



# Regulatory Insights:

## Executing CAH Physician JVs and Other Legal Developments

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October 29, 2021



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# Agenda

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**“Under Arrangements”**  
Joint Venture Option  
For Surgical Services

**For Qualifying Rural  
Areas Only Under the  
Stark Act**

## 2009 Change in Stark Law – Under Arrangements

- Under arrangements analysis – 2009 IPPS Final Rule
  - Person or entity that “has performed services that are billed as DHS” is a DHS entity
    - Services billed as hospital inpatient or outpatient services considered DHS even if not otherwise DHS
    - Person or entity that “has presented a claim to Medicare for the DHS” also continues to be a DHS entity
  - Effective October 1, 2009

# Stark "Rural Provider" Exemption

- Applies to Ownership but NOT Compensation Arrangements with Physicians

- Requirements:

- (a) The Facility where "Designated Health Services" (DHS) are provided must be located in a "Rural Area";
- (b) 75% or more of the DHS furnished by the facility must be furnished to residents of a "Rural Area".



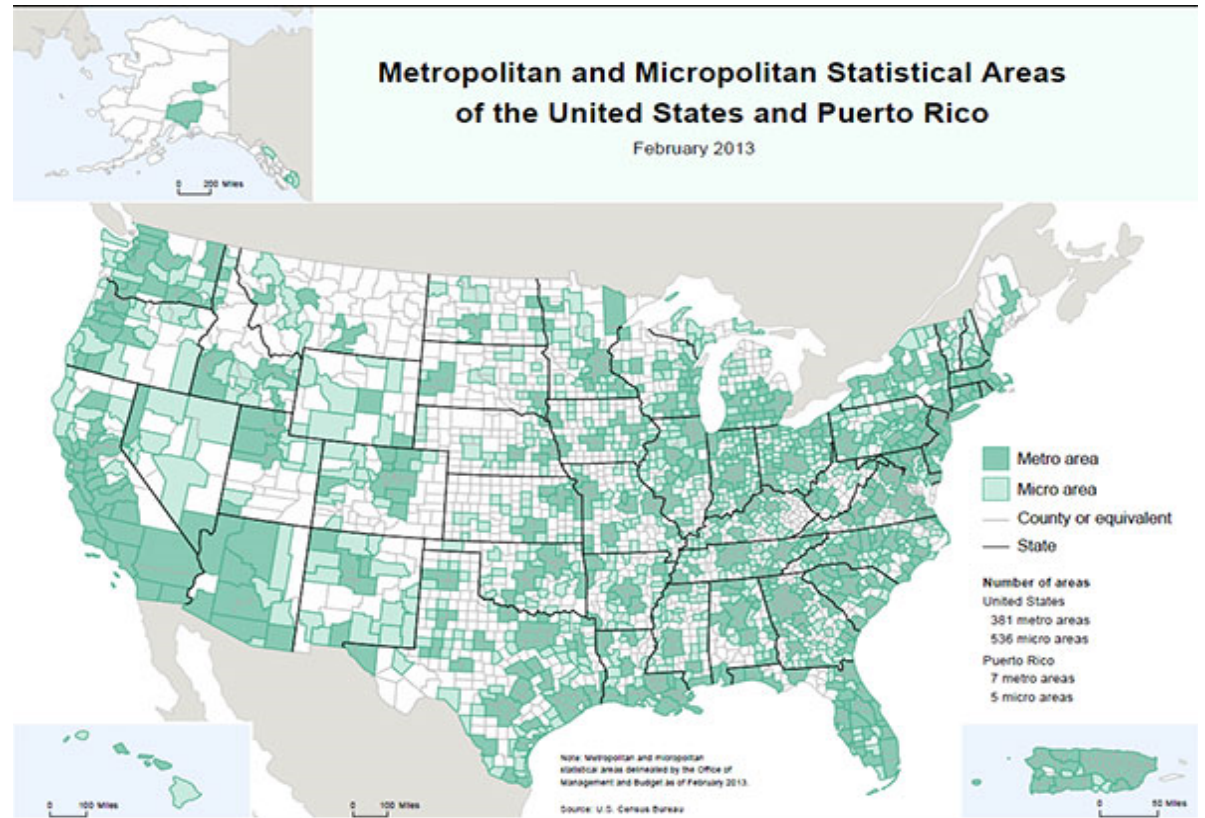
# Stark "Rural Provider" Exemption

## Definition of Rural Area:

- Any area not listed as a Metropolitan Statistical Area by the Office of Management and Budget (OMB)
- 83% of the US population lives within an MSA



# Metropolitan Statistical Areas



# General Concept

- Hospital contracts with a third party vendor to provide services to hospital patients
- Service is billed by the hospital as a hospital service but performed by the vendor
- Vendor is paid a fee by the hospital and agrees to look solely to the hospital for payment

