Fraud and Abuse Primer
Hypotheticals

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Hospital A is located in a rapidly growing community that has demonstrable need for more physicians, but is not a medically underserved area. The administrator has identified three possible physicians that might want to relocate if provided some incentives: (i) Doctor Failing Practice, who currently has privileges at a competing hospital in the same service area, has approached the hospital about relocating his practice which is not successful to the far side of Hospital A’s service area where new developments make it an attractive new market; (ii) Doctor Veteran, who currently practices at the local VA hospital, and wishes to leave the VA and establish a primary care practice in Hospital’s service area. The VA hospital is also located in the Hospital’s service area; and (iii) Doctor Smith, a primary care doctor who is currently practicing in another state, but is attracted by the growth possibilities of Hospital A’s area.
The Rule

The recruited physician must:

- Not already be a member of the medical staff (unless a resident)
- Relocate his or her practice from outside the Hospital’s service area (determined by the lowest # of zip codes yielding at least 75% of patients)
- Relocation can be established by either a physical move of 25 miles or having 75% of patients new to the practice.
Discussion

• Dr. Failing Practice - No - He is already in the service area

• Dr. Veteran - ? – It is unclear whether for purposes of the regulation, a hospital-based practice with a limited patient base, is the physician’s practice or the VA. Arguably, like a resident or newly minted doc, Dr. Veteran has no practice. Could use a advisory opinion or clarification.

• Dr. Smith – Yes – not on staff, out of area, move of more than 25 miles
Dr. Smith has decided that he doesn’t want to practice by himself any longer. Accordingly, he is only interested in practicing as part of a medical group. One of Hospital’s biggest admitting groups, Acme Medical Group, had a physician retire last year and is interested in replacing him. The Group is desperate to offset the overhead that had been picked up by the retired physician.

Dr. Smith and Acme agree to the following deal; the hospital will pay all the recruiting expenses to Smith, Smith will join the Acme and take over the retired physician’s space. Smith will receive a guarantee of $200,000 based on expected collections of $300,000 and overhead allocation of $100,000. Smith will enter into a non-compete and non-solicitation provision as part of his arrangement with Acme. Smith and Acme come to the Hospital to give a collections guarantee for the $300,000, subject to forgiveness over the three following years.
The Rule

In the case of remuneration provided by a hospital to a physician either indirectly through a physician or physician practice or directly to a physician who joins a group practice, the following additional

- Written agreement with doc is also signed with group
- Except for actual costs incurred by physician or practice in recruiting the doc, the remuneration is passed through or remains with recruited doc
- In case of income guarantee, the costs allocated by the practice to the recruit do not exceed the actual additional incremental costs
- Records of costs and pass throughs maintained for five years
- The remuneration from the hospital is not determined in manner taking into account the value or volume of actual or anticipated referrals by recruit or practice
- The practice may not impose additional practice requirements
- the arrangement can’t violate the AKS
Discussion

1. The arrangement won’t work. If Dr. Smith joins the practice, Acme is limited to its actual incremental costs. Since it has already been eating the overhead formerly shouldered by the retired physician, Acme cannot shift the costs to Dr. Smith. Moreover, Acme cannot impose a non-compete on Dr. Smith, although a non-solicitation provision is probably ok. Other options.

2. Acme can strike any deal it wants with Dr. Smith and fund it itself. Hospital could still pay for the recruitment costs.
3. Alternatively, Dr. Smith can rent office space and personnel from Acme at FMV, but not join the practice and or enter into any non-compete. The practices should be kept separate, with separate signage, and medical records.

4. The indirect compensation exception is highly questionable. CMS clearly says that recruitment has no benefit to Hospital and no FMV. CMS position is that an indirect compensation arrangement exists that cannot be protected by the exception b/c it is not FMV for services to Hospital.
Beta Hospital, a not–for–profit hospital in an urban area, is approached by Dr. Neuro, the head of the hospital’s only neurosurgical group. The five person Group’s just received notice that its medical malpractice premium is doubling. Dr. Neuro wants to know What Beta can do to help. Dr. Neuro says that two of the Group’s physicians are going to leave unless they get assistance. The Group generates a fair amount of inpatient revenue for the hospital, and also a fair amount of charity work on uninsured patients. The Group also provides on call coverage for the ER for which it is not paid. The State in which Beta is located is acknowledged to be in a medical malpractice crisis.
The Rule

The indirect compensation exception.

