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Capturing New Revenues: The Opportunity and Challenges

By

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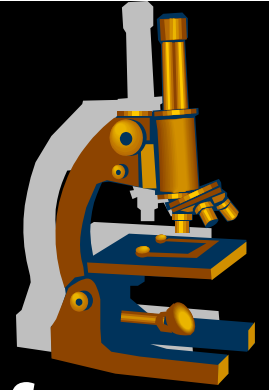


Opportunity: What's Hot?

- Ancillaries
- Joint Ventures
 - Upstream JV
 - Provider JV
- Pay for Performance
- Gainsharing
- Provider Speciality Alliances



Ancillary Services



- **Expansion of the scope of services**
- **Lab, imaging, pharma, PT**
- **Most physicians must find a way to bring these services inside their groups to avoid Stark problems**



Ancillary Services

- To fit within in office ancillary services exception:
 - Supervision
 - Location
 - Billing



Ancillary Services

- In office ancillary services exception difficult to satisfy for many smaller groups
- Alternatives . . .





Joint Ventures

- **Upstream**
 - **Generally do not involve clinical services– equipment leasing, management, etc**
- **Provider JV**
 - **Generally venture is involved in providing care**



Hypothetical # 1

- **Slice PC, a group of orthopedic surgeons, is looking for a way to expand revenues by capturing at least a portion of the technical revenues from the imaging studies (MRIs) ordered by Slice physicians. Slice, however, does not order a sufficient volume of MRI scans to justify buying its own magnet. Vision, a radiology group, offers to open a new site near Slice's offices and to form a joint venture with Slice to own the MRI and lease it to Vision. Rent would be calculated on a per click basis.**

