Permitted **Ownership** Interests:
  - Publicly-traded securities
  - Mutual Fund Investment
  - Rural Provider (75% of DHS to Rural Residents)
  - Hospitals in Puerto Rico
  - Hospital Ownership (whole, not department or floor)
    - Applies only to Physician-owned hospitals up to December 31, 2010 – such hospitals cannot i) Expand physician ownership percentage, or ii) Expand capacity such as patient rooms, procedure rooms, etc.
Exceptions

• Permitted Compensation Arrangements:
  - Rental of Office Space
  - Rental of Equipment
  - Employment Relationships
  - Personal Service Arrangement
  - Physician Recruitment
  - Isolated Transactions
  - Services Unrelated to Provision of Designated Health Services
  - Hospital-affiliated Group Practice Arrangements
  - Fair Market Value Payments Made by Physicians for Items and Services (i.e., clinical laboratory services)
Exceptions

• Permitted Compensation Arrangements:
  - Charitable Donations by Physician
  - Non-monetary Compensation (Benefits) up to $385 Per Year
  - Fair Market Value Compensation
  - Medical Staff Incidental Benefits
  - Risk-sharing Arrangements (i.e., withholds, bonuses, risk pools)
  - Compliance Training
  - Indirect Compensation Arrangements
  - Referral Services
Exceptions

• Permitted *Compensation* Arrangements:
  - Obstetrical Malpractice Insurance Subsidies
  - Professional Courtesy
  - Retention Payments in Underserved Areas
  - Community-wide Health Information Systems
  - Electronic Prescribing Items and Services
  - Electronic Health Records Items and Services
Group Practice Definition
Not Exception
Group Practice Definition

• To qualify as a *group practice*, the professional services must be performed:
  - Personally by another physician who is in same “group practice” as referring physician or
  - Under personal supervision of referring physician or another physician who is in same group practice
Criteria of Group Practice

- **Group practice** means a group of two or more physicians *legally organized* as a partnership, professional corporation, faculty practice plan or similar association where
  - Each physician in group provides substantially the **full range of services** that physician routinely provides (including medical care, consultation, diagnosis or treatment)
  - Professional services provided through **joint use** of shared office space, facilities, equipment and personnel
Criteria of Group Practice

- Substantially (75%+) of each physician member’s patient care services are provided through group (Must be able to document through time cards, personal schedules, etc.);
  - Must meet within 12 months of formation or 12 months of new physician relocating (25 miles+) to join group.
- All services are billed under group’s billing number
- All income is treated as receipts of group
- Overhead expenses and income from practice are distributed in accordance with previously determined methods
Member of Group Practice v. Physician in Group Practice

• Independent Contractors are Physicians in Group Practice but not Members of Group Practice

• Issues:
  - Range of Care—Members only
  - 75% Test—Members only
  - Productivity Bonuses and Profit-Share—All, including Independent Contractors
Criteria of Group Practice

- No physician in group may directly or indirectly receive compensation based on *volume or value of referrals* by physician. (However, physician may be paid share of overall profits or productivity bonus based on services personally performed or services incident to such personally performed services.)
Criteria of Group Practice

• Share of profits will not be related to volume or value of referrals if one of the following conditions is met:
  ➢ Profits divided per capita (i.e., equal share per physician in group);
  ➢ DHS revenues are distributed in the same manner as non-DHS revenues from any federal health care program or private payor; or
  ➢ DHS revenues for group practice is less than 5% of group practices’ total revenue and those revenues allocated to each physician in the group is 5% or less of each physician’s total compensation from the group.
Criteria of Group Practice

Permitted:

Patient → $ → GROUP PRACTICE

DHS $ Pooled → %of $ → DR.

