

## Structuring Physician Timeshare Arrangements: Leveraging the Stark Exception, Navigating the Limitations

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Today's faculty features:

Rick L. Hindmand, Member, **McDonald Hopkins**, Chicago

Kim C. Stanger, Partner, **Holland & Hart**, Boise, Idaho

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PHYSICIAN TIMESHARE  
ARRANGEMENTS:  
REGULATORY REQUIREMENTS AND  
PRACTICAL SUGGESTIONS

Rick Hindmand and Kim Stanger

# Preliminaries

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# Agenda

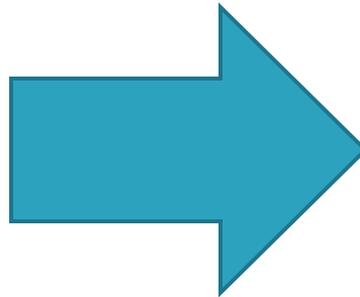
- Fraud and Abuse Laws
  - ▣ Anti-Kickback Statute
  - ▣ Ethics in Patient Referrals Act (Stark Law)
  - ▣ State Law Equivalents
- The Stark Timeshare Safe Harbor
- Drafting Timeshare Arrangements
- Practical Considerations in Implementing and Administering Timeshares

# Written Materials

- 42 CFR 411.357(y) Stark Timeshare Exception
- CMS Commentary re Stark Timeshare Exception, 80 FR 71325-33
- Stanger, *Physician Timeshare Arrangements: New Stark Option for Sharing Space with Visiting Specialists*
- Sample Timeshare Arrangement

# Fraud and Abuse Laws

Govt is concerned that inducements offered to physicians and other referral sources may prompt referrals for items or services payable by govt healthcare programs, e.g., free or discounted space or equipment.



- Anti-Kickback Statute
- Ethics in Patient Referrals Act (“Stark”)
- State law equivalents

# Anti-Kickback Statute

(42 USC 1320a-7b; 42 CFR 1001.952)



# Anti-Kickback Statute

- Cannot knowingly and willfully offer, pay, solicit or receive remuneration to induce referrals for items or services covered by government program unless transaction fits within a regulatory safe harbor.

(42 USC 1320a-7b(b))

- Penalties

- 5 years in prison
- \$25,000 criminal fine
- \$50,000 penalty
- 3x damages
- Exclusion from Medicare/Medicaid

(42 USC 1320a-7b(b); 42 CFR 1003.102)

Anti-Kickback violation = False Claims Act violation:

- Repayment
- \$5,500 to \$11,000 per claim
- 3x damages

# Anti-Kickback Statute:

## Lease of Space/Equipment Safe Harbor

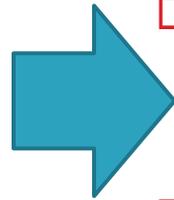
- ❑ Written lease agreement set out in writing
- ❑ Covers all premises leased between the parties and specifies premises/equipment covered.
- ❑ If provide use for periodic intervals, specify exactly the schedule of such intervals, precise length, and exact rent.
- ❑ Term is for at least one year.
- ❑ Aggregate rent is set in advance, consistent with FMV, and not determined by volume or value of referrals or other business generated between parties.
- ❑ Aggregate space/equipment do not exceed that which is commercially reasonable.

(42 CFR 1001.952(b)-(c))

# Anti-Kickback Statute: Timeshare Safe Harbor

□ ***There is no  
AKS timeshare  
safe harbor!***

□ But probably okay if structure to fit within Stark safe harbor.



- But AKS is intent-based statute.
- Test: is “one purpose” of the remuneration is to induce referrals. (*U.S. v. Greber*, 760 F.2d 68 (3d Cir. 1985)).



# Ethics in Patient Referrals Act (“Stark”)

(42 USC 1395nn; 42 CFR 411.351 et seq.)