- An indirect compensation arrangement must exist
  - There is a chain of financial relationships bet. Beta and MDs
  - The amount of $$ to physician must vary or otherwise reflect the value or volume of referrals to Beta
  - Beta must have reason to suspect the connection to referrals
- The compensation received by Group MDs must be FMV for services provided and not determined in any manner that takes into account V/V of referrals or other business generated
- The arrangement between Beta and the doctor is set out in writing (unless it is an employment agreement), signed by the parties, specify the services, and be commercially reasonable even if no referrals are made to the employer.
- Comply with AKS
Discussion

Medical Malpractice subsidies probably don’t work under Stark unless the subsidy can be tied to the provision of services to the hospital. Like Physician recruitment, CMS has suggested that a subsidy to a group creates an indirect financial arrangement since the payment to the group would not be made unless the group referred to the hospital. Accordingly, the group’s compensation to the physician will “otherwise reflect” referrals or other business generated by the physician to the Hospital. As a practical matter, CMS has to take that view or the entire statute could be avoided by giving everything to the Group. While CMS may be wrong, the Hospital would be at enormous risk.
Discussion (cont’d)

If the subsidy does create an indirect financial arrangement, it cannot fit in an exception because the subsidy is not for any services provided by the Group or the physicians.

One possible fix is to tie the subsidy amount to the value of services provided, such as the on-call coverage. The Hospital could also seek concessions on malpractice litigation management (waiver of veto on settlement, common counsel) and get a valuation of such concessions.
SAME BUILDING SHARED EQUIPMENT HYPO

Hospital owns a MOB in which it locates its radiology department, including the independent radiology group that has an exclusive arrangement for hospital radiology professional services, and a MRI and other imaging equipment.

Neurology Group also has its offices in the MOB. Neurology wants to share Hospital’s MRI. It proposes to enter into a space/equipment/staffing lease with the hospital to rent the MRI equipment, the MRI room and preparation area, and the technicians on a “per use” basis. In addition, the Neuro Group will enter into a separate contract with the Radiology Group to supervise the MRI equipment and staff when it is being used by the Neuro Group. The agreement would be for a per use supervision fee.
The Rule

In office ancillary permits a group practice to bill for DHS if they are provided:

- In same building
- Supervised by physician or physician in the group
- Billed by group, referring doc or wholly owned entity
Discussion

The Stark regulations clearly permit shared ancillaries in the same building. However, the arrangement must comply with the in-office ancillary exception and the relevant Medicare billing rules. Assuming the Neuro Group qualifies a group practice pursuant to §411. And has regular office hours in the building, the issues are whether the arrangement meets the necessary supervision and billing requirement.

The first issue is whether the “supervision” test can be met. According to the Stark Preamble, compliance requires the same level of supervision as is required by Medicare  [To BE Continued]
GAINSHARING HYPO

• Emboldened by recent OIG Opinions on gainsharing, Our Lady of Perpetual Regulatory Issues decides to implement a gainsharing program with its cardiac surgeons in an effort to improve outcomes, decrease length of stay, lower costs and create a warm and fuzzy relationship with the surgeons
Gainsharing: Potential Types of Services

- Standardization of Medical Device/Supply Purchases
- Development of Treatment Protocols/Clinical Pathways
- Utilization Management
- Education of Medical Staff and/or Employees
Gainsharing: Potential Conditions For Payment

- Cost Savings Measured Against Budget or Base Year Costs
- Improved Quality of Care Measured By
  - Patient satisfaction surveys
  - Mortality/Morbidity Measures
  - Other Measures
- Completion of Specified Consulting Duties
Potential Manners of Payment

