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***UNDERSTANDING AND
WORKING WITH THE
LATEST STARK LAW
DEVELOPMENTS***

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Stark Prohibition

- Physician may not refer:
 - Medicare or Medicaid patients
 - For “designated health services” (DHS)
 - To an “entity” with which the physician or an “immediate family member” has a “financial relationship”;
 - Unless covered by an exception
 - 42 U.S.C. § 1395 nn

Sanctions

- Denial of payment
- Refund of amounts collected due to improper billing
- Civil Money Penalties
- Civil Money Penalties for circumvention schemes
- Exclusion
- Potential False Claims Act Liability

Designated Health Services ("DHS")

- Clinical laboratory services
- Physical therapy, occupational therapy, and speech-language pathology services
- Radiology and certain other imaging services
- Radiation therapy services and supplies
- Durable medical equipment and supplies
- Parenteral and enteral nutrients, equipment and supplies
- Prosthetics, orthotics and prosthetic devices and supplies

DHS - *cont.*

- Home health services
- Outpatient prescription drugs
- Inpatient and outpatient hospital services
- Except: DHS does not include services reimbursed under composite rate: ASC or SNF Part A. [Exception not available for home health services]
- Note: Outpatient speech-language pathology services is now a specific category of DHS

Entity

- A physician's sole practice or a practice of multiple physicians or any other person, sole proprietorship, public or private agency or trust, corporation, partnership, limited liability company, foundation, nonprofit corporation, or unincorporated association that furnishes DHS.

Entity *-cont.*

- Does not include referring physician, but does include his or her medical practice.
- Does not include a physician's practice when it bills Medicare for a purchased diagnostic test.

Entity - *cont.*

- Changed definition of “Entity” at §411.351
 - Prior to October 1, 2009, a person or entity is considered to be furnishing DHS if it is the person or entity to which CMS makes payment for the DHS
 - On and after October 1, 2009, both parties to an arrangement may be considered an “entity” if one party performs DHS and the other party bills for DHS
 - Affects services provided “under arrangements” with DHS entities

Financial Relationship

§411.354

- A direct or indirect ownership or investment interest in an entity that furnishes DHS; or
- A direct or indirect compensation arrangement with an entity that furnishes DHS

Indirect Ownership/Investment

- Unbroken chain of persons or entities between physician and DHS entity
- DHS Entity has actual knowledge (or reckless disregard or deliberate ignorance) of interest

Indirect Compensation

- Unbroken chain of entities between physician and entity
- Aggregate compensation to physician from closest link in chain varies with volume or value or referrals to DHS entity
- Entity furnishing DHS has actual knowledge or acts in reckless disregard of relationship

Direct Compensation: Stand in the Shoes Concept

- Physician *deemed* to have *direct compensation arrangement* with DHS Entity if
 - only intervening entity between the physician and the entity is his or her physician organization; and
 - physician has an ownership or investment interest in the physician organization
- Physician is permitted to “stand in the shoes” of physician organization if only intervening entity between physician and DHS entity is the physician organization
- 42 C.F.R. §411.354 (c)(1)

Stand in the Shoes – *cont.*

- Stand in the Shoes concept does not apply to physician whose ownership or investment interest is ***titular only***.
 - Titular ownership or investment interest is an ownership or investment interest that excludes the ability or right to receive financial benefits of ownership or investment such as distribution of profits, dividends, proceeds of sale, or similar returns on investment.

Referral

- Request/ordering or certifying medical necessity (including tests ordered pursuant to consult)
 - Does not include personally performed services
 - Does not include “incident to” services
- Imputed to physician who “directs” or “controls” person making referral (ex. NPs & PAs)

Referral - *cont.*

- Special rules for pathologists, radiologists and radiation oncologists
 - Ordering additional services is not referral if:
 - Pursuant to request for consultation
 - Physician's opinion sought
 - Request documented on chart
 - Written report delivered
 - Under supervision of consulting physician

Other Key Definitions

“physician organization”

- A physician, a physician practice, or a group practice that complies with the requirements of §411.352
- Term used in applying “Stand in the Shoes” concept

Types of Exceptions

- General - Related to both ownership/investment interests and compensation arrangements (§411.355)
- Related only to ownership or investment interests (§411.356)
- Related only to compensation arrangements (§411.357)

General Exceptions Related to Ownership and Compensation (§411.355)

- Physician Services
- In-office Ancillary Services
- Services Furnished by an Organization to Enrollees
- Academic Medical Centers
- Implants Furnished by ASC
- EPO and Other Dialysis-related Drugs Furnished in ESRD Facility
- Preventive Screening, Immunizations & Vaccines
- Eyeglasses & Contact Lenses following Cataract Surgery
- Intra-family Rural Referrals