# Stark

- If a physician (or his or her family member) has a financial relationship with an entity:
  - ▣ The physician may not refer patients to that entity for designated health services (“DHS”), and
  - ▣ The entity may not bill Medicare for such DHS unless arrangement structured to fit within a regulatory exception.
- Penalties
  - ▣ Repayment
  - ▣ \$24,253 per improper claim

(42 CFR 411.353, 102.3, 103.310(a)(1))

Stark Violation =  
False Claims Act  
Violation

- Repayment
- Penalties

# Stark

- Applies to referrals by physician to entities with which the physician (or their family member) has financial relationship.

- Physician =

- MDs
- DOs
- Oral surgeons
- Dentists
- Podiatrists
- Optometrists
- Chiropractors

- Family member =

- Spouse
- Parent, child
- Sibling
- Stepparent, stepchild, stepsibling
- Grandparent, grandchild
- In-law

(42 CFR 411.351)

# Stark

- Applies to referrals for designated health services (“DHS”) payable in whole or part by Medicare.
  - ▣ Inpatient and outpatient hospital services
  - ▣ Outpatient prescription drugs
  - ▣ Clinical laboratory services
  - ▣ Physical, occupational, or speech therapy
  - ▣ Home health services
  - ▣ Radiology and certain imaging services
  - ▣ Radiation therapy and supplies
  - ▣ Durable medical equipment and supplies
  - ▣ Parenteral and enteral nutrients, equipment, and supplies
  - ▣ Prosthetics and orthotics
- CMS website lists some of the affected CPT codes.  
(42 CFR 411.351)

# Common Relationships Implicating Stark



# Common Relationships Implicating Stark

- Lease of space to/from physician who refers DHS.
- Lease of equipment to/from physician who refers DHS.
- Free use of space/equipment to physician who refers DHS.
- Office sharing arrangements.
- Equipment sharing arrangements.
- Visiting specialist arrangements.

# Stark: Rental of Office Space/Equipment Safe Harbors

- Written **lease** signed by the parties.
- Specifies premises covered.
- At least **one year**.
- Space/equipment do not exceed that which is reasonable and necessary for legitimate business purpose.
- Space/equipment **used exclusively by lessee**, not shared within anyone related to lessor except common areas....

(42 CFR 411.357(a)-(b))

