Impact of Stark II, Phase II Regulations on Existing and Future Hospital/Physician Arrangements

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Introduction

• Background of Phase II Regulations
  – Stark I
    • effective January 1, 1992
    • limited to clinical lab services
  – Stark II
    • effective January 1, 1995
    • broadened to include 11 “designated health services”
Introduction

• Background of Phase II Regulations, cont’d...
  – Stark II Regulations
    • issued in multiple phases
    • Phase I was issued on January 4, 2001
    • Phase II was issued on March 26, 2004 and became effective on July 26, 2004
    • Phase III is likely given the “interim final” status of Phase II
Introduction

• Objective of Presentation
  – Address selected provisions of the Phase II Regulations of interest to hospitals
  – Alert hospital administrators and counsel to those provisions in Phase II Regulations requiring revisions to pre-existing agreements
  – Provide a greater understanding of the Stark law
• Impact of Phase II Regulations
  – Focus on relocation of medical practice rather than relocation of his or her residence
  – Residents and new physicians in practice less than one year are exempt from the relocation requirement
  – FQHCs are permitted to make recruitment payments like hospitals
  – Joint recruitment with existing medical groups are specifically permitted, but are regulated
Physician Recruitment Exception

- Phase II Regulations Where Physician Not Joining an Existing Practice
  - The “geographic area served by the hospital” is the lowest number of contiguous zip codes from which the hospital draws at least 75% of its inpatients
Physician Recruitment Exception

– A physician will have relocated medical practice if:
  • Medical practice moves at least 25 miles; or
  • New medical practice derives at least 75% of its revenues from patients not seen or treated at prior medical practice site during the preceding 3 years

– Residents and physicians who have been in practice one year or less are not subject to the relocation requirement
Physician Recruitment Exception

• Phase II Regulations for Joint Recruiting
  – Written agreement must be signed by the party to whom the payments are made
  – Remuneration must be passed directly through to the recruited physician
  – In the case of an income guarantee, the costs allocated to the recruited physician may not exceed the actual additional incremental costs attributable to the recruited physician
Physician Recruitment Exception

– Remuneration may not take into account referrals by the recruited physician, the existing practice, or any physician in the existing practice

– The existing practice may not impose additional practice restrictions on the recruited physician, except those related to quality of care
Physician Recruitment Exception

• Impact on Pre-Existing Arrangements
  – CMS has issued the following guidance
    • All recruitment arrangements entered into after July 26, 2004 must comply
    • All pre-existing recruitment arrangements that continue in effect after July 26, must comply with Phase II Regulations, or must be restructured to comply
    • Income guarantees with continuing obligations must comply with the new regulations
    • In joint recruiting arrangements by a hospital and an existing physician group, non-compete provisions in physician employment agreements are not permitted
Physician Recruitment Exception

• Strategies for Dealing with Pre-Existing Non-Compete Agreements
  – Document that the non-compete provisions of the employment contract are void and will not be enforced
  – Terminate the hospital funded recruiting arrangement
  – Suspend enforcement of the non-compete provision
Retention Payment Exception

• Phase II Regulations
  – Create an exception for payments to retain physicians in hospital’s geographic area
  – Geographic area served by the hospital must be part of a HPSA (without regard to specialty)
  – the physician must have a firm, written recruitment offer from an unrelated hospital that requires physician to move practice at least 25 miles and outside of the geographic area served by the retaining hospital
Retention Payment Exception

- Retention payment is limited to lower of incremental value of new offer or hospitals cost of recruiting a replacement
Special Rule on Compensation “Set in Advance”

- Exceptions Requiring Compensation to be “Set in Advance”
  - Personal service arrangements exception
  - Office and equipment rental exceptions
  - Fair market value exception
  - Academic medical center exception
  - *Bona fide* employment and group practice exceptions do not require compensation to be set in advance
Special Rule on Compensation  
“Set in Advance”

- **Percentage Compensation Arrangements**
  - In the proposed Phase I Regulations, percentage compensation arrangements did not meet the set in advance requirement.
  - In the Phase II Regulations, CMS has dropped the language denying percentage-based compensation treatment as fixed in advance.
  - CMS acknowledges that most percentage compensation arrangements will satisfy this standard.
Special Rule on Compensation “Set in Advance”

