

**Stark Law, Phase II Regulations:
What Physicians Should Know**

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Overview

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The Law

- Statute: 42 U.S.C. § 1395nn
- Statute: 42 U.S.C. § 1396b(s)
- Phase I: 42 C.F.R. § 411 *et. seq.*
- Phase II: 69 Fed. Reg. 16053 (Interim Final Rule)
- Phase II: Final Rule (?)
- Phase III: (?)

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Prohibition

- Physician may not refer patient
- Entity may not submit claim or seek reimbursement from any entity or person
- Unless, an exception applies

Sanctions

- Denial. CMS will not pay claims for improperly referred DHS
- Refund. Entity has duty to refund
- Civil Monetary Penalties.
 - \$15,000 for knowingly presenting or causing another to present improper claim
 - \$100,000 for “scheme” to circumvent
- Exclusion.

Other Enforcement

- Civil False Claims Action
- Qui Tam Bar
 - Treble damages
 - \$5,500 to \$11,000 per claim fine
 - Relators’ legal fees
- See, e.g., Rapid City Regional Hospital
- See, e.g., United States ex rel. Barbera v. Tenet Healthcare Corporation

Reporting

- Entities furnishing > 20 Part A & Part B services per year may be required to submit information including:
 - identity of each physician with reportable financial relationship (excludes certain publicly traded investment interests)
 - covered services furnished by entity
 - nature of the financial relationship (limited to know/should know)

Reporting (Cont'd)

- Annual reports on changes no longer required (retention of documentation)
- 30 days request to provide information
- Up to \$10,000 CMP per day for failure to report
- Information furnished to CMS/OIG is subject to public disclosure

Key Definitions

Elements of a Stark Violation

- Physician
- Referral
- Medicare patient
- To
- Entity
- For furnishing of DHS
- Physician (immediate family member) has financial relationship with entity

Physician

- “Referring physician” = physician and his or her solely-owned professional corporation
- Note. Group practice is not a physician

Referral

- Physician “requests” item or service payable by Medicare, or “requests” or establishes a plan of care that includes DHS
 - Personally performed services do not give rise to referral; “incident to” services do
 - Referral is imputed to physician where he or she “controls” or “directs” person (e.g., PA) making the referral

Furnishing Entity

- Entity is deemed to be “furnishing” DHS if it is the entity to which CMS makes payment

Financial Relationship

- **Ownership/Investment**
 - Direct ownership/investment interest
 - E.g., Physician owns clinical lab company
 - Indirect ownership/investment interest
 - E.g., Physician is a member of LLC that owns clinical lab company

Financial Relationship

- **Compensation Arrangement**
 - Direct compensation arrangement
 - E.g., Hospital pays Physician to serve as a departmental medical director
 - Indirect compensation arrangement
 - E.g., Hospital pays Group to supply medical director (Physician) and Group pays Physician in a manner that varies with/reflects Physician’s referrals to Hospital

Indirect Compensation - Defined

- Three prong test
 - First, is there an uninterrupted chain of financial relationships?
 - Note. An excepted relationship does not interrupt (or “break”) the chain
 - Note. Two co-owners have an uninterrupted chain between them

Indirect Compensation - Defined

- Second, does aggregate compensation to physician vary with or reflect volume or value of DHS or other business generated?
 - Note. Per case and per click arrangements always trigger this prong (according to CMS)
- Third, does entity know or should it know of prong two?

Designated Health Services

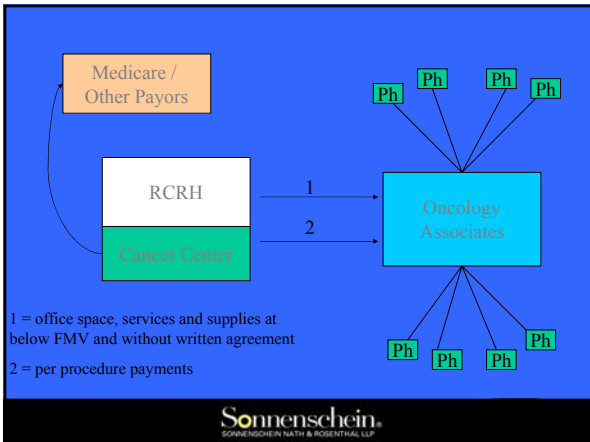
- Lithotripsy is not DHS
- Radiology services immediately after procedure to confirm placement of an item are not DHS
- CMS to revisit definition of outpatient prescription drugs in light of Medicare Part D

“Set In Advance” – Phase II

- Key term for many exceptions
- Modified to permit percentage compensation arrangements, provided formula is:
 - Prospectively established with specificity;
 - Objectively verifiable; and
 - Not changed over course of agreement