# Stark: Rental of Office Space/Equipment Safe Harbors (cont.)

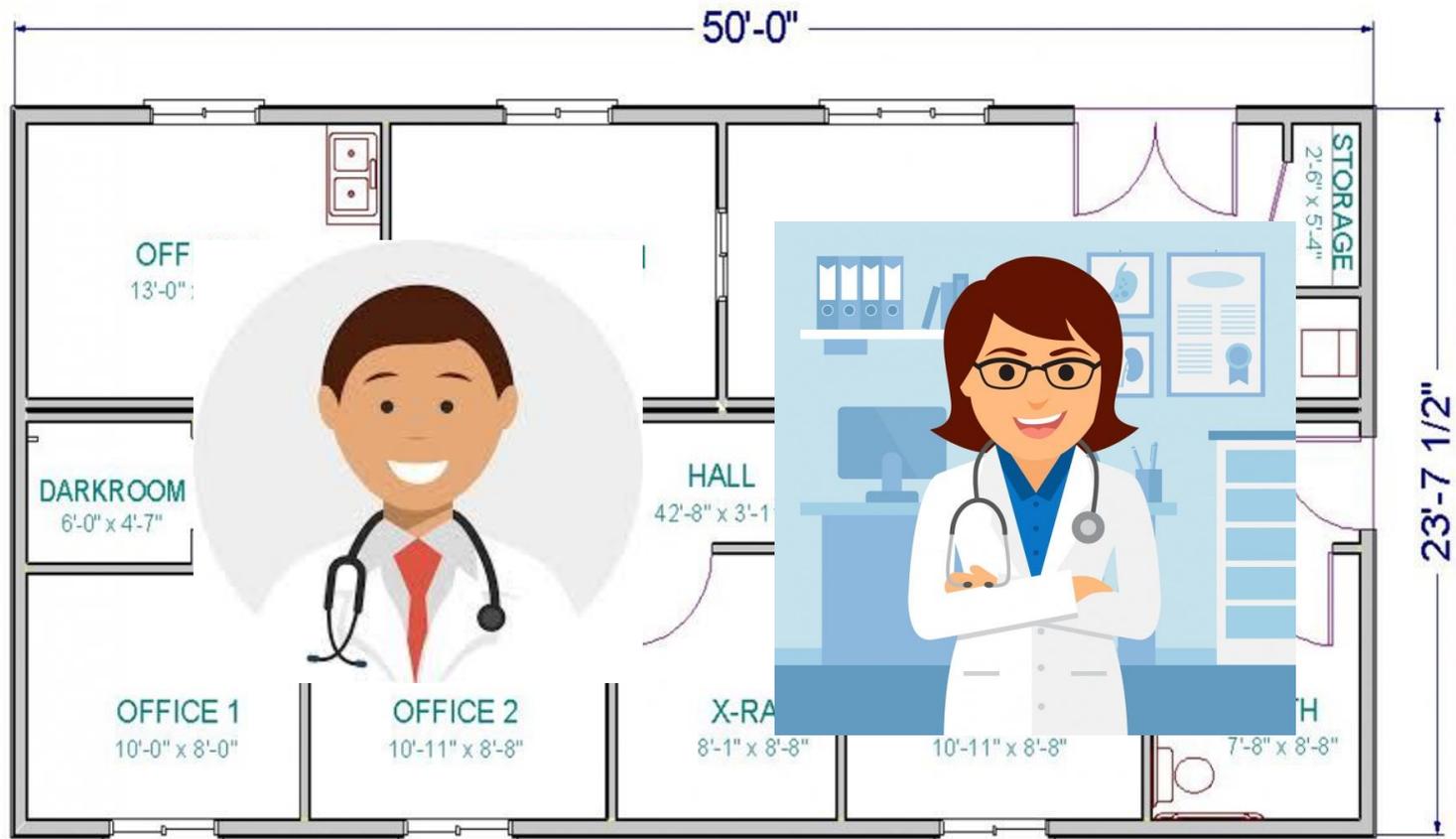
- Rental set in advance, consistent with FMV, and not determined:
  - ▣ Based on volume or value of referrals between entities; or
  - ▣ Using formula based on:
    - Percentage of revenue raised, billed, collected or otherwise attributable to services performed using space/equipment; or
    - Per unit of service reflecting referrals by lessor.
- Lease is commercially reasonable absent referrals.
- May have holdover for up to 1 year if terms don't change.

(42 CFR 411.357(a)-(b))

# Stark Lease Problems

- Lease = possessory interest
- Exclusive use by lessor
- At least one year
- Inefficient because it prohibits sharing of space and equipment.
- Promotes duplication.
- Increases costs to participants.
- Difficult to draft or apply to situations, e.g., periodic use.

# Stark Timeshare Exception (42 CFR 411.357(y))



# CMS Expansion of Exceptions

- Through the administration of the Stark Physician Self-Referral Disclosure Protocol ("SRDP"), CMS began to recognize the burdensome nature of these provisions and the importance of timeshare arrangements in situations where a full-time lease is not necessary or practical, especially in rural and underserved areas.
- In July 2015, CMS published a proposed rule pertaining to payment policies under the Physician Fee Schedule for CY 2016.
- CMS issued a final rule in November 2015.

# Timeshare Exception

- Since January 1, 2016, the Stark timeshare exception permits physicians, physician groups and hospitals to share space, equipment, personnel, items, supplies or services through non-exclusive time-share arrangements provided certain conditions are met. [42 CFR 411.357\(y\)](#).
- CMS's response to comments and explanation of new Stark exceptions can be found at Federal Register, Vol. 80, No. 220, 71300-379, with timeshare commentary at pages 71325-33.

"We believe that timeshare arrangements that permit the use of office space, equipment, personnel, items, supplies, or services can be structured in a way that does not pose a risk of program or patient abuse."  
80 Fed. Reg. 71326.

