STARK II, PHASE II FINAL RULES

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Stark I and II: The Never Ending Story

- Stark I
  - Original bill in 1989 would have prohibited referrals by physician to entity in which physician has financial relationship – unless exception.
  - OBRA 89 limited to clinical labs and only Medicare.
  - Effective January 1, 1992
  - Proposed rules March 11, 1992
  - Final rule with comment period, August 14, 1995
The Never Ending Story (con’t)

- Stark II
  - OBRA 93 August 10, 1993; amended 1994
    - Covers ten designated health services
    - Adds Medicaid prohibition
    - Effective January 1, 1995
  - March 1996; HCFA (CMS) announced intent to publish Stark II rules by end summer.
    - Proposed Stark II rules, January 1, 1998
Never Ending Story: (cont’d)

• Phase I, Stark II Final rules with comment period, March 26, 2001, effective 1/4/02
• Phase II, Stark II Interim Final rules with comment period, Phase II, March 26, 2004, effective 7/26/04
Application to Medicaid

- OBRA 93 bars FFP in State expenditures for DHS furnished to individual if was from a prohibited referral under Medicare
- Stark II, Phase II rules reserve Medicaid issues for future rule-making
Stark II: Basics

- Is there a financial relationship?
  - DHS entity
  - Physician
- Is there a referral?
- For designated health services covered under Medicare and Medicaid.
- Is there an exception?
Penalties

- DHS entity
  - Cannot bill or collect for services
  - Referred by a physician
  - Who has “financial relationship” with entity
  - Unless an exception exists

- DHS entity
  - Is obligated to refund amounts collected
  - As result of submitting claims
  - For DHS performed pursuant to prohibited referral
Penalties (cont’d)

- Civil monetary penalties
  - 42 CFR Section 1003.100 \textit{et. Seq}
  - Up to $15,000 for each claim for a service
  - That person knows or should know
  - Is for a service for which payment may not be made
Penalties (cont’d)

- Civil monetary penalty
  - Of up to $100,000 for each arrangement or scheme
  - Which the physician or entity knows, or should know
  - Has a principal purpose of assuring referrals which
  - If directly made, would be in violation of the statute.
Penalties (cont’d)

- Permissive exclusion
- False Claims Act – 42 USC Section 1320a-7b(a) – may apply
Introduction

- CMS perspective on rule drafting
  - “Seeking to mitigate harshness of statute by creating exceptions to abate harshness of law”
  - “soften the statute”
  - Principles of drafting
    - Interpret prohibitions “narrowly” and exceptions “broadly”
    - Interpret statute so as not to effect patient care and services
    - Conform regulations to other CMS payment and supervision rules where possible
    - Establish bright lines as much as possible because of the strict liability of the statute
Reporting Requirement - New

- Proposed rules – mandatory reporting on essentially all DHS entities
- Final Rule: “on request” but still very onerous if requested
  - Name and UPIN of each physician (or immediate family member) has a financial relationship with the DHS entity
  - Description of the financial relationship
Reporting Requirement (cont’d)

- Form of report (cont’d)
  - The extent and/or value of the financial relationship
    - “as evidenced in records that the entity knows or should know about in the course of prudently conducting business.
  - Entities are to be given “at least thirty days from date of request
Reporting Requirement (cont’d)

- Entities retain documentation sufficient to verify
  - Reported financial relationships
  - Make that documentation available upon request
- CMP of up to $10,000 for each day does not meet deadline for filing
- Information is subject to public disclosure if not covered by Privacy Act.
Highlights

“Set in Advance” – modification definition

- Set in advance is common to several exceptions.
- Modified to permit some percentage compensation

  - Requirement is for units of compensation to be set in advance, not aggregate compensation
  - If the methodology for calculating the compensation
    - Does not change over the course of the arrangement
    - In any manner that reflects the volume or value of referrals
    - Or other business generated between the parties.
Intrafamily Rural Referrals - new
  – With which an immediate family member has a financial relationship
  – If the patient that is being referred resides in a rural area
    • And there is no other DHS entity available to furnish the DHS in a timely manner in light of the patient’s condition.
Highlights (cont’d)

- Space and Equipment - modified
  - To allow for termination without cause
    • As long as no further agreement is entered into
    • Within the first year of the original lease or contract term
  - Month to month holdover permitted for six months
  - Applies equally to capital and operating leases
Highlights (cont’d)

- Modification of the lease exception
  - Per click payments permitted
  - Equipment leases may fall under FMV exception, but not space leases.
Highlights (cont’d)

- New: Safe Harbor for “Fair Market Value” definition
- Applicable to hourly payments to physicians for their personal services.
- Two alternative methodologies
  - Payment must be less than or equal to the average hourly rate for emergency room physician services in the relevant physician market or
  - The average of the 50% salary for the physician's specialty of four national surveys and dividing by 2000 hours to establish an hourly rate
    - Six listed in F.R. – CMS qualifies, only five
Physician Recruitment - Clarification