Distribution of Profit from DHS Should Reflect Pooling
Criteria of Group Practice

Group Practice

Can Pool Profits from DHS Into Components If Each Component Has at Least 5 Physicians
Criteria of Group Practice

Not Permitted:

$ Passes Through

Group Practice Cannot Be Used To Pay Physician Directly for DHS Ordered
<table>
<thead>
<tr>
<th>Terms of exception</th>
<th>Group practice physicians [1877(h)(4); 411.352]</th>
<th>Bona Fide employment [1877(e)(2); 411.357(c)]</th>
<th>Personal service arrangements [1877(e)(3); 411.357(d)]</th>
<th>Fair market value [411.357(1)]</th>
<th>Academic medical centers [411.355(e)]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Are overall profit shares allowed?</td>
<td>Yes—1877(h)(4)(B)(i) .........................</td>
<td>No ................................................................</td>
<td>No ................................................................</td>
<td>No ................................................................</td>
<td>No ................................................................</td>
</tr>
<tr>
<td>Written agreement required?</td>
<td>No ................................................................</td>
<td>No ................................................................</td>
<td>Yes, minimum 1 year term. ........................</td>
<td>Yes, written agreement(s) or other document(s). .........................</td>
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<td>Physician incentive plan (PIP) exception for services to plan enrollees?</td>
<td>No, but risk-sharing arrangement exception at 411.357(n) may apply.</td>
<td>No, but risk-sharing arrangement exception at 411.357(n) may apply.</td>
<td>Yes, and risk-sharing arrangement exception at 411.357(n) may also apply.</td>
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Direct Compensation Arrangement Created in Phase III with Physicians and their Physician Organizations

• “Stand in the Shoes”

  42 CFR 411.354 (c) (ii) - A physician is deemed to have a direct compensation arrangement with an entity furnishing DHS if the only intervening entity between the physician and the entity furnishing DHS is his or her physician organization. In such situations, for purposes of this section, the physician is deemed to stand in the shoes of the physician organization.
Direct Compensation Arrangement Created in Phase III with Physicians and their Physician Organizations

“Stand in the Shoes” continued

Pre-Phase III View

Physician

$ 

Group

$ Indirect

Hospital

Phase III View

Physician Organization

$ Direct

Hospital
Direct Compensation Arrangement Created in Phase III with Physicians and their Physician Organizations

• “Stand in the Shoes” continued
  - Implemented due to CMS’s concern that arrangements between DHS entities and group practices are often viewed as outside the application of the Stark Law
    - For example, an arrangement that did not meet the Stark Law’s definition of a direct compensation arrangement and that also failed to meet one of the prongs of the indirect compensation arrangement definition may allow a physician to make referrals to the entity for the furnishing of DHS without violating the Stark Law’s referral prohibition
  - Phase III definition applies to new arrangements or renewals entered into after September 5, 2007
  - Grandfather provision for arrangements that were “properly structured to comply with the indirect compensation arrangements exception”
Physician can refer designated health services if such services are performed by a physician in the referring physician’s group practice.
Physician Services Exception
(Applied to *Ownership* and *Compensation* Arrangements)
Physician Services Exception
(Applied to Ownership and Compensation Arrangements)

(Incident-to services performed by non-physician under Referring Physician’s Supervision)*

*Must meet all supervision requirements in payment coverage rules. Only incident-to services that are defined as physician services under 42 C.F.R. § 410.20(a). Does not include incident-to services like diagnostic tests, physical therapy, etc.
In-Office Ancillary Services Exception
(Applies To Ownership and Compensation Relationship)

Must answer 3 questions:

Who?

How?

Where?
In-Office Ancillary Services Exception
(Applies To Ownership and Compensation Relationship)

• Who May Provide Services?
  ➢ Referring physician;
  ➢ Physician who is member of same group practice as referring physician;
  ➢ Individuals who are directly supervised by physician or another physician in same group practice; and
  ➢ Physicians in the group practice such as employees and independent contractors of group practice
In-Office Ancillary Services Exception
(Appplies To Ownership and Compensation Relationship)

Where are services provided?

Same building
or
Centralized building
In-Office Ancillary Services Exception
(Applies To Ownership and Compensation Relationship)

Where are services provided?