Group Practice

- Key for two exceptions
- Phase II
 - Multi-state groups
 - Grace period for meeting “substantially all” tests
 - Unified business test simplified



Exceptions

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Exceptions

- Three types
 - Three (3) ownership-investment interests
 - Twenty-one (21) compensation arrangements
 - Nine (9) all-purpose

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Ownership Interest Exceptions

- **Publicly Traded Securities & Mutual Funds** (§§ 411.356(a), (b))
 - “ownership interest” in securities that are generally available to public at time of DHS referral rather than at time securities were obtained

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Ownership Interest Exceptions

- **Specific Providers**
 - Rural Provider Exception (§ 411.356(c)(1))
 - Puerto Rico Hospital Exception (§ 411.356(c)(2))
 - Whole Hospital Exception (§ 411.356(c)(3))
 - Definition of hospital narrowed in MMA (2003) to exclude (at least for 18 months) certain specialty hospitals (e.g., cardiac and orthopedics)
 - Grandfather clause



Original (Pre-Phase I) Compensation Arrangement Exceptions

- **Space & Equipment** (§§ 411.357(a), (b))
 - One year requirement liberalized
 - Month to month holdovers allowed
 - Category of eligible leases expanded (any *bona fide* lease including capital leases)
 - Subleases allowed



Original (Pre-Phase I) Compensation Arrangement Exceptions

- **Bona Fide Employment Relationships** (§ 411.357(c))
 - Entity may pay physician employees productivity bonuses based on personally performed DHS
 - **Note.** Personally performed DHS does not give rise to a referral
 - **Caveat.** Employee bonus may not be based on “incident to” services (which is allowed in group practice context)



Original (Pre-Phase I) Compensation Arrangement Exceptions

- **Personal Services Arrangements** (§ 411.357(d))
 - Termination w/out cause does not negate 1 year term
 - PSA may cover items and equipment
 - Physician may furnish personal services through employees, wholly owned entity and *locum tenens* physicians (but not independent contractors)
 - Fair market value: new deeming provisions

Fair Market Value

- Hourly payment for physician’s personal services qualify if:
 - Rate is less than or equal to average relevant ER rate; or
 - Rate is determined by averaging 50th percentile national compensation level for physicians with same specialty in at least four of six specified surveys
- Cannot adjust space/equipment rental to reflect lessee’s proximity/convenience

Original (Pre-Phase I) Compensation Arrangement Exceptions

- **Physician Recruitment** (§ 411.357(e))
 - “Geographic area” = area composed of lowest number of contiguous zip codes from which hospital draws at least 75 percent of inpatients
 - “Relocation” = physician must (1) move his/her medical practice at least 25 miles or (2) establish a substantial base of new patients (i.e., no less than 75 percent of revenue)
 - Note. Cross town recruitment theoretically possible

Original (Pre-Phase I) Compensation Arrangement Exceptions

- **Physician Recruitment (cont'd)**
 - Exception covers medical residents and new physicians
 - **Note.** Residents/new physicians do not have to meet relocation requirement
 - Hospitals may provide financial support through existing medical groups, provided certain conditions are met
 - E.g., financial support in the form of income guarantees may only reflect incremental costs associated with recruited physician

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Original (Pre-Phase I) Compensation Arrangement Exceptions

- **Isolated Transactions (§ 411.357(f))**
 - Installment payments allowed, provided:
 - (1) total aggregate payment is set in advance and does not take referrals into account; and
 - (2) balance is guaranteed
 - Post dosing adjustments to purchase price permitted within six months of transaction

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Original (Pre-Phase I) Compensation Arrangement Exceptions

- **Remuneration Unrelated to the Provision of DHS (§ 411.357(g))**
 - Phase II narrowed this – only available when remuneration is “wholly unrelated” to provision of DHS
 - According to CMS, almost nothing is “wholly unrelated”
 - Wholly unrelated payment does not need to be FMV (CMS will scrutinize payments above FMV to ensure that they are not disguised payments related to DHS)

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Original (Pre-Phase I) Compensation Arrangement Exceptions

- **Group Practice Arrangements with a Hospital** (§ 411.357(h))
 - Provided pre-date Dec. 19, 1989
- **Payments by a Physician for Items and Services** (§ 411.357(i))
 - Payment must be at FMV
 - Exception doesn't cover payments for items & services covered by another exception (e.g., rent payments)
 - Proposed discounts exception rejected



Original (Phase I) Compensation Arrangement Exceptions

- **Non-monetary Compensation Under \$300 Per Year** (§ 411.357(k))
 - CMS declined to increase \$300 limit to \$600
 - CMS did agree to adjust limit annually to keep up with inflation
 - Does not cover gifts to groups
 - Tracking: According to CMS, tracking should not be "problematic"



