



The Evolution of Stark – How It Applies to Physician- Hospital Arrangements, Physician Recruitment, and Joint Ventures

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- I. Background and History of Stark Law
- II. Overview of Laws Restricting Hospital-Physician Financial Relationships
- III. Applying Stark to Common Financial Models
- IV. Applying the Laws to Physician Recruitment
- V. Applying the Laws to Joint Ventures
- VI. Questions-Discussion





I. Background and History of Stark Law



Background and History of Stark Law

- Federal law proposed in initial form in 1989 with first regulations promulgated in 1995. 42 USC §1395nn; 42CFR §411.350
- Prompted by OIG report showing Medicare patients got 45 percent more lab services when doctor owned lab
- Sponsored by Representative Pete Stark – D CA, Representing 13th District CA (East San Francisco Bay Area) see www.house.gov/stark
- Stark named by Modern Healthcare one of 100 Most Powerful people in Healthcare in 2005





Background and History of Stark Law

The Faces of US Representative Pete Stark, D-CA (13th Dist.)



Background and History of Stark Law

Generally, Stark Law prohibits

- A physician
 - from referring
 - to an entity
 - if financial relationship exists
- UNLESS, satisfy an exception



Background and History of Stark Law

The Stark Law is

- detailed
- technical
- confusing
- counter-intuitive
- unforgiving
- strict liability
- unfair?

Not something to dabble in without expert advice



Background and History of Stark Law

Technical Violations of Stark Count

- Lack of written contract
- Expired contract
- Modification of contract without writing
- Inaccurate business terms such as square footage, rent
- Compensation not fair market value
- Excessive freebies to physicians (>\$322 per year)



Background and History of Stark Law

Generally, Stark Law is Implicated by

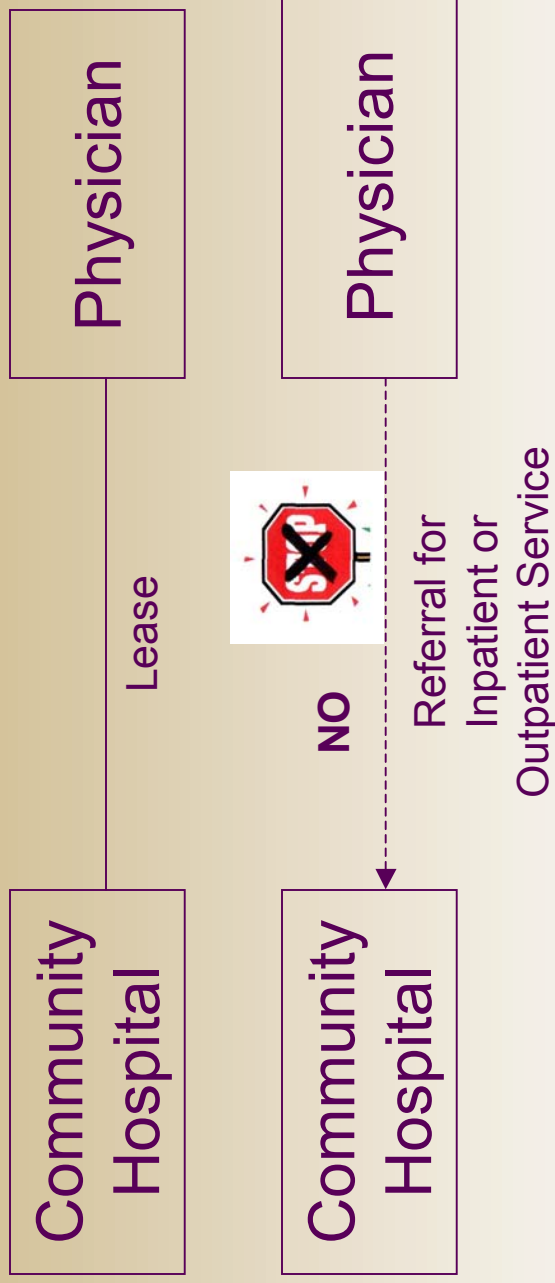
- Arrangements between a hospital and a physician who refers to that hospital
- Office Leases
- Equipment Leases
- Medical Director Agreements
- Call Coverage Agreements
- Employment Agreements