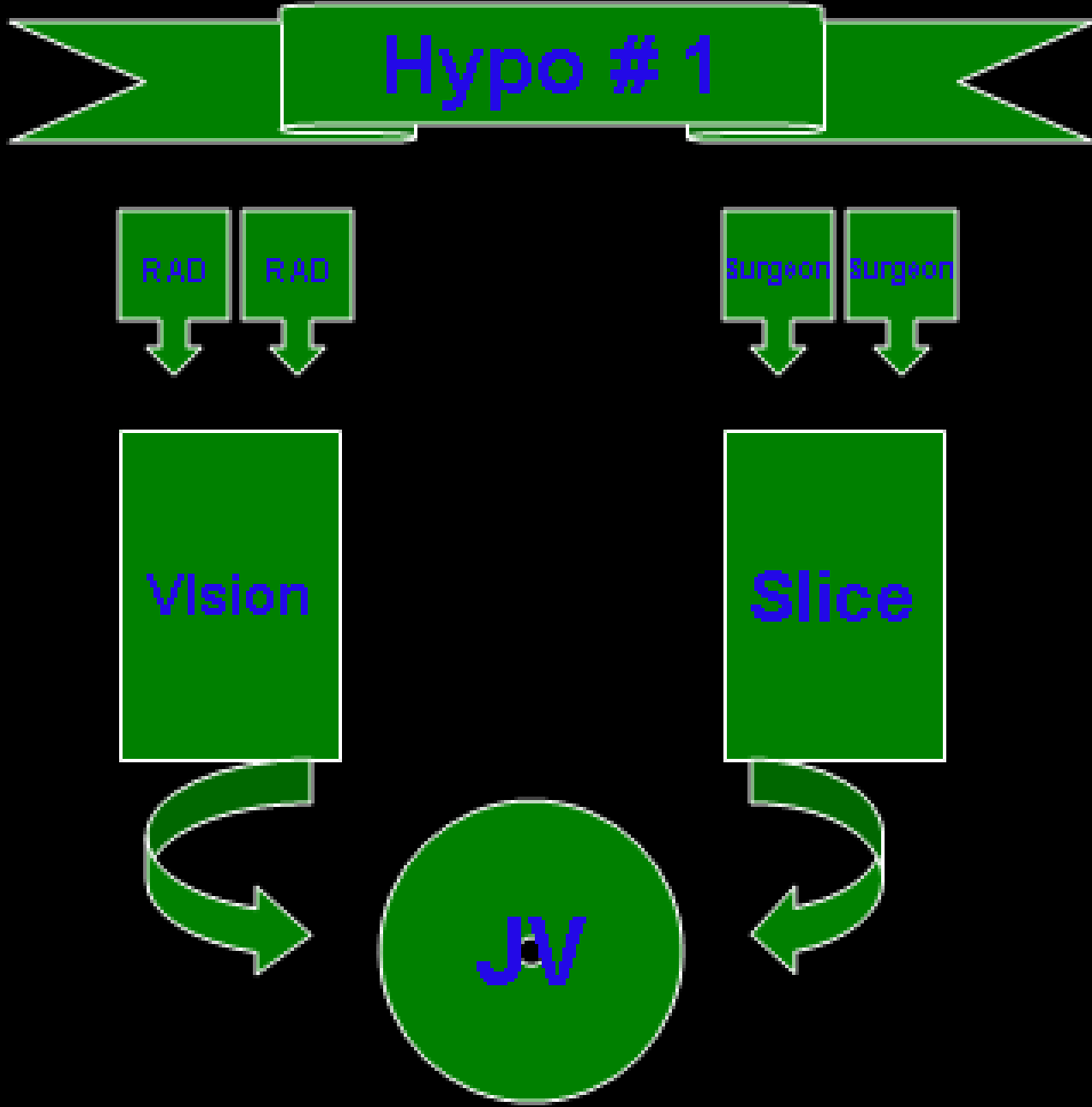


Analysis

- **This simple JV raises several regulatory issues:**
 - **Stark**
 - **Anti-kickback**
 - **Reimbursement**
 - **State law restrictions**



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Upstream Joint Venture

- An equipment leasing company is a prime example of an “upstream” joint venture
- Key distinction: the joint venture entity is not a provider
- This avoids the Stark prohibition (at least in most cases)



Stark Analysis

- Slice and Vision physicians have ownership interest in joint venture
- Joint venture has compensation arrangement (lease) with Vision, a provider of designated health services
- Analyzed as an indirect financial relationship under Stark



Stark: Vision Physicians

- Vision physicians are radiologists – under Stark radiologists don't refer
- Thus, Vision physicians financial relationship with a provider of diagnostic imaging generally not relevant under Stark



Stark: Slice Physicians

- Orthopedic surgeons do refer under the Stark law
- Thus, Slice physicians ownership interest in the joint venture does create a financial relationship that must be analyzed



Indirect Compensation Relationship

- **3 part test**
 - **Unbroken chain of financial relationships between physician and DHS entity**
 - **Compensation arrangement closest to the physician varies with the volume or value of referrals**
 - **DHS entity knows**



Indirect Compensation

- **Slice physicians who are employees and do not have an ownership interest in the group, the closest compensation relationship is their salary from the group**
- **Does their salary vary with volume or value of their referrals to the Vision Imaging Center?**
- **If not– no financial relationship**



Indirect Compensation

- For the Slice shareholders, however, the closest compensation arrangement will be the lease payments from Vision to the joint venture
- Rent is per click and, for purposes of the definition of indirect compensation arrangement is considered to vary with volume or value
- Thus, Slice shareholders likely have a financial relationship with Vision Imaging



Indirect Compensation Exception

- **This exception requires:**
 - **Agreement in writing, signed by the parties**
 - **Describes services covered**
 - **Payment fair market value and not based on volume or value**
 - **Arrangement does not violate Anti-kickback statute**



Indirect Compensation Exception

- Parties should be able to structure the lease to fit within the exception
- Key distinction: for the indirection exception per click payments are deemed not to be based on volume or value



Anti-kickback

- The joint venture and related lease do raise kickback issues
- No safe harbor protection for either the investment interest or for the lease
- Facts and circumstances analysis
- Hanlester instructive in this analysis



Anti-kickback

- **Bottom line: some risk under the kickback law**
- **Try to structure the transaction to meet as many of the applicable safe harbor criteria as possible**



Reimbursement

- Joint venture is upstream, so reimbursement issues are really Vision's problem
- Lease of equipment should not trigger the purchased diagnostic test rule



State law issues

- **Washington:**
 - **Medicaid Stark and Kickback statutes**
 - **RCW 19.68**
- **California:**
 - **Speier**
 - **State Kickback laws**



Hypothetical #2

- Slice reviews the pro formas for the Joint Venture equipment leasing company and is dissatisfied. Slice wants to operate the imaging center on a part time basis and bill under its group provider number. What are Slice's options?