Exceptions Related only to Ownership or Investment Interests (§411.356)

- Publicly-traded Securities and Mutual Funds
- Hospitals Located in Puerto Rico
- Rural Providers
- Ownership Interest in a Whole Hospital

Exceptions Related only to Compensation Arrangements (§411.357)

- Rental of Office Space
- Rental of Equipment
- Bona Fide Employment
- Personal Service Arrangements
- Physician Recruitment
- Isolated Transactions
- Remuneration Unrelated to DHS
- Group Practice Arrangements with a Hospital

Exceptions Related only to Compensation Arrangements (§411.357) *cont.*

- Payments by a Physician
- Charitable Donations by a Physician
- Nonmonetary Compensation
- Fair Market Value Compensation
- Medical Staff Incidental Benefits
- Risk-sharing Arrangements
- Compliance Training
- Indirect Compensation Arrangements

Exceptions Related only to Compensation Arrangements (§411.357) *cont.*

- Referral Services
- Obstetrical Malpractice Insurance Subsidies
- Professional Courtesy
- Retention Payments in Underserved Areas
- Community-Wide Health Information

Statutory Framework and Regulatory History

- Section 1877 of Social Security Act, in effect since January 1, 1995
- January 9, 1998 – Proposed rule (63 FR 1659)
- January 4, 2001 – Phase I final rule, effective January 4, 2002 (66 FR 856)
- March 26, 2004 – Phase II interim final rule, effective July 26, 2004 (69 FR 16054)

Regulatory History – *cont.*

- July 12, 2007 – Proposed rule (72 FR 38122,38179)
- September 5, 2007 – Phase III final rule, effective December 4, 2007 (72 FR 51012)
- November 15, 2007 – Final rule delaying effective date of “stand in the shoes” provisions of certain compensation arrangements (72 FR 64161)
- April 30, 2008 – Proposed rule (73 FR 23683)
- August 19, 2008 – Final rule (73 FR 48434)

Significant Issues in Final Rule

- Effective October 1, 2008
 - Burden of Proof
 - Period of Disallowance
 - Physician “Stand in the Shoes” provisions
 - Alternative method of compliance for missing signatures
 - Revisions to obstetrical malpractice insurance subsidies
 - Ownership/investment interest in retirement plans

Significant Issues in Final Rule - *cont.*

- Effective October 1, 2009
 - Percentage-based compensation formulae prohibitions addressing exceptions applicable to office space and equipment lease arrangements
 - Prohibition of certain unit-of-service (“per-click”) payments in lease arrangements
 - Revisions to definition of “Entity”) (referred to as “services provided ‘under arrangements’” proposal)

Burden of Proof

- Burden of proof at each level of appeal is on provider submitting claim for payment
- Must establish that service was not furnished pursuant to prohibited referral
- Burden of production is initially on claimant; but may shift to CMS or its contractors

Period of Disallowance

- Begins when financial relationship fails to satisfy applicable exception
- Ends no later than:
 - Date financial relationship satisfies exception (where not related to compensation); or
 - Date excess compensation is returned by party that received it, or if additional compensation is owed, on the date additional compensation is paid by party owing it, and all other requirements of exception are met

Stand in the Shoes

- Physician deemed to Stand in the Shoes of his or her Physician Organization if the physician has an ownership or investment interest in the Physician Organization
 - Exception: Physician with “Titular” only ownership or investment interest

Alternative Method of Compliance: Missing Signatures

- Grace period to obtain signatures on written agreement of
 - 90 consecutive calendar days for “inadvertent noncompliance” with signature requirement
 - 30 consecutive calendar days for knowing noncompliance with signature requirement

Obstetrical Malpractice Insurance Subsidy

- Retains existing exception that incorporates Anti-kickback Safe Harbor
 - Applies to subsidies provided by any entity
- Provides alternative criteria - §411.357(r)(2)
 - Applies to subsidies provided by hospitals, FQHCs and rural health clinics

OB Malpractice Insurance Subsidy - *cont.*

§411.357(r)(2)

- Physician's practice is
 - Located in rural area, primary care HPSA, or area with demonstrated need for OB services (determined by CMS Adv. Op.), or
 - At least 75 % of OB patients of practice reside in MUA or are a medically underserved population
- Arrangement is
 - In writing, signed by parties, specifies payments and terms
 - Not conditioned on referrals
 - Payment amount not determined based on volume or value of referrals or other business