- Residents and physicians who have been in a medical practice for less than one year not considered to have an “established practice”
- Residents and physicians in practice for less than one year will be eligible for the recruitment exception regardless of whether relocates practice.
- Exception expanded to include federally qualified health centers (FQHCs) as well as hospitals.
Highlights (cont’d)

- Recruitment (cont’d)
  - Separate requirements for recruitment payments made through existing medical groups
  - A new exception for retention payments made to physicians with practices in health professional shortage areas
  - Must look to the relocation of the recruited physician’s medical practice, rather than the physician’s residence.
    - 25 miles or 75% of physician revenues derived from services to new patients (or reasonably expect physician to meet this test)
Recruitment (cont’d)

- Must allow physician to establish staff privileges
  - At other hospitals
  - To refer to other entities (except if meets new restrictions on directed referrals)
  - Use reasonable credentialing restrictions on physicians becoming competitor does not violate this
Recruitment payments to existing group

- Arrangement between hospital and physician practice is in writing and signed by the parties.
- Remuneration is passed directly through to or remains with the recruited physician
  - Exception is actual costs incurred by the physician or physician practice in recruiting the physician
- Records of the actual costs and passed through amounts must be maintained for a period of at least 5 years and made available to Sec’y
Highlights

- Recruitment into Group (cont’d)
  - In case of income guarantee
    - Costs allocated by the physician practice to the recruited physician
    - May not exceed actual additional incremental costs to the practice
    - Attributable to the physician
  - New physician must establish medical practice in hospital’s geographic service area
  - Must join hospital’s medical staff
Highlights (cont’d)

- Recruitment into Group (cont’d)
  - New physician not required to refer patients to hospital
  - Allowed to establish staff privileges at any hospital
  - May refer business to other entities unless meets new directed referral exception
  - Remuneration from hospital does not take into consideration referrals or anticipated business
  - Practice group may not impose any practice restrictions such as a covenant not to compete but may establish quality considerations.
Highlights (cont’d)

- Isolated Transaction exception-modified
  - Now allows for installment payments
    - Provided total aggregate payment is set before the first payment is made
    - Does not take into account referrals or other business generated by the referring physician
  - Installments guaranteed by a 3rd party, secured by a negotiable promissory note or similar mechanism
  - Post closing adjustments may be made within 6 months of closing “if” commercially reasonable.
  - Prohibit other transaction within 6 months
    - Includes non-DHS’s transactions
Highlights (cont’d)

- Information Technology Items and Services – New

- Hardware and Software provided by a DHS entity to a physician to participate in a community-wide health information system
  - That allows access to, and sharing of
    - Electronic health care records and complementary drug information systems
    - General health information
    - Medical alerts and related information
    - For patients served by community providers and practitioners.
Highlights – (cont’d)

- Information Technology – (cont’d)
  - Conditions for new exception
    - Items and services are available as necessary to enable the physician to participate.
    - Items and services are principally used by the physician as part of the community-wide health information system.
    - Items and services are not provided in a way that takes into account volume or value of referrals or other business generated.
    - The community-wide health information systems are available to all providers, practitioners and residents who desire to participate.
    - The arrangement does not violate the anti-kickback statute or any federal or state law related to billing or claims submission.
Professional Courtesy exception - new

- Def: Free or discounted health care items or services to a physician or his or her immediate family members or office staff
  - Must be offered to all physicians on medical staff or to all physician’s in the entity’s local community or service area without regard to volume or value or other business generated.
  - Courtesies are type routinely provided by entity
  - Policy set out in writing and approved by entity’s governing body prior to providing the courtesy
Professional Courtesy (cont’d)

• If courtesy involves total or partial waiver of patient’s co-insurance, insurers must be informed in writing.
• Courtesy arrangement does not violate anti-kickback statute.
• May be granted by hospital or other DHS entity
• Not offered to a physician who is a Federal healthcare program beneficiary, unless showing of financial need
Highlights (cont’d)

- Medical Staff Incidental Benefits-modified
  - Provides for non-monetary compensation up to $300
    - To allow for the $300 per year limit for non-monetary compensation
    - $25 limit per item/occurrence to be adjusted annually for inflation
    - Only while making rounds or performing other services (web site exception)
    - Only used on hospital’s campus
Highlights (cont’d)

- Incidental benefits (cont’d)
  - Not solicited by physicians, groups or medical staff
  - If to group, $300 limit, not number of physicians in group times $300
  - May be offered by other facilities and healthcare entities that have bona fide medical staffs may also use this exception
Highlights (cont’d)