# Requirements of the Timeshare Exception

- The timeshare exception requires the following conditions:
  1. The arrangement is set out in writing, signed by the parties, and specifies the premises, equipment, personnel, items, supplies, and services covered by the arrangement;
  2. The arrangement is between a physician [or the physician's group in whose shoes the physician stands] and (i) a hospital; or (ii) a physician organization of which the visiting physician is not an owner, employee, or contractor.
    - The exception applies **only** to physicians, physician organizations and hospitals.
    - The exception does not protect timeshare arrangements with other DHS entities, such as laboratories or independent diagnostic testing facilities. 80 Fed. Reg. 71329.

# Requirements of the Timeshare Exception

3. The premises, equipment, personnel, items, supplies, and services covered by the arrangement are used predominantly for the provision of evaluation and management ("E/M") services to patients; and (ii) on the same schedule.
  - The purpose of the new provision is to increase access to care, not to facilitate the physician's ability to provide DHS in supplemental medical practice sites.
  - According to CMS, "the use of office space by the physician *solely* or *primarily* to furnish DHS to patients would not be protected by the new exception." 80 Fed. Reg. 71330.

# Requirements of the Timeshare Exception

4. The equipment covered by the arrangement is:
  - a) located in the same building where the E/M services are furnished (i.e., the same U.S. Post Office address);
  - b) not used to furnish DHS other than those incidental to E/M services furnished at the time of the patient's E/M visit; and
  - c) not advanced imaging equipment, radiation therapy equipment, or clinical or pathology laboratory equipment (other than equipment used to perform CLIA-waived laboratory tests).
    - CMS's reasoning is that advanced imaging and other excluded equipment were likely already available onsite and, therefore, allowing the physician to use such equipment and bill for such use would not promote access, and could create a potential for fraud or abuse. [80 Fed. Reg. 71330-31](#).

# Requirements of the Timeshare Exception

5. The arrangement is not conditioned on the referral of patients by the physician who is a party to the arrangement to the hospital or physician organization of which the physician is not an owner, employee, or contractor.

# Requirements of the Timeshare Exception

6. The compensation over the term of the arrangement is set in advance, consistent with fair market value, and not determined:
  - a) In a manner that takes into account (directly or indirectly) the volume or value of referrals or other business generated between the parties; or
  - b) Using a formula based on:
    - i. A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services provided while using the premises, equipment, personnel, items, supplies, or services covered by the arrangement; or

# Requirements of the Timeshare Exception

- ii. Per-unit of service fees that are not time-based, to the extent that such fees reflect services provided to patients referred by the party granting permission to use the premises, equipment, personnel, items, supplies, or services covered by the arrangement to the party to which the permission is granted.
  - The new exception generally only applies if the compensation is based on forms such as a flat-fee or time-based formula (e.g., per-hour or per-day);
  - Timeshare arrangements based on a percentage of compensation, per-unit of service, or "per click" compensation formulas are not protected due to the potential to incentivize overutilization and patient steering. 80 Fed. Reg. 71331-32

# Requirements of the Timeshare Exception

7. The arrangement would be commercially reasonable even if no referrals were made between the parties.
  - Arrangements that are above and below farm market value, or that do not make business sense but for inducing referrals will be suspect.

# Requirements of the Timeshare Exception

8. The arrangement does not violate the federal anti-kickback statute ("AKS") or any federal or state law or regulation governing billing or claims submission.
  - The AKS is generally violated if "one purpose" of the transaction is to generate referrals for items or services payable by federal programs between the parties unless the transaction is structured to fit within an AKS safe harbor, including the lease or services safe harbors. (See 42 CFR 1001.952(b)-(5)).
  - Although providers should carefully analyze the AKS implications in each case, arrangements based on fair market value for needed space, items or services that satisfy the timeshare exception should pose relatively little risk, especially when they promote access to care in the area.

# Requirements of the Timeshare Exception

9. The arrangement does not convey a possessory leasehold interest in the office space that is the subject of the arrangement.
  - The arrangement only grants permission (“license”) for the visiting physician (“licensee”) to use the space, equipment and/or other items of the hospital or physician organization (licensor”).
  - The arrangement does not grant to the licensee a possessory leasehold or similar interest to use or occupy the space or equipment, i.e., the licensor retains the right to control the property. 80 Fed. Reg. 71327-28.