OB Malpractice Insurance Subsidy - *cont.*

§411.357(r)(2)

- Physician allowed to establish staff privileges at any hospital, FQHC or rural health clinic
- Payment made to organization providing insurance
- Physician treats Federal program OB patients in nondiscriminatory manner
- Bona Fide insurance
- Not violate Anti-kickback Law or other laws governing billing or claims submissions

Ownership/Investment Interest in Retirement Plan

- Clarifies exception from definition of “ownership”
- Excepts: Interest in entity that arises from retirement plan offered by entity to physician (or immediate family member) through physician’s (or family member’s) employment with that entity
- Does not protect MD referrals to DHS Entity owned by Group Practice’s retirement plan

Percentage-based Compensation: Office Space and Equipment Leases

- Rental charges can not be determined using formula based on –
 - Percentage of revenue raised, earned, billed, collected, or otherwise attributable to services performed on or business generated
 - in the office space or
 - by the use of the equipment

Percentage-based Compensation: Office Space and Equipment Leases

- Amends four compensation exceptions
 - Office space lease arrangements
 - Equipment lease arrangements
 - Fair market value compensation arrangements
 - Indirect compensation arrangements

Percentage-based Compensation

- Applies only to office space and equipment leases
- Still allowed for
 - personal services arrangements,
 - management contracts
 - physician compensation

Per Click Payments: Office Space and Equipment Leases

- Rental charges for rental of office space or equipment can not be determined using a formula based on –
 - Per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred between the parties

Per Click Payments: Office Space and Equipment Leases

- Includes both physician as lessor and DHS entity as lessor
- Amends four compensation exceptions
 - Office space lease arrangements
 - Equipment lease arrangements
 - Fair market value compensation arrangements
 - Indirect compensation arrangements

Per Click Payments: Office Space and Equipment Leases

- CMS intends to monitor block leases
- Caution: Block lease could be considered a “per click” payment depending on length of time for block use and number of procedures which can be done during block time

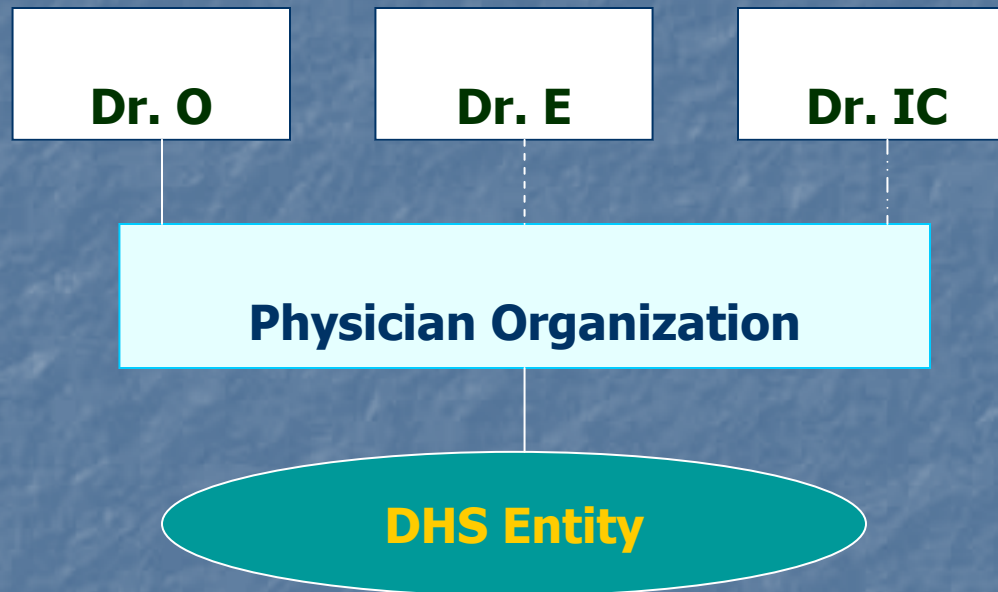
Services Provided “Under Arrangements”

- Under revised definition of Entity, a person or entity is considered to be furnishing DHS if it –
 - Is the person or entity that has ***performed services***, that are billed as DHS to which CMS makes payment for the DHS, directly or upon assignment on patient’s behalf; or
 - Is the person or entity that has ***presented a claim*** to Medicare for the DHS

Hypothetical Discussions

- Stand in the Shoes
- Definition of Entity – Services Under Arrangement
- Per Click and Percentage-based Leases
- Period of Disallowance