Provider Joint Venture

- In Hypo #2 Slice wants to capture at least a portion of the technical reimbursement for imaging studies
- The Stark Law creates significant challenges



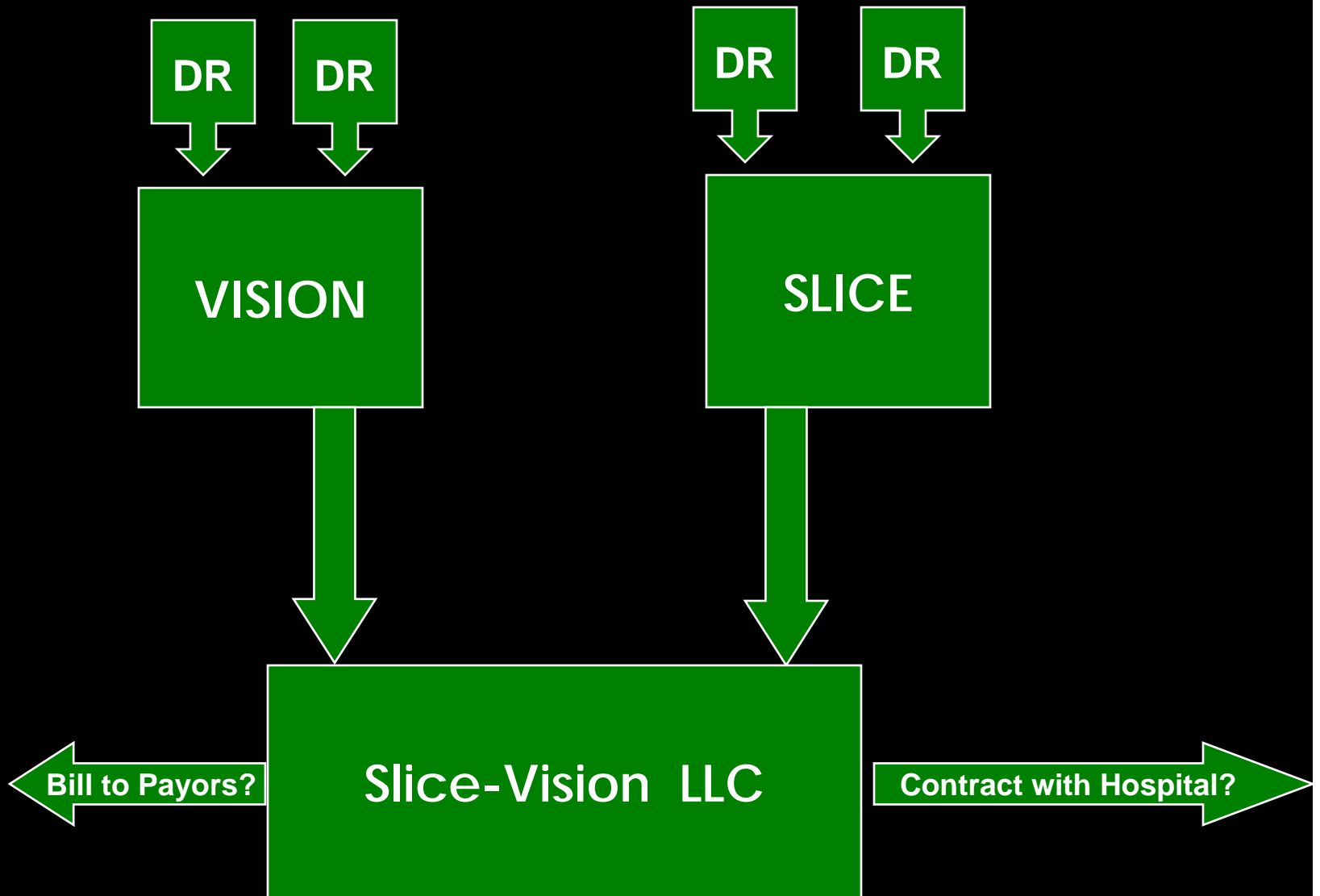
What are the options?