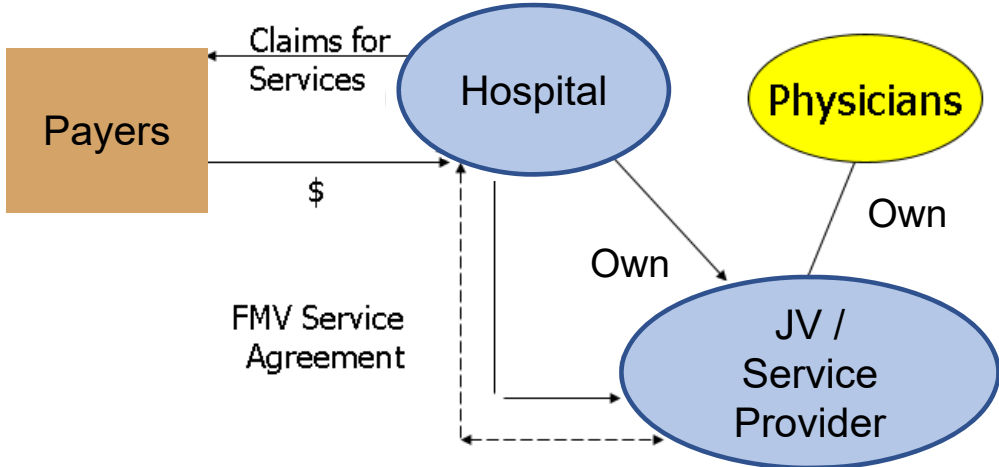




## Under Arrangements Principle, Coverage and Payment Conditions

- Hospitals expressly permitted since 1966 to furnish items and services to patients through arrangements with third parties under the Medicare statute, regulations and manual provisions (see: 42 U.S.C. §1395x(w); 42 U.S.C. § 1395x(b)(3); 42 C.F.R. § 409.3; Medicare General Information, Eligibility and Entitlement Manual (Pub. 100-01), Chapter 5, § 10.3)
- Payment of the hospital must discharge liability of beneficiary or any other party to pay for the items and services
- Hospital cannot “merely serve as a billing mechanism”

# Under Arrangements with a Joint Ventured Services Provider



# Under Arrangements



## Hospital Requirements

- Patient is registered as a hospital patient prior to receiving services from the under arrangements vendor
- Individual receives the same notices and signs the same forms as a patient receiving services directly from the hospital
- Hospital has a written contract with the under arrangements vendor that details the hospital's professional responsibility obligations
- Hospital pays FMV for services performed if there is a referral relationship

# Under Arrangements



Hospital exercises professional responsibility over arranged for services

- Accept patient for treatment in accordance with admission policies
- Maintain complete and timely clinical record on patient
- Maintain liaison with attending physician regarding patient's progress
- Hospital's utilization review and quality assurance programs apply to the service



# Potential Issues Under Anti- Kickback Statute



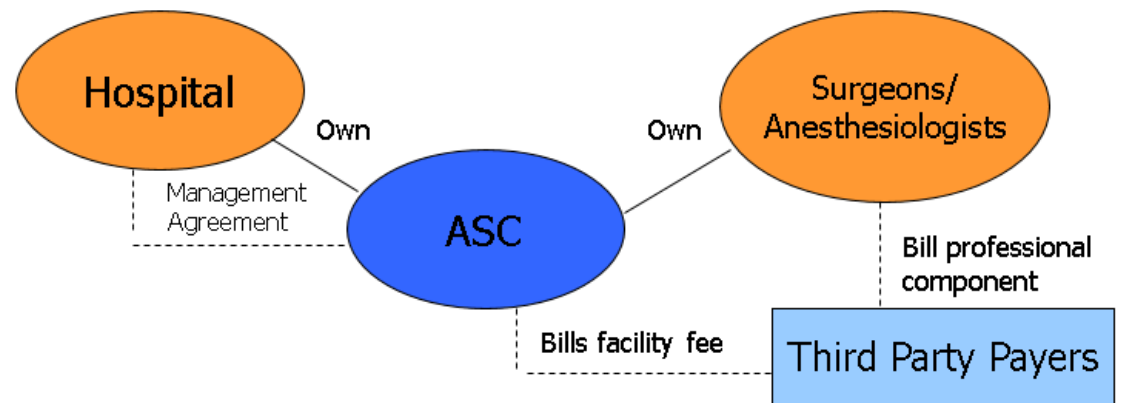
## Suspect characteristics under arrangements transactions:

- Hospital pays above market rates to influence referrals. Entity is in a position to influence referrals if it provides marketing services, has independent patient base, or is owned by referral sources.
- Entity accepts below-market rates to secure referrals from hospital to entity, its owners or affiliates.
- Hospital owns an interest in the entity so that investment returns may reward referrals. This also raises specter of undue influence in awarding contract.
- Transaction involves a separate service not covered in the “under arrangements agreement” that is the real purpose of the arrangement

## Entity that Would Provide the “Under Arrangements” Services

- LLC that would be jointly owned by Hospital and Physicians (51%/49%).
- Physician Interests would be Syndicated At Fair Market Value.
- Physician Participation could (should) be expanded.
- Physicians would need to be actively involved with LLC and management.
- Employees could be leased from Hospital.
- Equipment could be purchased from Hospital.

