



# STARK II REGULATORY UPDATE

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# HISTORY OF STARK

- Stark I Law 1992
- Stark I Regs 1995
- Stark II Law 1995
- Stark II, Phase I Regs 2002
- Stark II, Phase II Regs 2004
- Stark II, Phase III Regs 2007  
(12/4/07 effective date)

# PHASE III MAJOR CHANGES:

## *Stand in the Shoes*





*Stand in the Shoes:*

## *Who Does the Concept Apply To?*

- ✓ Physicians
- ✓ Physician organizations
- ✓ Third parties contracting with physician groups


*Note: Delay application for one year to academic medical centers & nonprofit integrated health systems*



*Stand in the Shoes:*

***What Type of Arrangements Does the Concept Apply To?***

- ✓ Only applies to indirect compensation arrangements
- X Does not apply to indirect ownership arrangements



*Stand in the Shoes:*  
***“Physicians in the Group”***

- ✓ Members
- ✓ Employees
- ✓ Independent contract physicians
  - Must have direct contract relationship



*Stand in the Shoes:*  
***Definition of “Physician Organization”***

**Includes:**

- ✓ Stark qualifying “group practices”
- ✓ Professional corporations
- ✓ “Physician Practices” (not defined)

**Does not include:**

- X Other physician owned entities

**Unclear if includes:**

- Academic Medical Centers or components



*Stand in the Shoes:*

***Are any arrangements grandfathered?***

- Arrangements in place as of September 5, 2007
  - Which are compliant with the indirect compensation exception
  - Need not be amended during the original or renewal term in order to comply

# PHASE III MAJOR CHANGES: Physician Recruitment





## *Physician Recruitment:*

### **MAJOR CHANGES**

- Who can recruit?
- Scope of “geographic area served” defined
- Clarification of “Relocation” requirement
- Imposition of practice restrictions by group
- Allocation of expenses



## *Physician Recruitment: Who Can Recruit?*

### *Historically*

- Hospitals
- Federally Qualified Health Centers (FQHCs)

### *Phase III adds*

- Rural Health Clinics



*Physician Recruitment:*  
**“Geographic Area Served”**

*Historically*

- Area composed of “lowest number of contiguous zip codes from which the hospital draws at least 75 percent of its inpatients”



## *Physician Recruitment:* **“Geographic Area Served”**


Phase III clarifies

1. “Contiguous zip code areas” must be next to each other (not the zip code in which the recruiting entity is located)
2. Physician may relocate into a “hole” zip code area if the “hole” is surrounded by contiguous zip codes ...
3. If hospital draws fewer than 75% of inpatients from contiguous zip codes, the geographic service area is defined as all of the contiguous zip codes
4. Hospital may use any zip code configuration if multiple configurations meet the threshold of inpatient admissions




*Physician Recruitment:*  
**“Geographic Area Served”**

5. Hospital may use different areas for different recruitment arrangements as long as the definition is met on the date the agreement is signed
6. Geographic service area is determined at the hospital level (not the hospital system level)



## *Physician Recruitment: Rural Health Providers*

- Hospital located in qualified rural area
- Service area based on contiguous zip codes from which hospital draws with 90% of inpatients OR may include non-contiguous zip codes based on the order of descending percentages of inpatients



*Physician Recruitment:*  
**Clarify “Relocation Requirement”**

- 2 components to “relocation” requirement
- 1) Physician must relocate practice from outside to inside the geographic area served by the hospital
  - 2) Physician must either: (1) move practice a minimum of 25 miles; or (2) derive at least 75% of practice revenues from new patients



*Physician Recruitment:*

## ***When does the relocation requirement not apply?***

*Historically*

- Medical residents and physicians in practice for less than one year

*Clarified and expanded to include*


- All training programs, including fellowships
- Physicians who work for at least 2 years for certain government agencies
- Mid-level practitioners NOT included



# *Physician Recruitment:* ***Recruitment by Physician Groups***

## Permitted Restrictions:

- Moonlighting
- Patient and/or employee non-solicitation
- Requirement to treat Medicaid and indigent patients
- Confidentiality
- Requirement for recruited physician to repay losses that are absorbed by group in excess of any hospital payment
- Liquidated damages if physician leaves group and remains in community



## *Physician Recruitment: Allocation of Expenses*

### *Historically*

- Allocate actual, additional incremental costs

### *Phase III Creates Narrow Exception*

- Group may allocate expenses per capita, not to exceed 20% of group's aggregate costs, if physician is replacing a deceased, retiring, or relocation physician in a rural area or Health Professional Shortage Area (HPSA)




## *Physician Recruitment: Repayment Obligation*

Q: Can the practice let the physician off the hook for payments under the hospital recruitment agreement?

A: CMS believes this creates a financial relationship between the practice and the physician that would not meet a Stark exception.

# PHASE III MAJOR CHANGES: Fair Market Value Exception & Safe Harbor





Fair Market Value:  
**MAJOR CHANGES**

*Historically*

- Limited to compensation paid by DHS entity to physician for provision of items and services

*Expanded to include*

- Payments to DHS entities from physicians



*Fair Market Value:*

***Exception of Last Resort***

“Payments by a physician” may no longer be applicable to most physician payments to DHS entities.

FMV exception is unavailable if another exception if potentially applicable (i.e. lease of space or equipment)



# *Fair Market Value:* **Eliminate FMV Safe Harbor**


## *Historically*

- Safe harbor for calculating the FMV of physician services
- Phase III Eliminates Safe Harbor*

- Compliance burdensome or unrealistic

## *Preamble Guidance*

- “reference to multiple, objective, independently published salary surveys remains a prudent practice” for evaluating FMV
- Can use hourly compensation rate to calculate annual salary if hours used reflect hours “actually worked”




## Phase III Regulations: ***ISSUES TO WATCH***

- %-Based Compensation Methodologies
- Indirect compensation
- Scope of the in-office ancillary services exception



## *Phase III Changes:* **Group Practice Issues**

- Important to understand scope of “incident to” services when calculating productivity bonus
- Group cannot obtain IC services through an intermediary entity



***Phase III Changes:  
In-Office Ancillary Services Exception***

- No substantive changes made
- Preamble suggests significant changes in interpretation
  - Shared space in “same building”
  - Centralized building




## *Phase III Regulations:* ***Changes to Other Exceptions***

- Retention Payments in Underserved Areas
- Intra-Family Rural Referrals
- Compliance Training
- Academic Medical Center
- Personal Service Arrangements
- Charitable Donations by a Physician
- Nonmonetary Compensation
- Professional Courtesy
- Temporary Non-Compliance



***Phase III Regulations:  
Revisions to Defined Terms***

- ***Downstream Contractor - New***
- ***Rural Area - Revised***
- ***Ownership & Investment Interest - Revised***
- ***Radiology and Certain Other Imaging Services  
- Guidance***
- ***Referral - Guidance***



***Phase III Regulations:  
Revisions to Final Rule***

- Elimination of Stark “On-Site” Interpretation Requirement (Nov. 1)
- Delay application for one year to academic medical centers & nonprofit integrated health systems (Nov. 15)