Background and History of Stark Law



Example



UNLESS Lease satisfies Stark Lease Exception





II. Overview of Laws Restricting Physician-Hospital Financial Relationships



Physician Ownership and Referral Statute (42 U.S.C. §1395nn) (“Stark Act”)

- Prohibited Activity
 - Physician (or family member) with a direct or indirect (i.e. unbroken chain) financial relationship (ownership or compensation arrangement) with an entity
 - May not make referrals to the entity for the furnishing of “designated health services” or “DHS” for which federal payment may be made (Medicare, Medicaid, etc.)
 - The entity may not present a claim to the patient or any third party payer

The Stark Act is a strict liability statute





Stark Act, cont'd

- DHS (includes the professional, if any, and technical component) of:
 - Clinical laboratory services
 - Physical, occupational therapy, speech-language pathology services
 - Radiology, imaging and x-ray (including nuclear medicine) services
 - Radiation therapy services and supplies
 - DME
 - Parenteral and enteral nutrients, equipment and supplies
 - Prosthetics, orthotics and prosthetic devices and supplies
 - Home health services and supplies
 - Outpatient prescription drugs
 - Inpatient and outpatient hospital services



Stark Act, cont'd

- **“Referral”**
The request by a physician for, or ordering of, or the certifying or re-certifying of the need for, any DHS
Does not include:
 1. Request by a pathologist for clinical lab services
 2. Request by a radiologist for diagnostic radiology services
 3. Request by a radiation oncologist for radiation therapy
 4. Any professional service personally performed by the referring physician



Stark Act, cont'd

- Penalties
 - Denial of Payment
 - Refunds
 - Civil monetary penalties of up to \$15,000 for each service
 - Civil monetary penalties of up to \$100,000 for circumvention schemes
 - Exclusion from Medicare and Medicaid programs
- Can be basis of False Claims Act Case



Stark Act, cont'd

III. Applying Stark to Common Financial Models



Stark Act Exceptions – Exception for Ownership and Compensation

- Physician Services (e.g., E&M services, surgery)
- “In-Office Ancillary Services”
(Excludes most DME, POS & PEN)
 - Furnished or supervised by the referring physician or a member of the referring physician’s group practice. Depending on service performed, level of supervision may be: general, direct or personal
 - In the same building in which the group performs substantially the full range of physician services or a centralized (exclusive ownership or lease) building of group. Mobile units in parking lot do NOT qualify
 - Billed by referring physician or group



In-Office Ancillary Services Exception - Same Building Test - Three (3) Alternatives

- A building in which the referring physician or group has an office open to patients at least 35 hours per week, and the referring physician or group member(s) regularly practices medicine and furnishes physician services, some of which are unrelated to DHS, at least 30 hours per week



In-Office Ancillary Services Exception - Same Building Test - Three (3) Alternatives, cont'd

- A building in which the referring physician or group has an office open to patients at least 8 hours per week, and the referring physician practices medicine and furnishes physician services, some of which are unrelated to DHS, at least 6 hours per week; the patient must come to that building to receive non-DHS services from the referring physician or group



In-Office Ancillary Services Exception - Same Building Test - Three (3) Alternatives, cont'd

- A building in which the referring physician or group has an office open to patients at least 8 hours per week, and the referring physician or group practices medicine and furnishes physician services, some of which are unrelated to DHS, at least 6 hours per week, and the referring physician must be present and order the DHS in connection with a patient visit during the time the office is open or the referring physician or a group member is present while the DHS is furnished during the time the office is open



In-Office Ancillary Services Exception - Definition

- “Group Practice”
 - Single legal entity formed for the purpose of being a group medical practice
 - Unified business: centralized decision-making; consolidated billing and accounting; centralized UR
 - Practice ownership not limited to physicians, but must include at least two physician members (informal affiliations and separate group practices with common control do not qualify)
 - Each physician member must furnish full range of care within group practice
 - Substantially all patient care services of the member physicians must be furnished through and billed by the group (75% of each member’s total patient care service)