- **New Joint venture entity: Slice-Vision LLC**
- **Full time operation of Imaging Center as a part of Slice group practice (purchase or lease from Vision)**
- **Part time lease of space/equipment by Slice**



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HYPO # 2





Slice-Vision LLC

- Slice-Vision LLC would be a provider of DHS, if it bills Medicare for diagnostic radiology
- No ownership exception is available for Slice (unless in rural area)
- Vision ok because Radiologist don't refer
- Under Arrangements? (Slice-Vision would not be "entity" under Stark because it would not bill Medicare)



Slice: Sole provider

- If Slice PC has sufficient volume it could lease MRI from Slice-Vision and provide the diagnostic imaging services through its group practice
- This is not always practical



Slice: Part Time Imaging Arrangements

- **Slice-Vision could lease the MRI center to Slice PC on a part time basis**
- **When leased to Slice, the group would provide the imaging services and bill under its number**
- **Must fit within Stark Exception**



In Office Ancillary Services Exception

- To bill for DHS under this exception:
 - Supervision
 - Location
 - Billing



Slice: Part time Provider

- **Locational Test**
 - **Centralized location**
 - **Same Building**

24/7

Fit inside or build inside



Carve Out Option



- Stark applies to referrals of Medicare patients for designated health services
- If Medicare patients are carved out of the joint venture then Stark prohibitions avoided
- Beware: Practical Challenges



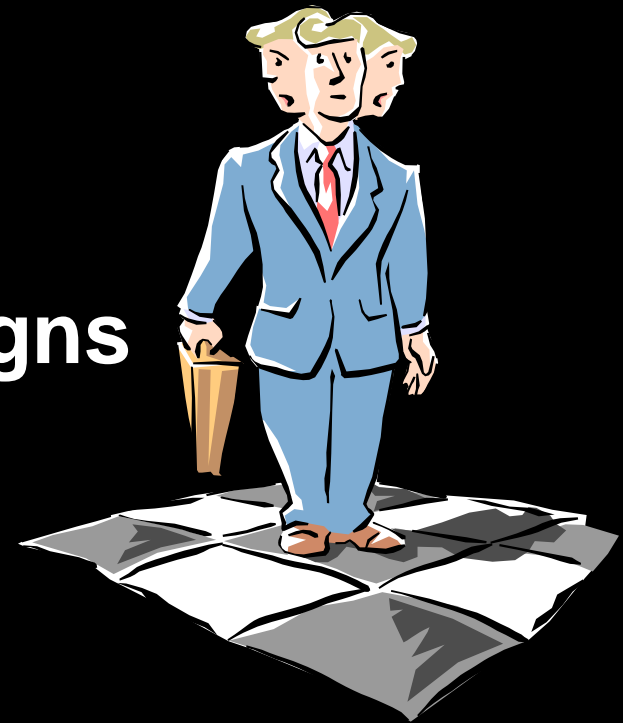
Carve Out Option

- **Carve outs are not favored by the regulators**
- **Anti-kickback issues should be carefully considered**
- **“Swapping” arrangements should be avoided**



Pay for Performance

- Over 100 Pay for Performance initiatives currently underway
- Wide variety of criteria used
- Array of goals
- Strong Support
- But, confusion reigns





Pay for Performance

- Traditionally reimbursement based on volume not on quality or outcome
- Perception that the system creates the wrong incentives
- PFP in all of its iterations is an attempt to link payment to quality or to some outcome measure



Pay for Performance

- **The Pay for Performance Programs are essential to the emerging concept of consumer driven health care**
- **In theory, as patients assume more control and financial responsibility they will need good cost and quality data to make informed choices**





Pay for Performance

- **Pay for Performance also has many advocates among large employers and health plans**
 - **LeapFrog**
- **Some of the rhetoric suggests that PFP should be relatively easy to implement**



Pay for Performance

- **Two types of PFP programs:**
 - **Programs that focus on process**
 - **Programs that focus on outcomes**



Pay for Performance: Process

- **Process focused PFP programs may be based on:**
 - **Adoption of Clinical Pathways**
 - **Implementation of EHR systems (i.e. CPOE)**
 - **Preventive care**
 - **Performance of screening or tests**