Original (Phase I) Compensation Arrangement Exceptions

- **Fair Market Value Compensation** (§ 411.357(l))
 - Payment to physicians for items and services
 - Covers payments to group of physicians



Original (Phase I) Compensation Arrangement Exceptions

- **Medical Staff Incidental Benefits** (§ 411.357(m))
 - Benefits do not have to be commensurate with those offered by other hospitals, but cannot exceed \$25 in value (indexed for inflation)
 - Communication methods used away from campus to access information on campus are covered
 - Exception may be relied on by all facilities that have *bona fide* medical staff
 - Transcription services example



Original (Phase I) Compensation Arrangement Exceptions

- **Risk Sharing Arrangements** (§ 411.357(n))
- **Compliance Training** (§ 411.357(o))
 - Does not cover CME



Original (Phase I) Compensation Arrangement Exceptions

- **Indirect Compensation Arrangement Exception** (§ 411.357(p)) :
 - Compensation is set out in writing, signed and specifies services
 - Comp. does not vary with or reflect volume or value of DHS referral or other business generated
 - Note. Per case and per click payments may satisfy this requirement if set in advance and are not adjusted
 - Arrangement does not violate AKL



Compensation Arrangement Exceptions Created in Phase II

- **Charitable Donations By Physician** (§ 411.357(j))
 - Donation cannot be solicited
 - Donation cannot take volume or value of DHS referrals or other business generated
- **Referral Services** (§ 411.357(q))
- **Obstetrical Malpractice Insurance** (§ 411.357(r))

Compensation Arrangement Exceptions Created in Phase II

- **Professional Courtesy** (§ 411.357(s))
 - Uniform treatment
- **Retention Payments in Underserved Areas** (§ 411.357(t))
 - In reaction to *bona fide* offer to move physician's medical practice 25 miles
- **Community-Wide Health Information Systems** (§ 411.357(u))

Original (Pre-Phase I) All-Purpose Exceptions

- **Physician Services** (§ 411.355(a))
 - Covers referrals to physician in same group practice
 - Note. Does not cover incident to services

Original (Pre-Phase I) All-Purpose Exceptions

- **In-Office Ancillary Services (§ 411.355(b))**
 - Three prongs:
 - Who performs in-office services?
 - Where services are performed
 - Same building as non-DHS (groups/solos)
 - Group's centralized DHS building
 - Who bills for services?

Original (Pre-Phase I) All-Purpose Exceptions

- CMS substantially revised “same building” test
 - Three interchangeable tests (with hour requirements)
 - Require “some” rather than “substantial” quantum of non-DHS physician services
 - Note. Physician services may be unrelated to the furnishing of DHS, even if they lead to the ordering of DHS
 - Accommodate occasional weeks in which office is open fewer hours than required (e.g., vacations)

Original (Pre-Phase I) All-Purpose Exceptions

- **Services Furnished to Enrollees of Prepaid Plans (§ 411.355(c))**
 - Covers services furnished to beneficiaries of Medicaid plans
- **Certain Clinical Laboratory Services**
 - Eliminated as an exception

Phase I All-Purpose Exceptions

- **Academic Medical Centers** (§ 411.355(e))
 - Exception has been relaxed through broadening of key definitions
 - For example, “AMC” may include teaching hospital without accredited medical school and faculty plan does not have to be a 501(c)(3) or 501(c)(4)

Phase I All-Purpose Exceptions

- **Implants Furnished in an ASC** (§ 411.355(f))
 - Note. ASC must bill and be paid for implant
- **Certain Dialysis Related Outpatient Prescription Drugs** (§ 411.355(g))
 - Note. Category of covered drugs expanded

Phase I All-Purpose Exceptions

- **Preventive Screening Tests** (§ 411.355(h))
 - Note. Exception covers all such tests regardless of payment methodology
 - Note. Exception does not cover diagnostic mammography
- **Eyeglasses and Contact Lenses** (§ 411.355(i))
 - Note. Exception applies to glasses/lenses provided after cataract surgery

All-Purpose Exceptions Created in Phase II Regulations

- **Intra-Family Rural Referrals** (§ 411.355(j))
 - Covers referrals in a rural area by physician to immediate family member or to an entity that has a financial relationship with family member
 - Focus on (1) location where services furnished, and (2) availability of other providers to furnish same services in timely manner

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Grace Period

- § 411.353(f) provides 90 day immunity for certain instances of “temporary noncompliance,” provided:
 - Financial relationship fit within an exception for at least 180 consecutive days prior to noncompliance
 - Reasons for lapse in compliance “beyond the control of the entity”
 - Entity took prompt steps to rectify noncompliance
- Note. CMS did not adopt use of “discovery” rule

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