• Directly to Physician Participants

• Indirect Payments
  – Physician Group
  – PHO
  – Outside Consultant
Potential Payment Methodologies

- Flat Fee
- Hourly Rate
- Percentage of Cost-Savings
- Risk Pools
Gainsharing Advisory Opinion

• Advisory Opinion 05-01 approved gainsharing plan:
  – Hospital shared 50% of cost savings with surgeons related to
    • Opening package items only as needed
    • Blood cross-matching only as needed
    • Substituting lower cost supplies
    • Standardizing surgical devices, where medically appropriate
Gainsharing Advisory Opinion

- Key favorable factors
  - Clarity of written agreement gave transparency that permitted public scrutiny and accountability
  - Credible evidence of no adverse patient-care effect
  - Applies to all payers
  - Independently set baselines protect against inappropriate reductions in care
  - Full disclosure to patients
  - One year limit
  - Doctors paid on per-capita basis
Gainsharing Advisory Opinion

• Potential negative factors
  – No demonstrable direct connection between individual actions and any reduction in the hospital’s out of pocket costs
  – Individual actions that would result in savings not specifically identified
  – Insufficient safeguards against the risk that other unidentifiable actions might account for any “savings”
  – Quality of care indicators of questionable validity and statistical significance
  – No independent verification of cost savings, quality of care indicators or other essential aspects of the arrangement
Gainsharing Advisory Opinions

• OIG: Gainsharing potentially implicates the Anti-kickback Statute, the CMP for physician incentives to reduce services, and Stark

• OIG: Reviewed arrangements would not be subject to enforcement action under the first two

• What about Stark?
Stark Issues In Gainsharing

• Availability of Exceptions
  – Employment
  – Personal Services
  – Fair market value
  – “Indirect” Compensation
  – Legislative action?
Personal Service Exception

- Arrangement is in writing, signed by the parties, specifies the services covered.
- Arrangement covers all services to be provided by physician to entity.
- Aggregate services contracted for may not exceed those reasonable and necessary for the legitimate business purposes.
- Term must be at least one year (if terminated may not enter into the same arrangement during the first year of the original term).
Personal Service Exception

• Compensation must be set in advance and except for physician incentive plans, does not take into account the volume or value of referrals or other business generated between the parties.
• Services may not involve the counseling of an unlawful business arrangement.
Personal Service Exception

• Requires agreement to cover all services provided by physician to entity
• Allows either incorporation by reference of all other agreements or cross reference to master list of contracts maintained centrally
• Permits physician incentive plan exception to include downstream payments
Applicability of Personal Service Exception to Gainsharing

- Type of services
  - Can work for
    - Development of clinical protocols
    - Conducting training of staff and other physicians
    - Discrete utilization management services
  - Problematic for
    - Following protocol that result in savings
    - Standardizing purchases
Applicability of Personal Service Exception to Gainsharing

• Compensation method
  – Can work for
    • Flat fee
    • Hourly rate
  – Problematic for
    • Share of cost-savings
    • Risk pools
Fair Market Value Exception

• Arrangement is in writing, signed by the parties, specifies the services covered
• Set timeframe of one year
• Arrangement covers all services to be provided by physician to entity
Fair Market Value Exception

- Compensation must be set in advance and not take into account the volume or value of referrals or other business generated between the parties.
- Arrangement must be commercially reasonable
- Cannot violate other laws
- Services may not involve the counseling of an unlawful business arrangement
Applicability of Fair Market Value Exception to Gainsharing

• Applies only to provision of goods and services by physician
  – Unclear if those types of services outside personal services exception would qualify
    • Following treatment protocols
    • On-time starts
    • Agreeing to standardized purchases

• Determination of fair market value may be problematic
Indirect Compensation Arrangements

• “Unbroken Chain” of any number of entities between physician and entity
• Compensation to physician from closest link in chain varies with volume or value of referrals to entity providing DHS
• Entity providing DHS has actual knowledge or acts in reckless disregard of existence of such relationship
Indirect Compensation Exception