- Incidental Benefits (cont’d)
  - Transcription services limited to hospital medical records is not an “incidental benefit” to physicians
  - CME offered to physicians to satisfy CME requirements may be remuneration
  - Deemed: “Compensation, including, but not limited to, 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 Website or in hospital advertising, will meet the “on campus” requirement….”
Charitable Donations by Physicians – New

– Conditions

• Made to an exempt organization
• No solicitation of donation made in a manner takes into consideration value and volume or other business
• Not violate anti-kickback statute
Charitable Donations (cont’d)

- Reaffirmed that “gifts otherwise constitute remuneration” and create a compensation arrangement
  - Higher threshold if target is only physicians
  - Lower threshold if broad-based, non-targeted solicitation such as charity ball tickets.
Highlights (cont’d)

- Academic Medical Center Exception - modified
  - To allow for greater flexibility by making it easier to qualify as an academic medical center or a component of an academic medical center
  - And clarification of the exception’s terminology
Directed Referral

- Revised conditions under which a physician’s compensation is conditioned on the physician making referrals to a particular provider
  - Employee or under managed care or other contractual relationship such as ER service
  - Set in advance
  - FMV, not related to value, volume, other business
  - Otherwise fits another exception (employment)
  - Referral requirement set out in writing
  - Not apply to patients’ preferences; insurance contracts; best interest of patient
  - Only to services within scope of employment, etc.
Highlights (cont’d)

- Employment Exception
  - Compensation may be conditioned on referrals in compliance with new directed referral rule
  - Eliminated proposed limitation on productivity bonus
    - “incident to” cannot be used to calculate productivity bonus
    - Personally performed DHS can be basis for bonus
    - Personally supervised services that are not DHS can be basis for bonus
  - Leased employees not excepted – must be IRS employee
  - Eliminated restriction on compensation related to other business generated (language not in statute)
Highlights

- **Personal Services Exception**
  - Can receive compensation that takes into account the volume or value of services personally performed so long as set in advance (i.e. percentage arrangements)
    - Aggregate compensation need not be “set in advance”
  - Limited to services. Limited to contracts with physicians or physician groups.
  - Do not need two separate agreements for “services” and “equipment”
Highlights (cont’d)

- Personal Services (cont’d)
  - Must separate services and equipment for determining fair market value if in same arrangement but may be in same agreement
  - Eliminated requirement to incorporate by reference all other agreements between the parties.
    - Option to either incorporate by reference or cross-reference to a master list of contracts
  - Compensation safe harbor for hourly rates
    - Voluntary. Safe Harbor not a requirement
    - Limited to services personally performed
Changes to In-Office Ancillary Exception

- There is no “group practice” exception. Group practice definition is a definitional part of the in-office ancillary service.
- Exception applies to
  - Services performed personally by the referring physician, a physician in the group or other directly supervised by the physician or the physician group.
- Clarifies that supervision is that required for reimbursement.
- Requires DHS must be furnished to patients in the “same building” where regular services performed (group practice in a centralized location).
Highlights – (cont’d)

- In-Office Ancillary (cont’d)
  - Revised same building test to be more flexible.
    - Three alternative test for “same building”
    - Does not include mobile van or parking lot
  - Hospital employed physicians cannot meet group practice definition but hospital can organize, own and operate a separate legal entity that is a group practice.
Highlights (cont’d)

Retention Payments to Physicians

- Only applies to physicians with practices in health professional shortage areas (HPSAs)
  - Physician has firm written recruitment offer from unrelated hospital or FQHC that specifies remuneration
  - Location requirement (25 miles) outside hospital’s (FQHC) service area
  - Retention payment limited by current income difference or reasonable costs hospital would incur to recruit.
  - Reasonable methodology to calculate income
  - Retention agreements no more often than every 5 years.
  - No protection for payments to group practice
Highlights

- New – Compliance Training
  - By a DHS entity to a physician (or physicians immediate family members or staff)
  - Must be held in local community or service area
  - Definition of compliance training
    - Not include continuing education
Highlights (cont’d)

- Obstetrical Malpractice Insurance Subsidies - New
  - New exception for subsidies that meet the anti-kickback requirements
    - Limited to the obstetrical part of the individual’s practice
    - Must be an expectation that 75% of the patients treated will be in an underserved area (HPSA, MUA) or an MUP.
Remuneration Unrelated to DHS

- Very narrow exception
  - “wholly unrelated”, cannot “in any way” take into account volume or value of physician’s referrals or other business generated
- Limited to remuneration from a hospital to physician, not immediate family member.
- Withdraws 1998 preamble best suggesting that “general administrative and utilization review services were not related to DHS”
- Payment for covenant not to compete is related to furnishing of DHS
Highlights (cont’d)