Pay for Performance: Outcomes

- **Pay for Performance based on clinical outcomes may measure:**
 - **Morbidity**
 - **Infection rates**
 - **Readmission rates**
 - **Complications**
 - **Medical Errors**
 - **Compliance with Best Practices**



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Pay for Performance

- Problem
- **BAD DATA**





The Rand Corporation Study

- February '06 Rand Study found that the methods commonly used to create quality “report cards” generally overstate quality of care provided



Rand Study

- **Report Cards typically rely on administrative records collected by insurers because data is computerized and available**
- **In Rand Study administrative records indicated patients received 83% of recommended care**
- **When Medical Records reviewed, percentage dropped to 55%**



GAO Report on CMS Project

- Under MMA Hospitals required to submit data on 10 quality measures
- Failure to submit the data result in loss of .4% of payment update
- Quality Measures cover 3 conditions: heart attack, heart failure and pneumonia



GAO Report

- CMS has gathered data and launched website “Hospital Compare” to convey the information to consumers
- Congress directed GAO to assess the reliability of the publicly reported information on quality



GAO Report

- In January 2006 GAO released report
- Data found to be incomplete and “statistically uncertain”



GAO Report

- **Bottom line:**
- **CMS needs more rigorous methods to ensure reliability of the quality data it is publishing**
- **Note the limited scope of project– does this bode well?**



Data Problems

- **The GAO Report and Rand study are not alone in pointing out the foibles of the data used to measure quality**
- **Other common problems:**
 - **Age of data (doesn't reflect current care provided)**



Dated Data

- If the data upon which payment is made (or which consumers rely on to make choices) is not current . . .
- Study in Northeast of Cardiac Bypass Surgery at Several Hospitals over 10 year period



Dated Data

- There was a 2 year delay in publishing data
- Hospital ranked 1st in 1996 was last in 1998
- So when the patient shopped for the highest quality hospital in 1998 relying on 1996 data . . .



Data Problems

■ Accuracy of standards

- If recent improvements not reflected in measurement tool, providing better quality is punished
- Example: CMS / Premier project requires use of ACE inhibitors despite fact that new evidence suggests that some patients better treated with ARB (angiotensin receptor blockers)



Data Problems

- **Acuity adjustments flawed**
 - **Difficult to adjust for all variables**
 - **Adverse selection can skew data**
 - **Foibles allow providers to game the system**



But, the beat goes on

- Despite the data problems Pay for Performance is a growing trend





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Physician Consortium for Performance Improvement

- **AMA and Specialty Societies collaborating over past several years**
- **Developed 90 quality measures covering 15 conditions**



Ambulatory Care Quality Alliance (AQA)

- New National Pilot Program on quality measurement
- AQA endorsed set of 26 performance criteria that have started gaining acceptance
- Pilot Program will aggregate and report data on physician performance across all public and private programs
- 6 Health care consortiums will participate (CA, IN, MA, AZ, MN, WI)– Data collection begins May 2006



AMA & Congress

- Late February 2006 AMA signed an agreement with Congress to develop 140 performance measures covering 34 clinical areas by end of 2006
- Specialty Societies unhappy (not at the table)
- No commitment either to pay for voluntary compliance with performance criteria or to revise physician compensation to more accurately reflect costs



Pay for Performance: Prediction



- PFP Movement will continue
- PFP, however, will continue to be plagued by inaccurate standards, incomplete data and the pace of change in medicine





PFP Prediction



- PFP success is directly tied to development of strong information technology systems
- PFP will improve quality and will affect provider reimbursement
- Current high quality providers will be the biggest winners
- But, the winners in PFP will include those who can game the system as well as those who provide quality care



Gainsharing and its Progeny

- **Gainsharing is difficult to precisely define. Most use the term to refer to hospitals sharing cost savings with the physicians who help generate those savings**
- **Programs generally intended to align incentives:**
 - **Hospitals paid DRGs-- at risk**
 - **Physicians paid FFS-- no stake in hospital costs**



Gainsharing: Early Programs & Legislation

- In 1980s a Texas Hospital System adopted a program that paid physicians \$200 per day for discharging patients early
- Congress, not amused, enacts Civil Money Penalty Law addressing Physician Incentive Plans (PIPs)
- 1990 PIP statute bifurcated between health plans and hospitals (hospital law much more restrictive)



Gainsharing: Range of Regulatory Issues

- In addition to the Physician Incentive Plan (PIP) law, gainsharing programs raise several regulatory issues:
 - Stark
 - Anti-kickback
 - Tax exemption requirements
 - State law restrictions



Gainsharing: Stark

- Stark Law prohibits physician from referring Medicare patients to an entity (including a hospital) if the physician has a financial relationship with the entity that does not fit within an exception
- Gainsharing programs difficult
 - what is fair market compensation?
 - Is cost savings tied to value of referrals?