• Compensation at fair market value w/o taking into account volume or value of referrals
  – Need not be “set in advance”- Per-use payments permitted even if referrals from physician can effect total units
• In writing, signed by parties, that specifies covered services (not required for employment relationships)
• Does not violate anti-kickback statute or Program billing rules
Applicability of Indirect Exception to Gainsharing

• Exception with the greatest potential applicability
  – Physician Group
  – PHO
  – Outside Consultant

• Potential legislation?
  – MedPac recommends creating a gainsharing exception
ASC HYPO

A local hospital and a group of physicians are in discussions about opening an ambulatory surgery center (ASC) in a fast-growing suburb about 20 minutes from the main hospital. The group of physicians includes:

- Two internists, who will not personally perform any procedures at the ASC and will refer to other ASC investors.
- One otolaryngologist, who will perform 100% of his ASC procedures at the investment ASC, but due to the nature of his practice only 15% of his medical practice income comes from ASC procedures.
ASC HYPO (cont’d)

- Four orthopedic surgeons. Two of the orthopedic surgeons, will each perform about 40% of their ASC procedures at the investment ASC, one orthopedic surgeon will perform about 25% of her ASC procedures at the investment ASC, and one is semi-retired and will perform only about 5% of his ASC procedures at the investment ASC and refer the remainder of his patients who need surgery to the other orthopedic surgeon investors.

- One plastic surgeon, who does not participate in Medicare or Medicaid, performs 80% of his surgeries at the investment ASC.
ASC HYPO (cont’d)

• Two anesthesiologists. One of the anesthesiologists splits his practice between hospital anesthesiology and pain management and performs 90% of his pain management procedures in the investment ASC. The other anesthesiologist does not do any pain management, but has a contract to provide all of the anesthesia services at the investment ASC.

• Who should be permitted to invest in the ASC?
The Rule – Common ASC Safe Harbor Requirements

• ASC must be Medicare-certified under 42 C.F.R. part 416.
• ASC’s operating and recovery room space must be dedicated exclusively to the ASC.
• Patients referred by physician investors must be fully informed of the physician-investors’ investment interest in the ASC.
• Terms on which the investment is offered to investors may not be related to the previous or expected volume of referrals, items or services furnished, or business otherwise generated for the ASC.
The Rule – Common ASC Safe Harbor Requirements (cont’d)

• Neither the ASC nor any investor may loan funds or guarantee a loan for an investor to use in obtaining the investment interest.

• The amount of payment to an investor for the investment interest must be directly proportional to the amount of the capital investment.

• All ancillary services provided by the ASC must be directly and integrally related to the primary procedures performed at the ASC and may not be separately billed to any Federal health care program.

• The ASC and any physician or hospital investors must treat Federal health care program beneficiaries in a nondiscriminatory manner.
The Rule – Hospital/Physician ASC Safe Harbor

- Investors include at least one hospital and all of the remaining investors are (i) physicians who meet the requirements of a surgeon-owned ASC, single-specialty ASC, or multi-specialty ASC; (ii) surgical group practices; (iii) group practices composed exclusively of such physicians; or (iv) non-referral source investors.

- The ASC may not use hospital space unless there is a lease that complies with the space rental safe harbor, hospital equipment unless there is a lease that complies with the equipment rental safe, or hospital services unless there is an agreement that complies with the personal services and management contracts safe harbor.
The Rule – Hospital/Physician ASC Safe Harbor (cont’d)

• The hospital may not include any costs associated with the ASC on the hospital’s cost report or any claim for payment from a Federal health care program.

• The hospital may not be in a position to make or influence referrals directly or indirectly to any investor or ASC.
The Rule – Multi-Specialty ASC Safe Harbor

• All investors are (i) physicians who are in a position to refer patients directly to the ASC and perform procedures on such referred patients; (ii) group practices composed exclusively of such physicians; or (iii) non-referral source investors.

• At least one-third ($\frac{1}{3}$) of each physician-investor’s medical practice income from all sources for the prior fiscal year or 12-month period must be derived from the physician-investor’s performance of ASC procedures.