- **Same Building**, which is defined as a structure with a single street address assigned by the U.S. Postal Service, *not including* interior loading docks, mobile vehicles, vans or trailers that meet one of the following three tests:
  
  1) The physician or group practice has an office that is open to the group’s patients for medical services at least 35 hours per week and a member of the group provides physician services (including non-DHS services) to patients at least 30 hours per week
In-Office Ancillary Services Exception
(Appplies To Ownership and Compensation Relationship)

Where are services provided?

• Same Building (Continued)
  
  2) Referring physician’s group owns or rents an office that is normally open to patients for medical services at least 8 hours per week and referring physician provides physician services (include non-DHS services) to patients at this office at least 6 hours per week
  
  3) Referring physician’s group owns or rents an office that is normally open to patients for medical services at least 8 hours per week, either referring physician orders DHS services while seeing the patient on the premises or a member of referring physician’s group practice is on premises when DHS is performed and referring physician or member of group practices at site at least 6 hours per week
Where are services provided?

A Centralized Building, which means all or part of a building that is owned or leased on a full-time basis by a group practice including a mobile vehicle, van or trailer where some or all of the group practices DHS is provided.
In-Office Ancillary Services Exception
(Appplies To Ownership and Compensation Relationship)

Not Covered By Exception

Given to Patient in Physician’s Office But Intended To Be Used at *home* or *outside*
Physician’s Office
How Are Services Billed?

- By physician performing or supervising services
- By *group practice* of which such physician is member, employee or independent contractor under billing number assigned to *group practice*; or
- By entity that is wholly owned by such physician or such *group practice*
In-Office Ancillary Services Exception
(Appplies To Ownership and Compensation Relationship)

Supervision

- In Phase III, CMS stated that because of the supervision requirements, per-use fee arrangements may not work. May have to use block time arrangements. See page 51033 of the Phase III regulations.
In-Office Ancillary Services: How Are Services Billed?

DME

- **How** is equipment used by patient?
- Durable medical equipment ("DME"), like canes, crutches, walkers, blood glucose monitors, can be subject to in-office ancillary exception if:
  - the DME is required by the patient to depart from the physician’s office, or is a blood glucose monitor
  - it is furnished in the *same building* as the patient-physician encounter; and
  - the DME is furnished personally by the physician, a physician in the same group practice, or an employee of the same group practice
IOAS Exception: Notification Requirements

Key Provisions

- Applies only to MRI, CT and PET
  - CMS has not extended to any other radiology services under PPACA specific authority
  - CMS did not use its section 1877(b)(4) authority to extend to other DHS
- Notice of 5 other suppliers of service
- Physician groups need not identify hospital competitors
- Applies to services furnished on or after January 1, 2011
Intra-Family Rural Referrals
(Applies To Ownership and Compensation Relationship)

- Permits physician to refer patients for DHS to immediate family member (or to entity with which immediate family member has financial relationship) when several conditions are met including:
  - Patient resides in rural area
  - No other person or entity is available within 25 miles of patient’s residence
    - Phase III incorporates alternative test of 45 minutes transportation time from beneficiary’s residence
    - Physician free to select either test
Intra-Family Rural Referrals  
(Applies To Ownership and Compensation Relationship)

- However, test chosen must also be applied to make reasonable inquiry as to availability of services requirement
- CMS (in preamble) states that if 45 minute standard is utilized physician should maintain documentation of information used in determining transportation time (for example Mapquest) and published weather reports should be consulted

- Financial relationship does not violate anti-kickback statute
- Referring physician (or immediate family member) makes reasonable inquiry as to availability of services of other persons/entities to furnish DHS

Note: Quality of available provider cannot be considered.
Captain Integrity

I have a deal for you Dr. Smith. You can be our Medical Director. We will pay you $10,000 and you don't have to do much!

I thought I had to perform services equal to the pay received!