# Caveats

- CMS warns:

“We do not intend to protect potentially abusive arrangements such as exclusive-use timeshare arrangements that essentially function as full-time leases for medical practice sites; arrangements in which physicians are selected or given preferred time slots based on their referrals to the party granting permission to use the premises, equipment, personnel, items, supplies, or services; or consecutive short-term arrangements that are modified frequently in ways that take into account a physician's referrals.” [80 Fed. Reg. 71328](#).

# Caveats

- The timeshare exception does not protect arrangements between physicians and DHS entities other than hospitals or physician organizations.
- The new exception is limited to arrangements where the occupant is given **non-exclusive** use of the space.
  - The Rental of Office Space exception continues to be the only exception that applies to leasing arrangements (full-time and timeshare arrangements) where the occupant is given exclusive use of the premises.

# General Takeaways

- ❑ Physicians, physician organizations and/or hospitals may still use the lease exceptions to the Stark Law, where appropriate.
- ❑ The new timeshare exception, however, creates an opportunity for hospitals and other entities to share space, equipment, personnel, and services without violating Stark.
- ❑ The new exception has significant potential impact in rural and underserved areas by allowing the operation of part-time specialty clinics through physician offices and other arrangements.
  - But, the new exception is not limited to use in rural areas (as was initially proposed).

# Structuring the Timeshare

Is it a timeshare? A Lease?

- ▣ Possessory leasehold interest (right against the world) – lease
- ▣ License
- ▣ Words matter

# Structuring the Timeshare

Is the arrangement documented under lease and/or other exceptions?

- ❑ Office/equipment lease
- ❑ Personal services
- ❑ Payments by a physician
- ❑ Fair market value

Should the lease be revised to a timeshare?

- ❑ Do all aspects of the current arrangement satisfy exception(s)

# Structuring the Timeshare

## Per-unit of service formulas

- Avoid:
  - Fees that are not time-based, and reflect services provided to patients referred by the licensor to the licensee
  - % of revenue attributable to services provided while using the space, equipment, personnel, items, supplies or services

# Structuring the Timeshare

## Permissible compensation formulas

- ❑ Flat-fee
- ❑ Time-based – usage fee is payable regardless of referrals or the services performed
- ❑ Permissible unit of service usage fee: not reflecting services furnished to patients referred by the licensor