“Stand in the Shoes” (SITS)



O – “Owner”

Stand in the Shoes is Mandatory

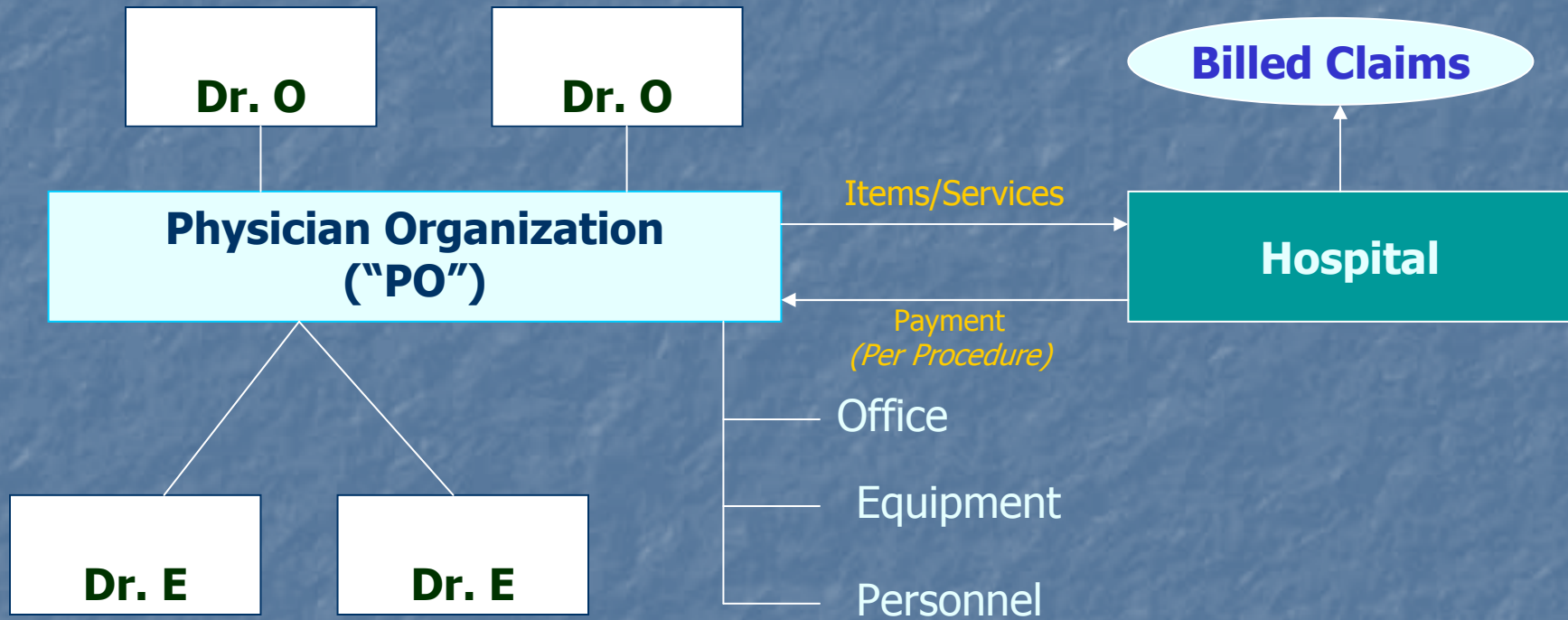
E – “Employee”

Permissive SITS or analyze using indirect compensation rules

IC – “Independent Contractor”

Same as “Employee”