Group Practice, definition, cont'd

- Members of the group must personally perform at least 75% of the patient-physician encounters
- “Group Members:” owners, employees, locum tenens, on-call physicians, not independent contractors
- Income and expenses distributed according to pre-determined method



Group Practice, definition, cont'd

- No compensation based upon volume or value of referrals made, except:
 - Productivity bonus based upon services personally performed, including “incident to” services, but excluding all referrals of DHS
 - Overall profits derived from DHS on a per capita basis, or other basis not related to referrals
 - Location and specialty-based compensation (≥ 5 physicians) may be permitted with respect to DHS revenues



Stark Act Exceptions – Exceptions for Compensation Relationships

- Equipment/Space Lease (exclusive use of space/equipment required)
- Personal Services Contracts
- Fair Market Value Compensation
- Employment
- Physician Recruitment
- Isolated Transactions



General Requirements of Stark Act Compensation Exceptions

- Written agreement identifies items and/or services
- Specific time frame for any time period as long as only one arrangement for same items during the course of a year
- Fair market value compensation set in advance that does not take into account the volume or value of referrals
- Transaction commercially reasonable in absence of referrals
- Meets an anti-kickback safe harbor or does not violate anti-kickback statute



Stark Act – Special Rules on Compensation

- Per use/per service based compensation will be considered “set in advance” if per use/per service fee is consistent with fair market value and set forth in sufficient detail to allow objective verification



Stark Act – Special Rules on Compensation

- “Fair market value” safe harbor: the hourly rate for physician’s personal services is
 - less than or equal to the average hourly rate for ED physician services in the relevant market including at least 3 hospitals with EDs
 - The average of the 50th percentile for the physician specialty in at least 4 out of 6 national compensation surveys: Sullivan, Cotter; Hay Group; MGMA; ECS Watson Wyatt; Wm. Mercer
 - Provider has the burden of proof to establish fair market value



Stark Act – Special Rules on Compensation

For Stark Law what is Fair Market Value?

- “the value in arm’s – length transactions, consistent with the general market value”
- “general market value is the price based on *bona fide* bargaining between well-informed buyers and sellers who are not otherwise in a position to generate business for the other party”
- market price for other *bona fide* sales or arrangements in the same market



Stark Act – Special Rules on Compensation

- Documentation of fair market value is key
- Consider how you would prove fair market value if regulators came knocking
- Sources of fair market value
 - National Surveys
 - *Bona fide* third party offers
 - Market Comparables
 - Professional Valuations (real estate or business appraisers)





IV. Applying the Laws to Physician Recruitment



Physician Recruitment

- Stark
- Anti-Kickback law
- Internal Revenue Service



Stark II Act, 42 U.S.C. 1395nn

- The Stark Act prohibits physicians who have financial relationships with providers from referring patients for DHS for which payment will be made under the Medicare or Medicaid programs
- Violation may result in mandatory refunds of payment for such services and \$15,000 civil monetary penalties for each service billed



Stark II Act Exception, 42 U.S.C. 1395nn(e)(5) Statutory Exception for Physician Recruitment

- Compensation provided by hospital to physician to induce physician:
 - to relocate to the geographic area served by the hospital
 - in order to be a member of the hospital medical staff
- No requirement for recruited physician to refer patients to the hospital
- The amount of remuneration is not determined in any manner that takes into account directly or indirectly the volume or value of referrals by the recruited physician
- The arrangement meets other requirements as the Secretary may impose



Stark II Regulation Exception
42 C.F.R. 411.357(e)
(Effective Date: July 26, 2004)

- Exception available to hospitals and Federally Qualified Health Centers
- Common requirements applicable when recruiting into solo practice or existing group practice
 - Physician must relocate medical practice (as opposed to residence) to hospital's geographic area
 - “Geographic area” defined as “lowest number of contiguous zip codes from which the hospital draws at least 75% of its inpatients”