Gainsharing: Anti-kickback

- **Anti-kickback statute also implicated by Gainsharing**
- **Government worried that programs will influence physician choice of hospital (steering) and distort medical decision making (stinting)**



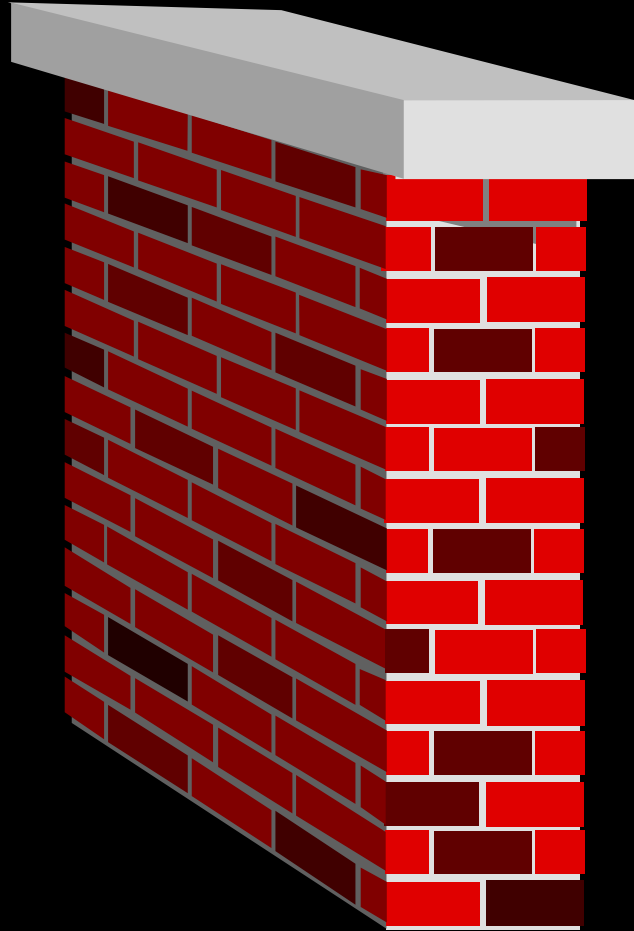
The Gainsharing Bandwagon

- Health care industry in late 1990s began embracing concept
- Focus: Cost per case programs
 - Cardiology leading the way
- IRS Private Letter Ruling approves program
- Advisory Opinion requests submitted: initially mixed signals from OIG
- Cottage Industry created



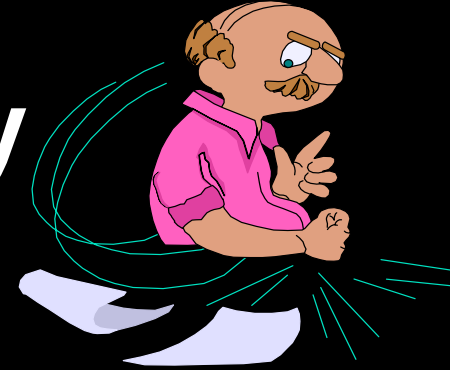
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OIG 1999 Special Advisory Bulletin





OIG Special Advisory Bulletin (SAB)



- SAB indicates that hospital PIP law: clear prohibition on gainsharing
 - SAB equates incentive to reduce cost w/incentive to reduce care
- OIG suggests Gainsharing Advisory Opinions inappropriate (just kidding?)
- Look to Congress for solution?
- Providers instructed to dismantle existing programs expeditiously



2005: Advisory Opinion Wave

- About Face?
- In rapid succession, OIG issues 6 advisory opinions approving specific gainsharing programs
- All opinions address gainsharing between Hospital and cardiac surgeons or cardiologists
- All involve the same consultant





