

AHLA Physicians Organizations Law Institute Phoenix, AZ February 11, 2013

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- Nothing herein is the position (official or unofficial) of Community Health Systems Professional Services Corporation, HealthCare Appraisers, McDermott, Will and Emery, or any affiliate thereof.
- This presentation is based on the personal observations and opinions of the speakers, based on our experiences.
- Priced Higher in California and Hawaii. Your Mileage May Vary. Objects in Mirror May Appear Closer Than They Are. Don't Put the Dog In the Microwave.





Presentation Overview

- Review of Definitions
- AKS/Stark Law Considerations
- Ways to Establish Commercial Reasonableness
- Hypotheticals
- Questions and Answers
- 24 Substantive Slides





Overview

- For purposes of this presentation, a "commercially reasonable" financial arrangement is:
 - □ an arrangement that would
 - make commercial sense if entered into by
 - a reasonable healthcare provider entity of similar type and size, and
 - a reasonable physician (or group thereof) of similar scope and specialty,
 - even if there were NO potential business referrals between the parties.





Overview (cont.)

- This definition is based on guidance provided by the Centers for Medicare and Medicaid Services ("CMS,") in the preamble to the Stark II, Phase II regulations at 69 F.R. 16093 (March 26, 2004)
- This definition is also is consistent with guidance provided in the "OIG Supplemental Compliance Program Guidance for Hospitals" at 70 F.R. 4866 (January 31, 2005).





OIG, AKS, Commercial Reasonableness, & "Swapping"

- For purposes of the Anti-Kickback Statute ("AKS") the US-DHHS Office of the Inspector General ("OIG') considers whether the provision of discounted or free services or items to a buyer in one line of business is "commercially reasonable", SEPARATE AND APART from purchases or referrals by the buyer in another line of business when, evaluating whether the discounted or free services or items are a kickback (referred to by the OIG as "swapping arrangements.")
- OIG Advisory Op. 99-2 (Feb. 26, 1999); OIG Advisory Op. 10-26 (Dec. 20, 2010) OIG Advisory Op. 12-9 (July 23, 2012).





OIG, AKS, Commercial Reasonableness & Real Estate Space Rentals

- The OIG considers facts indicating that a lessee has:
 - leased from a potential referral source more space,
 OR
 - □ leased space for more time,
 - □ than it has a commercially reasonable need, as evidence that the real estate rental arrangement is actually a disguised payment for referrals.
- OIG Special Fraud Alert on Rental of Space in Physician Offices by Persons or Entities to Which Physicians Refer, 65 Fed. Reg. 9279 (Feb. 24, 2000).





OIG, AKS, Commercial Reasonableness & Data/Research

- The OIG considers whether:
 - □ data to be collected OR
 - research to be performed by a referral source
 - □ has intrinsic value to the purchaser, (*i.e.*, has a legitimate business purpose), or if the arrangement is merely a disguised payment for referrals.
 - □ 64 Fed. Reg. 63525-26 (Nov. 19, 1999).





OIG, AKS, Commercial Reasonableness and Call Coverage Arrangements

- The OIG considers whether there are legitimate reasons to pay physicians for providing emergency department call coverage.
- Specialty, Payer Mix, Call Volume and Call Presence all may play into the analysis.
 - □ OIG Advisory Op. 07-10 (Sept. 20, 2007) ("the circumstances giving rise to the Arrangement suggest that the Medical Center had a legitimate, unmet need for on-call coverage and uncompensated care physician services")





OIG, AKS, Commercial Reasonableness and Call Coverage

- Call Coverage (cont'd)
 - □ OIG Advisory Op. 09-5 (May 14, 2009)
 - Hospital has a legitimate rationale for revising its on-call coverage policy.
 - Hospital reports that there are weeks when it does not have needed specialists on-call
 - Hospital's doctors have reduced on-call coverage to the minimum allowed under the Hospital's Medical Staff By-laws, citing the lack of compensation for on-call coverage
 - Hospital having to outsource its Emergency Department obligations.