Stark II Regulation Exception, cont'd

- “Relocate” defined as
 - Relocation of medical practice at least 25 miles or
 - New medical practice derives 75% of professional revenues from new patients
 - » Revenues to be measured on an annual basis (fiscal or calendar year)
 - » “New patients” defined as patients not seen by recruited physician or his/her previous practice for at least three years
 - Residents and physicians in practice one year or less not subject to relocation requirement





Stark II Regulation Exception, cont'd

- Arrangement set in writing, signed by both parties
- Arrangement not conditional on referrals to hospital
- Amount of recruitment incentives not based upon volume or value of referrals
- Recruited physician is allowed to establish privileges at any other hospital and refer business to other entities (permits reasonable credentialing restrictions on physicians becoming competitors with the hospital)



Stark II Regulation Exception, cont'd

- Additional requirements applicable to recruited physicians who join existing practices
 - Certain additional requirements apply whether or not payments made to group
 - Written Agreement is also signed by group if group will receive payment, directly or indirectly
 - Remuneration is passed directly through to or remains with the recruited physician, except for actual costs incurred by the physician or practice in recruiting the physician
 - In the case of income guarantees, the costs allocated to the recruited physician do not exceed the “actual additional incremental costs attributable to the recruited physician”



Stark II Regulation Exception, cont'd

- Records of actual costs and pass through amounts maintained for five years and made available to HHS upon request
- Amount of remuneration not based upon referrals from group
- Physician group may not impose additional practice restrictions (e.g., covenant not to compete) on recruited physician
- Arrangement does not violate anti-kickback statute



- CMS comments in teleconference
 - Incremental expense means incremental expense
 - Allocation of existing practice overhead impermissible

Stark II Regulation Background

- Recruitment exception drafted in the wake of OIG investigation of Tenet Health System
 - December, 2002 - Search warrants served on Alvarado Hospital Medical Center
 - Cause of investigation: Physician charged with billing fraud, as part of a plea agreement, told the government he received bribes from hospital in exchange for referrals; physician allegedly received \$600,000 for four recruited physicians who joined his practice
 - Search related to physician recruitment and relocation payments; Hospital funded more than 100 relocations, worth over \$10 million over ten years



Stark II Regulation Background, cont'd

- Letter from physician group seeking assistance states recruitment “will definitely help to increase the flow of admissions to Alvarado Hospital”
- CEO indicted for illegal referrals under anti-kickback statute
- Associate Administrator, who is alleged to have received \$80,000 from three physicians who received \$1.1 million in recruitment incentives, indicted for witness tampering and obstruction of criminal investigation
- Government: Why would physicians pay Associate Administrator \$80,000 if physicians believed \$1.1 million payments were legitimate?



Stark II Regulation Background, cont'd

- July, 2003 – Investigation expanded to seven additional Tenet hospitals in California
- 2 trials; 2 hung juries
- CMS proposes to exclude Alvarado Hospital
- Tenet pays \$21 Million to resolve “civil” claims of kickback violations
- Tenet sells Alvarado Hospital



Medicare Anti-Kickback Safe Harbor 42 C.F.R. 1001.952(n)

- The anti-kickback provisions of the Federal Fraud and Abuse Statute [42 U.S.C. 1320a-7b(b)] prohibit the offer, solicitation, payment, or receipt of remuneration with intent to induce referrals for federal health plan reimbursement
- Violation is a felony; penalties include 5 years imprisonment, \$25,000 fine and automatic exclusion from federal health plan participation
- Physician Recruitment Incentives may be determined to be offered to induce future referrals from the recruited physician or to induce future and reward past referrals from the medical group the recruited physician joins



Medicare Anti-Kickback Safe Harbor, cont'd

- Criteria for Safe Harbor Protection
 - New “practitioner” (less than one year in specialty) or relocating practitioner
 - Written agreement
 - To locate primary place of practice in a HPSA for practitioner’s specialty
 - At least 75% of practice revenues generated from patients residing in HPSA or medically underserved area (MUA) or who are part of a medically underserved population (MUP)
 - 75% of revenues from new patients for practitioners leaving an established practice



Medicare Anti-Kickback Safe Harbor, cont'd

- Recruitment incentives
 - may not exceed three years
 - may not be renegotiated
- No requirement that practitioner make referrals
- No restriction of practitioner privileges at or referrals to other health care providers
- Amount of incentives do not vary based upon referrals