The 2005 Wave

- **The OIG drew a distinction between**
 - **Generalized gainsharing arrangements tied to overall cost savings (not permitted) and**
 - **Limited gainsharing arrangements tied to specific, identifiable and verifiable cost savings (subject to case by case review)**



Keys Elements of Acceptable Gainsharing Programs

- **1) Transparency**
- **2) Clinical Support for Criteria**
- **3) Non-Discrimination**
- **4) Baseline limits on cost savings**
- **5) Product Standardization Safeguards**
- **6) Limits in Scope and Duration of program**
- **7) Savings distributed to the physicians on a pro rata basis**



Gainsharing



- **Bottom Line: management contract or cost per case gainsharing opportunities are limited**
- **But MedPac Report endorses concept of gainsharing**
- **CMS Demonstration Projects in progress**
 - **Preliminary reports suggest cost savings not as significant as predicted**



A New Twist

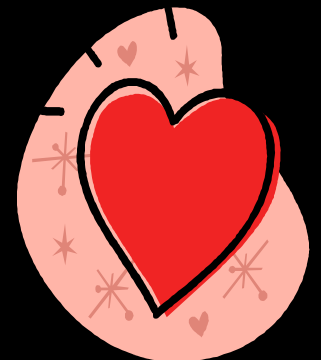
- If cost per case savings programs are too difficult, what are the other options?
- The New New Thing: Service Line Joint Ventures
- Sometimes call Provider Specialty Organizations





Provider Speciality Organizations (PSO)

- PSO is typically a joint venture between a hospital and a group of subspecialists
- PSO contracts with health plans to provide specific procedures on a globally priced basis (professional and facility fees combined)
- Most common in Cardiology



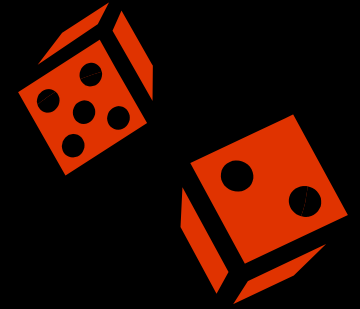


Provider Sponsored Organizations

- PSO members, the hospital and the specialist physicians, share risk
- Typically hospital and physicians agree to fixed base payments for facility and professional services for a procedure
- The remaining funds are placed in a risk pool



Provider Sponsored Organizations

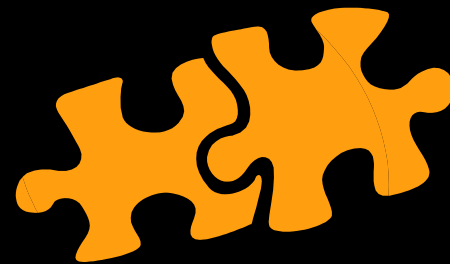


- If over the course of a year the PSO controls costs, the risk pool funds will be available for distribution to the participating physicians and hospital
- Criteria for distribution of risk pool proceeds set by PSO



Provider Sponsored Organizations

- This structure gives the member physicians and the hospital both an incentive and the flexibility to structure effective measures to ensure quality and promote efficiency





Why does this work?

- **The structure of the PSO and the sharing of risk mean**
 - **Health Plan (not Hospital) PIP Law should apply**
 - **Risk Sharing Exceptions under Stark and Anti-kickback statute available if program structured correctly**



What are the Challenges?

- **Physicians and hospital must develop sufficient knowledge of practice style and cost structure to be comfortable with risk sharing**
- **Payors in Community must be willing to contract with Joint Venture to provide globally priced procedures**





What are the Challenges

- **Payor should be involved incentive criteria**
- **Risk pool funds limited to patients covered by global contracts**
- **Criteria used to measure quality and efficiency should be applied only to this group of patients (difficult to isolate data; problem of small numbers)**



What are the Challenges?

- **State Laws may restrict ability of providers to share risk or impose burdensome requirements**
- **Developing risk pool criteria not as easy as it sounds**
- **Application probably limited to distinct service lines with procedure driven reimbursement**



Prediction: PSOs

- **Provider Sponsored Organizations will emerge as a viable, but somewhat limited way, to align the incentives of hospitals and physicians**