Dr. Smith is correct. We can pay physicians only fair market value for services actually performed!
Personal Service Arrangement Exception
(Applies to Compensation Relationships)

- Remuneration paid under personal service arrangement is not prohibited compensation arrangement if:
  - Arrangement is set out in *writing*, signed by parties and specifies services covered by arrangement
  - Arrangement *covers all services* to be provided by physician to entity
    - This condition is met if contract:
      » References all other arrangements; or
      » References *master list* of contracts that is maintained with historical record of all arrangements
  - Term for at least *one year*
Personal Service Arrangement Exception
(Applies To Ownership and Compensation Relationship)

- Services are *reasonable* and *necessary*;
- Compensation to be paid over term of arrangement is set in *advance*, does not exceed *FMV*, is *reasonable* and determined through *arm’s length negations*, and is not determined in manner which takes into account volume or value of referrals between parties.
Personal Service Arrangement Exception
(Applies To Ownership and Compensation Relationship)

- Hold over month-to-month following a term of at least one year, assuming all other provisions of the exception are met, continuing on a month-to-month basis for up to 6 months as long as the terms during the hold over period are fair market value will meet the personal service arrangement exception
Doctor, we can lease office space to you at below market rates.

I thought all leases had to be at fair market value.

All leases must be at fair market value.
Below market rates cannot be offered.
Rental of Office Space and Equipment Exception
(Applies to Compensation Relationships)

- Payments made by lessee to lessor for use of equipment and premises is not prohibited compensation if:
  - Lease is signed in writing, and specifies premises and equipment to be leased
  - Space and equipment rented does not exceed that which is reasonable and necessary for legitimate business purposes of lease and is used exclusively by lessee when being leased by lessee
Rental of Office Space and Equipment Exception  
(Applies to Compensation Relationships)

- Term of lease is for at least one year
- Rental charges over term of lease are set in advance, consistent with fair market value, and not determined in a manner that takes into account volume or value of referrals or other business generated between parties; and
- Lease would be commercially reasonable even if no referrals were made between parties
Rental of Office Space and Equipment Exception
(*Applies to Compensation Relationships*)

- Hold over month-to-month following a term of at least one year, assuming all other provisions of the exception are met, continuing on a month-to-month basis for up to 6 months as long as the terms during the hold over period are fair market value will meet the rental of office space and equipment exceptions.
Rental of Office Space and Equipment Exception
(Appplies to Compensation Relationships)

• Cannot base compensation on
  ➢ “Per click” if physician/owner is source of referral, or
  ➢ Percentage
Captain Integrity™

What is Dr. Jones doing in Suite 100?

She's allowed to see her patients in there one day a week?

Did she sign a contract?

No. Why, do we need one?

Yes, a contract is needed, even if a physician uses the space only one day a week to see their patients.

Contact your compliance officer for investigation.
One Year Requirement

- Agreement can be terminated within the first year with or without cause as long as the parties do not enter into a new agreement during the first year of the original term.
Captain Integrity™

I want more money or I won't be your employed physician!

But that would be above fair market value.

I don't care! If you don't pay me what I want, I will never refer to you again!

All payments to physicians must be at fair market value.

Fair market value should be well documented and be contained in a written contract.
Bona Fide Employment Exception
(Appplies to Compensation Relationships)

- Employment is for identifiable services;
- Amount of remuneration under employment is:
  - Consistent with *fair market value, reasonable* and determined through *arm’s length negotiations*
  - Not determined in manner which takes into account volume or value of referrals by referring physician; and
  - Remuneration is provided pursuant to agreement that would be commercially reasonable *even if no referrals* were made to employer
Bona Fide Employment Exception
(Appplies to Compensation Relationships)

- Productivity bonuses can be paid if based on services *performed personally* by the physician (i.e., worked RVUs)
Bona Fide Employment Exception
(Applies to Compensation Relationships)

• Requiring referrals
• An employer can require an employee to refer to a particular provider, practitioner or supplier so long as:
  ➢ the compensation is set in advance
  ➢ the compensation is fair market value
  ➢ the referral requirement
    • is in writing signed by the parties
    • is not required if the patient expresses a preference for a different provider
    • does not require physician to refer if patients’ insurance does not cover services at required providers
    • does not require physician to refer if the physician believes that the required referral is not in the patient’s best medical interest
• Requiring referrals (Continued)
  - The required referrals relate *solely* to the physician’s services covered by the scope of the employment and the referral requirement is reasonably necessary for the legitimate business purposes of the compensation arrangement between the employer and the employee.
Physician Recruitment Exception
(Appplies to Compensation Relationships)