• The Rule
  – Compensation will be considered “set in advance” if:
    • the aggregate compensation, a time-based or per unit of service based amount, or a specific formula is set in an agreement at the beginning
    • the formula for determining the compensation must be set forth in sufficient detail
    • the formula may not be changed or modified during the course of the agreement in any manner that reflects referrals or other business generated by the referring physician
    • Unit-based compensation must be fair market value per unit and not vary based on referrals or other business
Definition of “Fair Market Value”

• Exceptions Limiting Compensation or Other Payments to “Fair Market Value”
  – *Bona fide* employment
  – Personal service arrangements
  – Fair market value compensation
  – Academic medical centers
  – Rental of office space
  – Rental of equipment
  – Isolated transactions
  – Group practice arrangements with a hospital
  – Indirect compensation arrangements
Definition of “Fair Market Value”

• New Safe Harbors
  – New in the Phase II Regulations is a “safe harbor” methodology for setting hourly physician compensation
  – Hospitals are not required to pay according to the safe harbor
  – But those that pay higher amounts are likely to have a higher burden to establish that what they pay is fair market value for the services rendered
Definition of “Fair Market Value”

- Fair Market Value Defined
  - The value in arm’s-length transactions, consistent with the “general market value”
  - General market value means the price that an asset would bring as the result of *bona fide* bargaining between well-informed buyers and sellers who are not otherwise in a position to generate business for the other party OR compensation in a service agreement as the result of *bona fide* bargaining between well-informed parties who are not otherwise in a position to generate business for the other party.
Definition of “Fair Market Value”

• Safe Harbor for Hourly Physician Services
  – Hourly payment for a physician’s personal services shall be considered to be fair market value if:
    • The hourly rate is less than or equal to the hourly rate for emergency room physician services in the relevant physician market, or
    • The hourly rate is determined by averaging the 50th percentile national compensation level for physicians with the same physician specialty in at least four of the following surveys and dividing by 2,000 hours
Definition of “Fair Market Value”

• The surveys identified by CMS are:
  – Hay Group - Physicians Compensation Survey
  – Hospital and Healthcare Compensation Services - Physician Salary Survey Report
  – Medical Group Management Association - Physician Compensation and Productivity Survey
  – ECS Watson Wyatt - Hospital and Health Care Management Compensation Report
  – William M. Mercer - Integrated Health Networks Compensation Survey
Fair Market Value Exception

• Application of Exception Remain Unchanged
  – This exception continues to apply to arrangements for the provision of items and services by physicians
  – The creation of the safe harbor for physician services paid by the hour in the definition of fair market value is the material change made to this exception
Personal Service Arrangements Exception

- Impact of Phase II Regulations
  - One year term required but termination at will is permitted
  - Payments from downstream subcontractors are included in the physician incentive plan provisions of the exception
  - Physicians may use this exception for services performed personally, or by wholly owned practice entity, or through their employees, or through *locum tenens* physicians, but not through independent contractors
Personal Service Arrangements Exception

• Phase II Regulation
  – Each arrangement is in writing, is signed, and specifies the services covered
  – The arrangement(s) covers all of the services to the entity
  – All separate arrangements between the entity and the physician incorporate each other by reference or they cross-reference a master list of contracts that is maintained and updated centrally
  – The master list should preserve the historical record of contracts
Personal Service Arrangements Exception

- Services do not exceed those reasonable and necessary for the legitimate business purposes of the arrangement(s)
- Term of at least one year, but may be terminated with or without cause during such initial term if not reinstated with the one year initial term
- Compensation to be paid is set in advance, does not exceed fair market value, is not determined on volume or value of any referrals or other business
Personal Service Arrangements Exception

- Administrative Tasks
  - Hospitals should review all personal service arrangements it has with physicians
  - Ensure that each arrangement is set out in a written agreement that covers all services to be provided to the hospital, or each contains references to all of the other agreements, or contains cross references to a master list
Personal Service Arrangements Exception

- Assure compensation meets fair market value and set in advance definitions
- Agreements that don’t meet these requirements must be amended
Indirect Compensation Arrangements Exception

- Indirect Compensation Arrangement Redefined
  - An indirect compensation arrangement exists if:
    - Between the referring physician and the entity furnishing DHS there exists an unbroken chain of any number of persons or entities that have financial relationships between them.
Indirect Compensation Arrangement Exception

• The referring physician receives aggregate compensation from the person or entity in the chain with which the physician has a direct financial relationship that varies with, or otherwise reflects, the volume or value of referrals or other business generated by the referring physician.