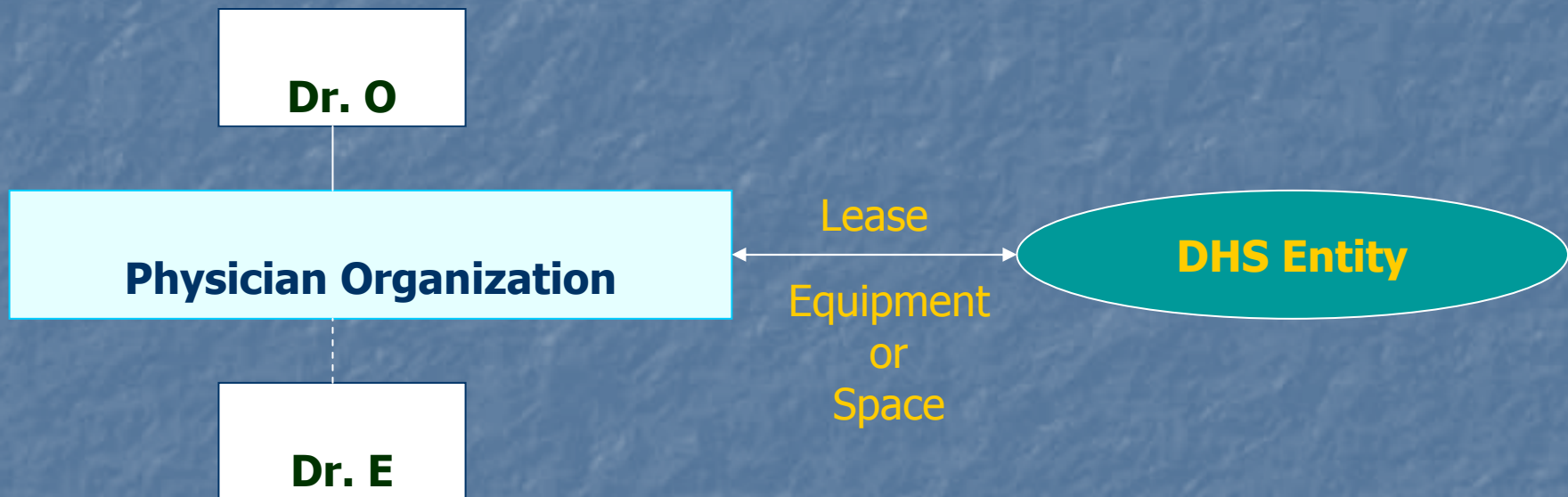
Services Under Arrangement



PO Becomes DHS Entity

No exception for Physician Ownership

Per Click or Percentage Based Leases: Direct Compensation



Analyze Physician ownership as Direct Compensation Arrangement under SITS

Direct lease exceptions do not allow per click or percentage compensation

Per Click or Percentage Based Leases: Indirect Rules



Analyze under Indirect Rules; SITS does not apply

Indirect Rules do not allow leases to have per click or percentage compensation

Examples of Periods of Disallowance

**Date Stark
Compliant Contract
Expires**

**End 6 month
holdover for lease
and personal services**

**New Contract
Signed**

Period of Disallowance

**Doctor begins Call
Coverage**

**Contract Signed 6
months later**

Period of Disallowance

Examples of Periods of Disallowance *cont.*



Disclosure of Financial Relationships Report

- Collection Instrument used to
 - Identify arrangements that potentially may not be in compliance with Stark Law and regulations
 - Identify practices to assist CMS in future rulemaking
- Status of Distribution to Hospitals

Reporting Requirements - §411.361

- All entities furnishing services for which payment may be made under Medicare must submit information to CMS or to OIG concerning reportable financial relationships in form, manner and at times that CMS or OIG specifies
- Exception: Reporting requirements do not apply to entities that furnish 20 or fewer Part A and Part B services during calendar year, or to any Medicare covered services furnished outside US

Reporting Requirements - §411.361 – *cont.*

■ Required information

- Name and UPIN or NPI of each physician who has a reportable financial relationship with entity
- Name and UPIN or NPI of each physician who has an immediate family member who has a reportable financial relationship with entity
- Nature of financial relationship

Reporting Requirements - §411.361 – *cont.*

- Reportable financial relationships
 - Any ownership or investment interest, as defined at §411.354(b)
 - Except ownership or investment interests that satisfy exceptions in 411.356(a) or 411.356(b) regarding publicly-traded securities and mutual funds
 - Any compensation arrangement, as defined at § 411.354 (c)

Additional CMS Guidance/Resources

- CMS Advisory Opinions
 - CMS-AO-2008-01 (hospital license of custom software interface for use by medical staff MDs in private offices to order or communicate results of tests and procedures)
 - CMS-AO-2008-02 (whether physician investment in diagnostic center meets rural provider exception)
- Frequently Asked Questions
- Preamble Commentary

Amending Agreements

- Amendments are allowed if
 - All requirements of applicable exception are met
 - Determine amended rental charges or other compensation (or formula) before amendment is implemented
 - Formula for amended rental charges or compensation does not take into account volume or value of referrals or other business generated between the parties
 - Amended rental charges or compensation (or formula) remains in place for at least 1 year from date of amendment
 - Applies to exceptions that have 1-year term requirement

New Developments

- November 19, 2008 Federal Register Publication of Medicare 2009 Physician Fee Schedule:
 - CMS solicits comments on Gainsharing Incentive Payments and Shared Savings Programs
 - 90 Day Comment Period
 - CMS publishes revised Anti-Markup Final Rules
 - Effective January 1, 2009