• Remuneration can be paid by hospital to physician to induce physician to relocate their practice to geographic area served by hospital if:
  ➢ Arrangement is set out in writing and signed by the parties
  ➢ Arrangement is not conditioned upon physician’s referral of patients to recruiting hospital
  ➢ Remuneration is not based on volume or value of any actual or anticipated referrals by physician to the hospital
  ➢ Physician is allowed to establish staff privileges at any other hospital and may refer business to other DHS entities

Note: This exception specifically references the referral requirement if a separate employment agreement with the physician requires the referrals
Physician Recruitment Exception
(Applies to Compensation Relationships)

- Note that the exception does not specifically state that the remuneration paid must be *fair market value* or *commercially reasonable*
- The intention and purpose of the payment, however, must solely be to induce the physician to relocate their practice, nothing more, nothing less
Physician Recruitment Exception
(Applies to Compensation Relationships)

Dr., what would it take for you to relocate your practice?
Physician Recruitment Exception
(Applies to Compensation Relationships)

- A physician will be considered to have relocated their medical practice if:
  - Physician moves their medical practice at least 25 miles into the “geographic area served by the hospital”; or
  - Physician’s new medical practice derives at least 75% of its revenues from professional services not seen or treated by the physician at their prior medical practice site during the preceding three years.
Physician Recruitment Exception
(Applies to Compensation Relationships)

- The “geographic area served by the hospital” consists of the lowest number of contiguous zip codes from which the hospital draws at least 75% of its inpatients

  - The “geographic area served by the hospital” can include zip codes from which the hospital draws zero patients as long as such zip codes are surrounded by contiguous zip codes that meet the 75% test

  - The “geographic area served by the hospital” can be lower than 75% if the contiguous zip codes cannot add up to 75%
Physician Recruitment Exception
(Applies to Compensation Relationships)

- Relocation requirement not required for i) residents, and ii) physicians who have been in practice one year or less.
- Relocation requirement not required for full-time physicians who have been employed for at least 2 years do not need to relocate if they worked for i) Federal or State Bureau of Prisons, ii) Department of Defense or Department of Veterans Affairs; or iii) an Indian health service facility
Physician Recruitment Exception
(Appplies to *Compensation Relationships*)

- Recruited physician may join *existing practice* if:
  - A written agreement is signed by party to whom payments are directly made
  - Except for actual recruiting costs, all remuneration is passed through to the recruited physician
  - Income guarantee can only apply to the *actual additional incremental costs* allocated to recruit
Physician Recruitment Exception
(Applies to Compensation Relationships)

- All records maintained for at least 5 years
- Remuneration from hospital not determined by volume or value of actual or anticipated referrals from the practice
- Practice imposes no unreasonable practice restrictions on recruit
Doctor Smith, if we recruit you to move to Megatown, will you refer all of your patients to us?

I want to move, but I don’t know if I’m comfortable with your request.

We don’t have to document this understanding.

I think this is a compliance issue.

Dr. Smith is right. A hospital cannot require a physician’s referrals in a recruitment arrangement.
Physician Recruitment Exception
(Applies to Compensation Relationships)

• **Reasonable practice restrictions.** Physician groups can place restrictions on recruited physicians as long as the restrictions do not unreasonably restrict the recruited physician’s ability to practice in the geographic area. CMS, in the preamble, concluded that such restrictions may include the following:
  1) Restrictions on moonlighting
  2) Prohibitions on solicitation of patients and/or employees
  3) Requiring the recruited physician to repay losses
  4) Requiring the recruited physician to pay reasonable damages if the physician leaves the practice
  5) Limited, reasonable, non-compete clauses

• **NOTE:** Non-competes that are enforceable by state law are not per se reasonable. Non-competes that violate state law would unreasonably restrict the recruited physician
Physician Recruitment Exception
(Appplies to Compensation Relationships)