- Referral Services – new –
  - Meets all conditions of anti-kickback safe harbor
    - Referral service must include those who meet stated qualifications
    - Charges are assessed equally and not based on volume or value or other business generated
    - Service imposes no referral or use obligation
Referral Service (cont’d)

- Services must make certain disclosures to individual as listed in exception
  - How the participants are selected
  - Whether participant is paid a fee
  - How it selects a particular participant from among those who qualify
  - The nature of the relationship between the referral service and the participants to whom it could make a referral
  - The nature of any restrictions that would prevent such an individual from continuing in the referral group
Highlights (cont’d)

- Additional clarifications
  - Volume and Value
    - Unit-based compensation is deemed not to take into account value and volume if unit is fair market value
    - And does not vary or take into account referrals for DHS
    - “Fixed aggregate compensation” can violate volume or value standard if it exceeds fair market value or is inflated to reflect other business
Highlights (cont’d)

– “Referrals”
  • Revised to allow pathologist, radiologist or radiation oncologist to refer to other member of group to supervise
  • Request still must result from consultation request of another physician

– “Other Business Generated”
  • Continues to include private-pay business, not just DHS
  • “personally performed” by physician are now excluded from the formula.
Highlights (cont’d)

– “Does not violate the anti-kickback statute.”
  • Many exceptions include
  • Clarifies does not require the transaction fit an anti-kickback safe harbor or obtain an advisory opinion.

– “Specialty hospital”
  • Adds definition corresponding to MMA definition and moratorium.
  • Currently limited to hospitals primarily or exclusively treating patients with cardiac conditions, orthopedic conditions or receiving surgical procedures.
Highlights (cont’d)

– Direct and indirect ownership and compensation – very complicated both in definition and application of exception
  • Most compensation relationships – direct
  • If not direct, must go through indirect analysis
– Implants furnished by an ASC
– Preventive Screening Tests, Immunizations and Vaccines
– EPO and Other Dialysis Drugs
Highlights (cont’d)

– Defines what are DHS and reference to list in Federal Register, see www.cms.hhs.gov and 69 FR 16143 –16146

• Lithotripsy provided by an independent group “under arrangement: to the hospital is not automatically a hospital inpatient or outpatient service.
  – Still constitutes a “financial relationship” and must fit a Stark exception
Highlights (cont’d)

– DHS (cont’d)
  • Five types of DHS are inclusively defined by reference to CPT and HCPCS codes:
    – Clinical laboratory services
    – PT services
    – OT and speech pathology services
    – Radiology and certain other imaging services
    – Radiation therapy services and supplies
  • Annual updates as part of the physician fee schedule. Current list at www.cms.hhs.gov
  • CMS did not add nuclear medicine to the list of designated health services – may reconsider
– DHS (cont’d)

• CMS will revisit the definition of outpatient prescription drugs in later rule-making based on MMA changes

• Numerous CPT and HCPCS code changes. See listing at 69 F.R. 16143-16146
Highlights (cont’d)

- Exceptions related to Ownership
  - Publicly-traded Securities
    - Must be purchased on terms generally available to the public at the time DHS referrals are made
    - Rejected have a small company exception. Kept $75 million shareholder equity standard
  - Rural Providers
    - “Specialty hospital” moratorium includes rural providers
    - DHS must be furnished in a rural area and at least 75% of total DHS must be furnished to residents of a rural area
    - Definition of rural area tied to one that is not an urban area under 412.62(f)(1)(ii)
Ownership (cont’d)
  – Whole Hospital Exception and “Specialty Hospital” Rules
   • “Whole hospital” is still in tact, but included moratorium on new ownership or investment in “specialty hospitals” under MMA
   • Def of “specialty hospital” – “primarily or exclusively” engaged in cardiology, orthopedics, surgery or any other category of service later determined by the Secretary to be inconsistent with the whole hospital exception.
Whole hospital (cont’d)

- Preamble states risk that ownership in whole hospital may also implicate anti-kickback statute
  - “For example, specialty hospital ventures in which investment opportunities are substantially limited to physicians in a position to refer to the specialty hospital may implicate the anti-kickback statute.”
- Specialty hospital moratorium
  - Effective for 18 months beginning Dec. 8, 2003
  - Negates whole hospital exception and rural ownership exception during moratorium
  - CMS says no intention to treat specialty hospitals more restrictively once the moratorium ends
Highlights

– Whole Hospital (cont’d)
  • Specialty hospital moratorium does not apply to “specialty hospitals”
    – Determined by Sec’y to be in operation or “under development” as of Nov. 18, 2003
    – The number of physician investors has not increased since such date
    – The type or categories of service have not changed since such date
    – “[A]ny increase in the number of beds occurs only in the facility on the main campus…and does not exceed 50% of the number of beds in the hospital as of Nov. 18, 2003 or five beds, whichever is greater
    – Meets other requirements specified by the Sec’y.