# Other Option- Ambulatory Surgery Center (ASC) Equity Joint Venture



New Stark Act  
Regulations Issued  
November 20, 2020

Final Rule Effective:  
**January 19, 2021**



# Clarification of Fundamental Terms/Definition

- Commercially Reasonable
- Fair Market Value
- Volume or Value of Referrals or Other Business Generated

# Common Components of Stark Law Exceptions

## Technical Components

- Writing Requirement
- Signature Requirement
- Set in Advance Requirement

## Substantive Components

- FMV Requirement
- Volume or Value Requirement
- Commercial Reasonableness

## New Definition of: Commercially Reasonable

- The particular arrangement furthers a legitimate business purpose of the parties to the arrangement and is sensible, considering the characteristics of the parties, including their size, type, scope, and specialty.
- An arrangement may be commercially reasonable even if it does not result in profit for one or more of the parties.

## New Definition for: Compensation/ Fair Market Value

- The value in arm's-length transactions, consistent with the general market value of the subject transaction.
- With respect to compensation for services, the compensation that would be paid at the time the parties enter into the service arrangement as the result of bona fide bargaining between well informed parties that are not otherwise in a position to generate business for each other.

## New Definition for: Space & Equipment Fair Market Value

- The value in an arm's-length transaction of the rental property or space for general commercial purposes (not taking into account its intended use), consistent with the general market value of the subject transaction and, with respect to space, without adjustment to reflect additional value based on proximity or convenience.
- With respect to rental of equipment or office space, the price that the rental property would bring at the time the parties enter into the rental arrangement as the result of a bona fide bargaining between a well-informed lessor and lessee that are not otherwise in a position to general business for each other.

## Volume or Value/ Other Business Generated Standard

- Compensation from an entity to a physician takes into account the volume or value of referrals by the physician only when:
  - The formula used to calculate the compensation includes the physician's referrals as a variable, resulting in an increase or decrease in compensation that positively correlates with the number or value of the physician's referrals to the entity.
- Compensation from an entity to a physician takes into account the volume or value of other business generated only when:
  - The formula used to calculate the compensation includes the physician's referrals as a variable, resulting in an increase or decrease in compensation that positively correlates with the number or value of the physician's referrals to the entity.

## Volume or Value/ Other Business Generated Standard (cont.)

- Positive correlation between two variables exists when one variable decreases as the other variable decreases, or one variable increases as the other variable increases.
- When physician pays entity (e.g., rent), must be negative correlation.
- Applies to definition of indirect compensation arrangement but modification proposed in Proposed Rule published on July 13, 2021.
- Supersedes previous rules and guidance

# Volume or Value/ Other Business Generated Standard

## Clarifications

- FMV requirement is separate and distinct from volume or value/other business generated standard.
- For employed physicians, a productivity bonus will not take into account the volume or value of referrals solely because corresponding hospital services are billed each time the physician personally performs a service.
- Under a personal service arrangement, a unit-based compensation formula for personally performed services that meets the special rule for unit-based compensation will not take into account the volume or value of referrals even when the entity bills for designated health services that correspond to the personally performed services.



# Stark Changes to Reduce Regulatory Burdens

## Writing and Signature Requirements/Grace Period

- Writing requirement satisfied by collection of documents, including contemporaneous documents evidencing course of conduct between parties.
- Set in advance requirement satisfied by consistent rate of payment during grace period.
- Signature requirement satisfied by electronic or other signature valid under law.
- The requirement for a written signed agreement is satisfied if:
  - The compensation arrangement meets an exception except with respect to the writing and signature; and
  - The parties obtain the required writing and signature within 90 days.

## Reconciling Compensation

- Permits reconciliation of discrepancies in payment within 90 days of termination of an arrangement.

# New/Modified Stark Exceptions

## Limited Remuneration to Physician

- Applied to items or services provided by physician to entity not exceeding \$5,000 per calendar year, adjusted for inflation.
- Compensation not determined in any manner that takes into account volume or value of referrals or other business generated.
- Compensation doesn't exceed fair market value.
- Arrangement is commercially reasonable.

## EHR Donation

- Added cybersecurity software and services.
- Removed December 31, 2021 sunset date.

## Isolated Transactions

- Excludes single payment for multiple or repeated services over a period of time (e.g., services previously provided but not paid).

# New/Modified Stark Exceptions



## Value-based Arrangements/Purpose

- Better and more efficient coordinated care for patients.
- Improved health outcomes.
- Move away from fee-for-service payment models.

# Split-pooling Prohibition For Distributions

## In-Office Ancillary Services Exception

- Permits a physician in a group to refer Medicare patients for DHS

## Group Practice Requirement

- Share of Overall Profits
- Productivity Bonus based on Personally Performed Services
- Allocate Overall DHS profits from the entire group
- Pool and allocate DHS profits of a sub-group of 5 or more physicians

## Final Rule

- Prohibits Pools Based on Service Lines
- DHS Profits—NOT Revenue—May be Divided
  - Profits should include the profits arising from ALL DHS referred by the physicians in the pool.
  - May NOT split profits based on split of non-DHS revenue if those services would be DHS if paid for by Medicare.
- Distribution Methodology May Vary



# QUESTIONS

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