# Structuring the Timeshare

## On the same schedule

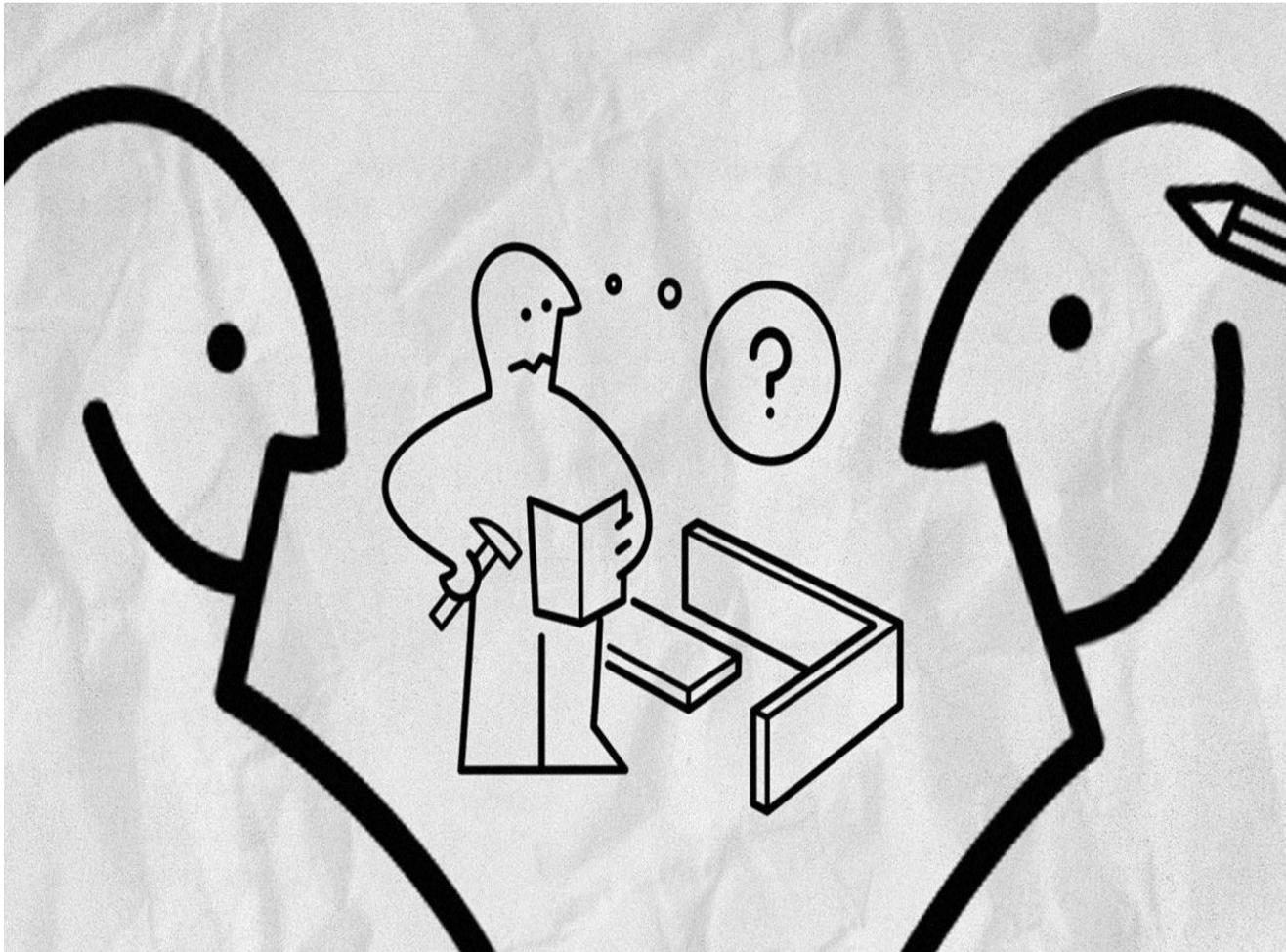
- ▣ All locations must be used on identical schedules
- ▣ How does this requirement apply if the licensee is scheduled to use different buildings on different days?

# Structuring the Timeshare

Don't forget the Anti-Kickback Statute (AKS) and state law

- AKS safe harbors:
  - Satisfaction of safe harbor protects an arrangement but is not mandatory
  - Office and equipment leases- 42 C.F.R. § 1001.952(b) &(c)
    - Exact schedule and payment for part-time leases
  - Personal services and management - 42 C.F.R. § 1001.952(d)

# Practical Considerations



# Is timeshare the right safe harbor?

- Timeshare
  - Physician, physician group, or hospital
  - Non-exclusive shared space and services
  - E/M services
  - On same schedule
  - Equipment in same building
- or
- Lease for space or equipment
- Personal services contract
- Fair market value contract
- Payments by physician
- Medical staff privileges
  - Physician bills pro fee with appropriate site of service
  - Lessor bills facility/tech fee

# Identify what will be shared

- Premises
- Equipment
- Personnel
- Supplies
- Services
- Other

Consider:

- Listing items/services in agreement or addenda
- Beware being overly specific

Remember: the more items you provide, the more risk you will likely have.

# Determine fair market value (“FMV”)

- Premises
  - Equipment
  - Personnel
  - Supplies
  - Services
  - Other
- The price that an asset would bring or compensation paid as a result of bona fide bargaining between persons who are not in a position to generate business for the other party.
  - Usually, FMV is the price at which bona fide sales have been consummated or compensation paid for comparable items or services in the market, not taking into account referrals.
  - With respect to leases, FMV means the value of rental property for general commercial purposes not taking into account its intended use and without regard to proximity to referral sources.