• In the case of an intervening ownership or investment interest in the chain of persons or entities, whether the aggregate compensation varies with volume or value or referrals or other business generated by the referring physician will be measured by the non-ownership or non-investment interest closest to the referring physician.
Indirect Compensation Arrangement Exception

- The entity furnishing the DHS has actual knowledge, or acts in reckless disregard or deliberate ignorance of, the fact that the referring physician receives aggregate compensation that varies with, or otherwise reflects, the volume or value of referrals or other business generated by the referring physician.
Indirect Compensation Arrangement Exception

• Example

A → ownership/investment → B

Determination made here

Compensation arrangement

*referrals

C

Compensation arrangement

D

*DHS Entity
Indirect Compensation Arrangement Exception

- The Phase II Regulations provide an exception for indirect compensation arrangements if all of the following are met:
  - Compensation received by the referring physician is fair market value
  - The compensation arrangement is set out in writing, signed by the parties, and specifies the services covered by the arrangement, except in the case of a *bona fide* employment relationship
  - The compensation arrangement does not violate the Anti-kickback Statute or any federal or state law or regulation governing billing or claims submission
Indirect Compensation Arrangement Exception

• Administrative Tasks
  – Hospitals should review their relationships with each physician in search of indirect compensation arrangements
  – Make sure that the compensation flowing to each physician from the indirect compensation arrangement is fair market value
  – Make sure that the per service, per use, per click, or other compensation unit paid by the DHS entity does not exceed fair market value and does not change over the term of the arrangement
Certain Other Phase II Changes

- Joint Ventures Do Not Create Indirect Ownership Interests
  - Common ownership or investment in an entity does not, in and of itself, establish an indirect ownership or investment interest by one common owner or investor in another common owner or investor.
Certain Other Phase II Changes

• Termination Without Cause
  – Phase II Regulations now permit one year agreements to be terminated with or without cause, but only if the parties do not enter into the same or a substantially similar agreement during the first year of the original term of the terminated agreement.
Certain Other Phase II Changes

- Isolated Transactions
  - Phase II Regulations permit installation payments for isolated transactions provided the total aggregate payment is fixed before the first payment is made, and adequate security to ensure repayment is in place.
  - Post-closing adjustments are permitted within 6 months of closing provided the adjustments are unrelated to referrals or other business generated.
• Community Wide Health Information Systems
  – The provision of information technology and services to community physicians now has its own exception under Phase II, subject to certain conditions
• Restrictions on Referrals
  – Referral restrictions may be imposed on a physician only in the context of employment, managed care contracts, and personal service arrangements
  – Required referrals must relate solely to the physician’s services under the arrangement and must be reasonably necessary to carry out the legitimate purpose of the relationship
• Rental of Office Space and Equipment
  – Leases may be terminated with or without cause
  – Month to month holdover leases are permitted
  – Capital leases, as well as operating leases, are permitted
  – Subleases are permitted
  – Per click payments are allowed
Certain Other Phase II Changes

• Temporary Lapses
  – The arrangement must have satisfied another exception for at least 180 consecutive days prior to the noncompliance
  – The reasons for noncompliance were beyond the control of the entity
  – The noncompliance is rectified within 90 calendar days of noncompliance
  – The exception may only be used once every three years
Certain Other Phase II Changes

• Reporting Requirement
  – DHS entities must report only in response to a specific request from CMS or the OIG
  – The reporting obligations will be burdensome for those receiving requests for “reportable financial relationships”
Certain Other Phase II Changes

• Reportable Financial Relationships:
  – Include virtually all ownership, investment, and compensation relationships with physicians
  – The information to be reported includes the name and UPIN of each physician and physician family member with a financial relationship to the entity, the covered services provided by the entity, and the nature of each financial relationship
  – Reports must be delivered within 30 days of the request
Certain Other Phase II Changes

– Failure to report by the deadline could result in daily fines of up to $10,000
– Hospitals should consider maintaining a current log of the information it would have to report if requested
Questions