• At least one-third ($\frac{1}{3}$) of the ASC procedures performed by each physician-investor for the prior fiscal year or 12-month period must be performed at the investment ASC.
Discussion

• **Hospital** – Yes. Although the hospital may need policies in place to address the safe harbor requirement that it not be in a position to make or influence referrals to any investors or the ASC.

• **Internists** – No. They do not perform procedures in the ASC and, in fact, refer patients to physicians who do.

• **Otolaryngologist** – Probably not. Although he satisfies one of the one-third, 15% is pretty far from the one-third practice income requirement.
Discussion (cont’d)

• Orthopedic surgeons
  – Yes for those who perform 40%.
  – Maybe to one who performs 25%.
  – No to semi-retired physician who performs 5%.

• Plastic surgeon – Probably. He satisfies the safe harbor requirements. In addition, he does not participate in Medicare and Medicaid.
Discussion (cont’d)

• **Pain management anesthesiologists** -- Probably. Assuming his pain management practice is enough to meet the one-third practice income requirements, he performs enough procedures in the investment ASC.

• **Other anesthesiologist** -- Probably. Normally, an anesthesiologist who does not perform pain management is considered a non-referral source physician. However, some recent guidance seems to question this view. Does the fact that the anesthesiologist has a contract with the investment ASC change the result?
A local hospital has decided to enter into the home oxygen business. Previously, the hospital referred about 75% of discharged patients to Jethro’s DME Company. The hospital is concerned that it lacks experience operating a home oxygen business. The hospital approaches Jethro’s DME Company, hoping to convince them to enter into a joint venture to operate a DME company to provide home oxygen. Jethro’s will contribute all of the working capital for the JV. The hospital will contribute the use of its name. The JV will enter into an agreement with Jethro’s to provide billing and collection services. The JV will have employees to operate the business. The JV will maintain an inventory, which it will purchase from Jethro’s DME company.
**JOINT VENTURE HYPO (cont’d)**

*Alternative 1:* What if the hospital and Jethro’s DME company did not form a JV, but rather entered into a subcontract arrangement whereby the oxygen services would be billed under the hospital name and number, but otherwise Jethro’s DME company would be responsible for providing “turn-key” management and operation of the oxygen business. Jethro’s would also provide billing and collection services. The hospital would not maintain any inventory with Jethro’s providing oxygen equipment on an as needed basis.
The Rule

- OIG Advisory Opinion 03-12 (May 22, 2003).
The Rule (cont’d)

• Bottom line: None of the guidance provides definitive answers as to how to structure a joint venture involving potential referral sources. According to the Advisory Opinions, a key issue is whether the joint venture appears to be “a legitimate, bona fide business.” OIG Advisory Opinion 03-13 (Jun. 16, 2003).
Discussion

• **Joint Venture** – It depends. Examine factors under Special Fraud Alert on Joint Ventures.

• **Alternative 1 (Subcontract)** – It depends. Examine factors under the Special Advisory Bulletin on Contractual Joint Ventures.
VOLUNTARY DISCLOSURE

HYPO

• Management at Oooops General Hospital has just discovered that their highest admitting neurosurgeon has been holding over on an expired lease in their medical office building for the last 19 months. It seems that the Hospital’s property manager retired just as the lease expired and the file was mislaid in the transition to his replacement. Medicare payments to the Hospital for the surgeons patient’s over this period total $18.5 million. What do you do?
Analysis of Voluntary Disclosure Hypothetical

• The problem
  – Stark states that “no payment may be made” for service rendered pursuant to a prohibited referral
  – Under this language, an overpayment is arguably created whenever there is a Stark violation
Analysis of Voluntary Disclosure

Hypothetical

- Applicable laws
  - Medicare/Medicaid-specific statutes (42 U.S.C. §1320a-7b)
    - False claims
    - False statements
    - Failure to refund
  - Potential False Claims Act liability
Analysis of Voluntary Disclosure Hypothetical

• The desperate search for applicable exceptions
  – Holdover exception only permits six months
  – Nunc pro tunc lease?
  – Indirect?

• How much discretion does the OIG have?