(42 CFR 411.351, definition of “fair market value”)

# Determine fair market value (“FMV”)

Ensure you use reasonable, supportable methodology

- Premises: broker; comparables; space ÷ usage + transaction costs; costs ÷ usage; price per square foot + 20% to 30%; premium for short term; other?
  - Equipment: comparables; costs ÷ usage + transaction costs; cost + reasonable rate of return; other?
  - Personnel: wages + benefits ÷ usage + transaction costs; temp agency; other?
  - Supplies: costs + transaction costs; other?
  - Services: costs + transaction costs; other?
  - Aggregate space, equipment, furnishings, etc. ÷ usage
- \* Remember: transaction must also be commercially reasonable.

# Track compliance with items shared

- Beware space, service or item “creep”.
  - ▣ People get lax, especially when dealing with referral sources
- Establish process for tracking and documenting compliance.
  - ▣ Itemize and invoice
  - ▣ Monthly or annual fee based on average usage
  - ▣ Periodic review of compliance
  - ▣ Renegotiation or modification as appropriate
- The more complicated the transaction, the more difficult it is to ensure compliance.

# Track compliance with usage

- “Predominantly” E/M services.
    - Not used to provide DHS except as incidental to E/M services.
    - Track “predominance” by any reasonable means, e.g., number of patients, CPT codes, time spent, etc.
  - All locations (E/M and DHS) are used on same schedule.
- Designated health services (“DHS”) =
- Clinical labs
  - Physical, occupational or speech therapy
  - Radiology and imaging
  - Radiation therapy
  - DME
  - Parenteral and enteral nutrients
  - Prosthetics and orthotics
  - Home health services
  - Outpatient prescription drugs
  - Inpatient and outpatient hospital services

# Monitor the equipment usage

- Equipment located in same building where E/M services rendered.
- DHS furnished using equipment covered by arrangement must be both:
  - ▣ incidental to E/M service.
  - ▣ furnished at the time the E/M service is provided.
- Arrangement does not include:
  - ▣ Advanced imaging equipment
  - ▣ Radiation therapy equipment
  - ▣ Clinical lab pathology agreement (except equipment used to perform CLIA-waived lab tests)

# Modify as necessary

- Unlike leases, may modify prospectively at anytime.
- Compensation must be set in advance.
- Add/delete items or services if appropriate.
- Beware modifications to compensation terms without corresponding modification to items or services.
  - ▣ AKS concerns
  - ▣ Suggests affected by volume or value of referrals

# Share the space, services or items

- Cannot grant:
  - ▣ Exclusive use as against others.
  - ▣ Preferential treatment or slots based on referrals.
- Determine process for scheduling
  - ▣ First scheduled, first served
  - ▣ Patient acuity or demands
  - ▣ Other?

# Additional terms to include in agreement

- ❑ License, not possessory interest
- ❑ Proscribe usage
- ❑ Usage consistent with applicable law and licensor policies
- ❑ Disclaim or affirm warranties and guarantees re space, items, personnel, etc.
- ❑ Non-exclusivity, cooperation, and scheduling
- ❑ Removal of items when not in use
- ❑ Term and termination
- \* See sample timeshare agreement

# Additional terms to include in agreement

- Independent contractor relationship
  - Supervision and control of personnel
  - Insurance
  - Indemnification
  - Non-interference
  - Confidentiality
  - Confirm who is billing for services
- \* See sample timeshare agreement

# Beware compliance with related laws

- Anti-Kickback Statute
- HIPAA
  - ▣ Technical and administrative safeguards
  - ▣ Business associate relationship
  - ▣ Organized health care arrangement
- Anti-Markup Rule
  - ▣ If physician billing for services performed by licensor personnel
- Physician supervision
- Site of service modifiers
- Others?

# Questions?

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Rick Hindmand

McDonald Hopkins

[rhindmand@mcdonaldhopkins.com](mailto:rhindmand@mcdonaldhopkins.com)

(312) 642-2203

Kim Stanger

Holland & Hart LLP

[kcstanger@hollandhart.com](mailto:kcstanger@hollandhart.com)

(208) 383-3913

THANK YOU