- Medical practices outside of geographic area in rural areas.
  - Hospitals in rural areas can establish a recruited physician’s medical practice outside of the “geographic area served by the hospital” as long as the hospital obtains an advisory opinion.
Physician Recruitment Exception
(Applies to Compensation Relationships)

• Recruitment to HPSA
  ➢ If a physician is relocating to a HPSA to replace a physician who, within the previous 12 months, retired, relocated outside of the geographic area, or died, if the physician joins an existing group, for allocation of expenses, the group can use the lower of a per capita allocation or 20% of the practice’s aggregate cost
Isolated Transaction Exception
(Applies to Compensation Relationships)

- Definition of compensation does not include isolated financial transactions, such as one-time sale of property or practice, if:

- Amount of remuneration is:
  - Consistent with FMV, is reasonable and determined through arm’s length negotiations;
  - is not determined in manner that takes into account volume or value of referrals by referring physician; and
  - Remuneration is provided pursuant to agreement that would be commercially reasonable even if no referrals were made to purchaser.

- No other transactions between parties for 6 months after isolated transaction
Charitable Donation By A Physician Exception
(Appplies to Compensation Relationships)

• Bona fide charitable donations by a physician to a DHS entity is permitted if:
  ➢ Donation is made to a tax-exempt organization; and
  ➢ Donation is neither solicited, or made, in any manner that takes into account the volume or value of referrals generated between the parties
Non-Monetary Compensation Exception
(Appplies to Compensation Relationships)

- Compensation (defined as *any benefit*), not including cash or cash equivalents (i.e., gift certificates that may be redeemed in whole or in part for cash), may not exceed an aggregate of $385 per year per physician as long as:
  - Benefit is not determined based upon volume or value of referrals
  - Benefit is not solicited by physician or anyone affiliated with their practice
  - Maximum cannot be aggregated to make a larger gift to a group
Non-Monetary Compensation Exception
(Applies to Compensation Relationships)

- The current $385 limit is updated annually.
- See:
  - www.cms.hhs.gov/PhysicianSelfReferral/
- See also:
  - http://www.kriegdevault.com/info/stark-act
Non-Monetary Compensation Exception  
(Applies to Compensation Relationships)

- If a hospital inadvertently exceeds the annual limit, the hospital will still be deemed to be in compliance if i) the value of the excess is no more than 50% of the limit, and ii) the physician returns the excess by the end of the calendar year or within 180 consecutive calendar days, whichever is earlier
  - NOTE: Can only be used once every 3 years
- Hospitals can now hold 1 formal medical staff event per year without including the cost in this exception
Non-Monetary Compensation Exception
(Appplies to Compensation Relationships)

• For example:
  - Cannot give $1,000 oil painting to 5 physician group and allocate $200 to each physician
Non-Monetary Compensation Exception
(Appplies to Compensation Relationships)

• Preamble, on Page 16112 of Phase II, stated that “[the Medical Staff Incidental Benefits Exception] was not intended to cover the provision of tangential, off-site benefits, such as restaurant dinners or theater tickets, which must comply with the exception for non-monetary compensation up to $385.” (emphasis added)
“[F]ree CME could constitute remuneration to the physician depending on the content of the program and the physician’s obligation to acquire CME credits.”

Phase II, page 16114
Fair Market Value Exception
(Applies to Compensation Relationships)

- Payments that are fair market value are permitted compensation arrangements if:
  - In writing
  - Covers all arrangements between parties
  - Does not have to be 1 year term as long as terms and conditions do not change during 1 year
Fair Market Value Exception
(Applies to Compensation Relationships)

- Compensation set in advance, FMV, and not related to volume or value of referrals
- Commercially reasonable and furthers legitimate business interests
- Complies with fraud and abuse provisions

• Note: Applies to payments by i) DHS entity to physician, and ii) physician to DHS entity. Also cannot base compensation on
  - 1) “per click” if physician/owner is source of referral or
  - 2) percentage
Medical Staff Incidental Benefits Exception
(Applies to Compensation Relationships)