CMS, Stark and Commercial Reasonableness

- "Commercial Reasonableness" is an Element of Key Compensation Exceptions to the Stark Law
 - □ The Space Lease AND Equipment Lease Exceptions BOTH require that:
 - the lessee not lease <u>more space or equipment</u> than is reasonable necessary for the legitimate business purposes of the lease or rental, and
 - the agreement would be commercially reasonable even if there were <u>no referrals</u> between the lessee and lessor.





CMS, Stark and Commercial Reasonableness

- The Employment Relationships and Isolated Transaction Exceptions BOTH require that:
 - the compensation to the physician (or immediate family member) be paid pursuant to an agreement that would be <u>commercially</u> <u>reasonable</u> even if there were no referrals by the physician to the employer or the entity involved in the isolated transaction.





CMS, Stark and Commercial Reasonableness

- The Personal Services Exception requires that the aggregate services contracted for not exceed that which is <u>reasonably necessary for the legitimate business</u> <u>purposes of the arrangement.</u>
- The Fair Market Value Exception requires that the arrangement be <u>commercially reasonable</u> (taking into account the nature and scope of the transaction) and furthers the legitimate business purposes of the parties.





Establishing Commercial Reasonableness

- Commercial reasonableness of a subject healthcare transaction can be established by confirming that:
 - each individual term that is *included* in the agreement is reasonable, expected to be present, and contributes to the accomplishment of the business purposes of the arrangement;
 - no individual terms are *excluded*, the absence of which would detract from the business purposes of the arrangement and/or the expected rights and protections of the parties; and
 - the overall transaction, taking into consideration each of the individual terms of each of the associated agreements (if applicable) makes commercial sense and accomplishes the intended business purposes in a logical manner,
 - iv. ABSENT any consideration for potential business referrals between the parties.





Establishing Commercial Reasonableness

- Questions to ask:
 - □ Is there genuine need for the services/property?
 - □ Is there a genuine need for the amount of services/property?
 - □ Is there a lower cost alternative to the referral source?
 - □ Does the referral source have the training, experience, skills and time to perform the service as well as a non-referral, or lower-referral source?
 - □ Is the hospital actually negotiating for the service/property?





Commercial Reasonableness Issues in Employment Arrangements

- Compensation Plans that Result in Practice Losses
 - What magnitude of losses is acceptable?
 - Are practice operating expenses fully allocated to the practice?
 - □ Can you use a compensation formula that guarantees losses?
 - Incremental/bonus compensation that increases losses?
 - □ Tuomey-type compensation arrangement concerns:
 - Part-time employment (for outpatient surgical services only)
 - Compensation formula tended to ensure practice losses
 - Fulltime benefits
- Purchasing "carved out" ancillaries





Hypothetical 1 – Acquiring a Chemo Infusion Business

Typical characteristics of a physician infusion business:

- Minimal capital expenditure requirements
- Minimal physical facility needs
- Minimal startup/lead time required
- Minimal regulatory requirements
- Captive referral base
- Attractive profit margins as a Part B provider
- Really attractive profit margins with provider-based reimbursement and 340B pricing (for non-profit providers)





Hypothetical 1 – Acquiring a Chemo Infusion Business (cont.)

If a hospital proposes to purchase a "chemo infusion business," what is being purchased?

- Hospitals can readily "compete" in the infusion business (and most hospitals already do).
- Invariably, the purchase price is expected to be based upon an income approach (which could yield substantial value) as opposed to a cost approach (which would yield nominal value).
- What would a hospital gain through the purchase of an infusion business (other than the expected ongoing referrals from a specific group of medical oncologists)?





Hypothetical 2 – Acquiring a Radiation Therapy Business

Characteristics of a radiation therapy business:

- Large capital investment required
- Long development/construction lead time
- Subject to significant regulations (e.g., CON)
- Typically entails a broad referral base
- As a "carved out" ancillary, the purchase of a radiation therapy center using a DCF appears to have favorable commercial reasonableness characteristics.