- Items or services used on the hospital's campus may be given to members of its medical staff if:
  - Item or service is provided to all members in the same specialty without regard to volume or value of referrals
  - Item or service is provided only during periods when the medical staff members are making rounds or involved in other services that benefit the hospital and its patients
Medical Staff Incidental Benefits Exception
(Applies to Compensation Relationships)

- The item or service is reasonably related to the delivery of medical services at the hospital
- Each item or service is less than $32 per benefit (updated annually)
The exception specifically recognizes that “internet access, pagers, or two-way radios, used away from the campus only to access hospital medical records or information or to access patients or personnel who are on the hospital campus, as well as the identification of the medical staff on a hospital Web-site or in hospital advertising, will meet the single “on campus” requirement…. (emphasis added)
Compliance Training Exception
(Appplies to Compensation Relationships)

• Compliance training to physicians in the local community or service area is permitted if it is related to:
  ➢ Basic elements of a Compliance Program
  ➢ Specific training regarding, billing, coding, documentation, and physician arrangements
  ➢ Other laws, rules and regulations governing the conduct of the parties

• Note: Does include continuing medical education
Indirect Compensation Arrangement Exception (Applies to Compensation Relationships)

The Definition:
An indirect compensation arrangement is any series of ownership or investment interest or compensation arrangements, and the compensation arrangement closest to the referring physician, in the **aggregate**, varies based upon the volume or value of referrals. For example:

- **Own**: A
- **Own**: B
- **Compensation**: C
- **Compensation**: D

**Aggregate varies on volume/value**

DHS Entity
Indirect Compensation Arrangement Exception (Applies to Compensation Relationships)

The Exception:
The individual payment of the compensation arrangement that is closest to the referring physician (in the example below, the compensation between company B and C) must be fair market value.

Individual payments are FMV

Note: Cannot base compensation on i) “per click” if physician/owner is source of referral; or ii) for percentage

Also, arrangement must be in writing!
Professional Courtesy Exception
(Applies to Compensation Relationships)

• Professional courtesy offered to a physician or a physician’s immediate family member or office staff is permissible if all of the following conditions are met:
  ➢ Professional courtesy is offered without regard to the volume or value of referrals
  ➢ The health care services are routinely provided by the DHS entity
  ➢ A professional courtesy policy is set out in writing and approved in advance by the governing body
  ➢ Professional courtesy is not offered to a Medicare/Medicaid beneficiary (except in the case of financial need)
Retention Payments In Underserved Areas Exception (Applies to Compensation Relationships)

- Hospital may provide benefits to a physician to retain the physician's medical practice in the geographic area served by the hospital if:
  - The arrangement meets all of the Recruitment Exception requirements for a new recruit establishing a solo practice.
  - The hospital is in a health professional shortage area ("HPSA") or is in an area deemed to be in need by the Secretary of DHHS in an advisory opinion.
Retention Payments In Underserved Areas Exception (Applies to Compensation Relationships)

- Also applies to rural health clinics
- Physician has a i) *bona fide* and firm written offer, or ii) physician can certify offer that
  - Offer received from an unrelated hospital
  - Remuneration offered is disclosed
  - Requires physician to move practice 25 miles or more and outside the geographic area of the hospital
Retention Payments In Underserved Areas Exception
(Applies to Compensation Relationships)

- If subject to a *bona fide* written offer, payment is limited to the lower of
  - Difference between the physician's current income and income proposed by offer for 24 months; or
  - Reasonable cost to recruit a replacement.

- If subject to physician’s written certification, payment is limited to the lower of
  - 25% of the physician’s current income; or
  - The reasonable cost the hospital would have to expend to recruit a new physician.

- Only one retention agreement every five years for same physician
Due to the recognition of a retention payment for the HPSA, no retention payment can be made outside a HPSA (without seeking advisory opinion)
Community-Wide Health Information System Exception
(Appplies to Compensation Relationships)

- Items or services of information technology can be provided to a physician to allow access to and sharing of electronic health care records if:
  - The items or services are necessary to enable the physician to participate in a community-wide health information system
  - The items or services are required to be used principally as part of the community-wide health information system
  - The items or services are not provided based upon the volume or value of referrals
  - The community-wide health information system available to all providers, practitioners and residents of the community who desire to participate
Reporting Requirements

• DHS entities must submit information in form, manner and times specified by CMS or OIG but not less than 30 days.

• Required information
  ➢ Name and UPIN of each physician and family member with financial relationship (except publicly traded and mutual fund shareholders)
  ➢ Nature of financial relationship “as evidenced in records entity knows or should know about in the course of prudently conducting business (e.g., IRS, SEC, Medicare record keeping requirements)
  ➢ DHS services provided by entity

• Penalty of $10,000/day for failure to comply on date
March 24, 2009
OIG Opinion Letter

- Use Self-Disclosure Protocol (SDP) only for:
  - Anti-Kickback issues
  - Minimum settlement amount of $50,000
- For pure Stark Law violations:
  - Fiscal Intermediary/Carriers/Medicare Administrative Contractors
  - Department of Justice
  - Simple reprocessing of claims
Self-Reporting

Effective September 23, 2010, DHHS is required to announce self-reporting process with authority to negotiate settlement
Stark Self-Referral Disclosure Protocol ("SRDP")

- Posted to CMS web site on September 23, 2010
- Not promulgated through notice and comment rulemaking
Self-Referral Disclosure Protocol

• Overpayment must be reported within 60 days of the date the overpayment was *determined* after “reasonable inquiry”

• Original and 1 copy must be mailed to CMS and a copy must be submitted electronically to 1877SRDP@CMS.hhs.gov
Stark Self-Referral Disclosure Protocol ("SRDP")

- Submission must include the following:
  - National provider identification number, CMS certification number, tax identification number
  - Name and address of disclosing entity
  - Nature of matter being disclosed
  - Complete legal analysis regarding why a potential violation of the Stark Law occurred
• Stark Self-Referral Disclosure Protocol (“SRDP”)

  Submission must include the following:
  
  - Circumstances under which the disclosed matter was discovered
  - Disclosure of past criminal, civil, or regulatory enforcement action
  - Description of party’s compliance program and efforts implemented by disclosing party to prevent reoccurrence
Stark Self-Referral Disclosure Protocol ("SRDP")

• Submission must include the following:
  - Notice as to whether disclosing party believes issue is currently under investigation by a government agency or contractor
  - Period of disallowance
  - Financial analysis, itemized by year, of potential amount owed during period of disallowance
Stark Self-Referral Disclosure Protocol ("SRDP")

- Submission must include the following:
  - Certification signed by high ranking officer (CEO, CFO) indicating that the information provided is truthful, to the best of the certificant's knowledge.
Stark Decision Tree

1) Are *Referrals* made?

- Yes  Go To 2
- No    Do The Deal
2) Is a *Designated Health Service* involved?

- Yes  Go To 3
- No   Do The Deal
3) Is the recipient of the referrals a **DHS Entity** [bills for or performs the DHS]?

- **Yes** Go To 4
- **No** Do The Deal
4) Does a *Financial Relationship* (ownership and/or compensation) exist with the referring physician?

- **Yes**
  - Go To 5

- **No**
  - Do The Deal
5) Does the relationship qualify, *in all respects*, with an exception?

- Yes
  Do the Deal

- No
Penalty

Denial of payment or refund; civil money penalties (up to $100,000) and exclusions from federal and state programs for improper claims or schemes
Summary
Anti Kickback Statute

• Criminal Statute
• Focus On *Intent* and *Payments*
  ➢ *Reasonable*
  ➢ *Fair Market Value*
  ➢ *Arm’s Length Negotiations*
• Qualify for Safe Harbor or Prove Lack of Intent
Summary
Stark II

• Civil Penalties
• Focus On *Relationships*
  ➢ *Referrals*
  ➢ *Designated Health Services*
  ➢ *Financial Relationships*
• Qualify for Exception or Guilty
• Beware of False Claims Act Liability
Questions