Hypothetical 3 – Inpatient GI & Endo Lab Coverage

- Sole GI practice in market has its own freestanding endo lab, i.e., diminishing need and desire to work at the hospital
- Gls abide by medical staff ED call coverage requirements
- Gls also provides (at no charge) non-emergent inpatient consults and onsite endoscopies for inpatients and outpatients, meeting minimum medical staff requirements
- GI practice is not providing inpatient and endo lab coverage as many days of the year as the hospital desires due to vacations and focus on its own endo lab
- Gls are willing to increase their coverage, but are asking for per diem payments for every day of:
 - □ ED call coverage; and
 - Inpatient/endo lab coverage
- The Hospital is also concerned that the GIs will stop taking <u>any</u> call, i.e., withdraw from the medical staff, if the hospital does not accept the GIs' terms





Commercial Reasonableness Considerations in Co-Management Arrangements

- OIG Advisory Opinion 12-22
- Is there an appropriate balance between the split of the base and incentive fees (e.g., 50/50)?
- To what extent are incentive metrics payable for "maintenance"?
- Is there "arbitrage" opportunity in the arrangement?
- If the management services are being provided jointly by the hospital and physicians, is the allocation of duties and responsibilities commensurate with the compensation?
- Are there ongoing medical director arrangements that appear to result in duplication of services (and compensation)?





Other Commercial Reasonableness Examples: The "Gratuitous Risk" Provision

- Physician-owned space is leased to a hospital. The term of the lease is one year, and carries a rent rate premium because of the short-term nature of the lease. However, the lease automatically renews year after year.
- NewCo is formed consisting of virtually all of the members of a hospital's medical staff. NewCo acquires all of the hospital's imaging equipment and leases the equipment back to the hospital. The lease contains a provision granting the hospital the unilateral right to cancel the lease with 90 days' notice. In light of this early termination risk borne by NewCo, the equipment lease carries a substantial premium.





Other Commercial Reasonableness Examples: Lease/Leaseback Scenario

A physician owned organization is hired to provide management services to a hospital service line. Most of the services are provided by specific personnel of the management company. However, these management company employees are actually employees of the hospital who are leased to the management company based upon a cost pass-through.





Other Commercial Reasonableness Examples: Arbitrage Opportunities

- A physician organization is paid to provide turnkey management services on behalf of a hospital service line. The physicians then engage a professional non-physician owned organization to provide material components of the services.
- A hospital pays a physician group \$1,500 per day for call coverage; that group in turn contracts with unrelated physicians to provide the coverage for \$1,000 per day.





Other Commercial Reasonableness Examples: Issues in Call Coverage

- Is a restricted call coverage arrangement (which typically carries a substantial pricing premium over non-restricted call) actually needed? Does the volume of patients and the patient care requirements support the need for restricted coverage? To what extent are the physicians seeing their own patients during periods of restricted coverage?
- Are potentially overlapping call coverage panels needed (e.g., general orthopedics and orthopedic joint)
- Paying for inpatient consults





Other Commercial Reasonableness Examples: Advertising Opportunities

- A pathology practice proposes to pay an internal medicine practice for ad banners on the PCP's Web site.
 - □ Web advertising arrangements are extremely commonplace, but does a pathology group benefit in any material respect through such advertising?





Other Commercial Reasonableness Examples: Equipment Lease vs. Purchase

- Urology Group wishes to enter into a lithotripsy services agreement with a hospital, priced on a per-click basis, as permitted by CMS' interpretation of the Equipment Lease Exception
- Over an 18 month period, the historical annual volume of "clicks" multiplied by an FMV per-click payment exceeds the cost for the hospital to purchase a new lithotripter.
- Is it commercially reasonable to enter into the requested arrangement?



Questions?







How to Determine Commercial Reasonableness of Hospital-Physician Compensation Arrangements

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