Medicare Anti-Kickback Safe Harbor, cont'd

- Practitioner agrees to treat Medicare and Medicaid patients in a non-discriminatory manner
- Incentives must not benefit other persons in a position to influence referrals
- Failure to satisfy all criteria of the safe harbor does not constitute a violation of the anti-kickback statute



OIG Advisory Opinion No. 01-4

“[P]ractitioner recruitment is an area that is subject to abusive practices”

- Factors considered when safe harbor requirements are not met:
 - Whether there is documented evidence of objective need for the practitioner’s services within the hospital’s service area
 - Whether the recruited practitioner has an existing stream of referrals within the hospital’s service area





OIG Advisory Opinion No. 01-4, cont'd

- Whether the incentives are narrowly tailored so as not to exceed incentives reasonably necessary to recruit a practitioner
- Whether the incentives directly or indirectly benefit other referral sources
- Implement safeguards to prevent benefits flowing to existing doctors



Additional OIG Guidance Applicable to both Stark II and Anti-Kickback Compliance

OIG Supplemental Compliance Program Guidance for Hospitals (2005)

- “Recruitment arrangements pose substantial fraud and abuse risk”
- Factors to be examined in assessing the degree of risk associated with recruitment:
 - Size and value of recruitment benefit
 - Does the benefit exceed what is reasonably necessary
 - Has the hospital tried and failed to

recruit or retain physicians

Additional OIG Guidance, cont'd

- The duration of the payout of the recruitment benefit should not extend beyond three years
- The practice of the recruited physician
 - Is the physician new or established?
 - Is the physician relocating from a substantial distance?
- The need for the recruitment
 - Is the recruited specialty necessary to provide adequate access to care?
 - Do patients already have reasonable access to comparable services?
 - Assessment of community need based wholly or partially on the competitive interests of the hospital or existing physician practices will be subject to heightened scrutiny





Additional OIG Guidance, cont'd

- Joint recruitment arrangements between hospitals and physicians or physician groups pursuant to which the hospital makes payment to the established physician group are not protected by the anti-kickback safe harbor and present a high risk of fraud and abuse
- Suspect payments to existing referral sources include:
 - Income guarantees that shift costs from existing practice to recruited physician
 - Overhead or build-out costs funded for the benefit of the existing group



Internal Revenue Service

Private Inurement and Intermediate Sanctions



Internal Revenue Service, cont'd

- Private Inurement/Excess Benefit Laws, 26 U.S.C. 4958
 - Prohibited conduct
 - Tax-exempt organization providing disqualified persons with an excess benefit
 - Penalty
 - Disqualified person must return excess benefit to tax-exempt organization plus pay a 25% or 200% excise tax to the IRS
 - Tax exempt organization manager must pay 10% of excess benefit, up to \$10,000, as excise tax



Internal Revenue Service, cont'd

- **Safe Harbor:**
 - Rebuttable Presumption based upon Board review and approval of reasonableness of transaction



Internal Revenue Service, cont'd

- IRS originally took the position that a charitable hospital could provide recruitment benefits to physicians



Internal Revenue Service, cont'd

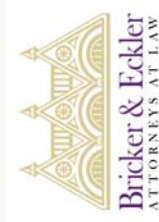
IRS Revenue Ruling 97-21

- Use guidelines established by Hospital Board
- Use community needs assessment
- Recruitment incentives must be reasonable and be related to the need for recruitment
- Must be in furtherance of Hospital's charitable purpose
- Cannot violate Medicare/Medicaid law (loss of the exemption)
- **Overall package must be reasonable**





V. Applying the Laws to Joint Ventures



Stark Act Exceptions – Exception for Ownership

- Joint Ventures Involving DHS
 - Limited to Health Providers
 - located in rural areas
 - Substantially all (75%) DHS furnished to individuals residing in a rural area



OLG Guidance On Joint Ventures

- OIG 1989 Special Fraud Alerts on Joint Ventures
- OIG Compliance Program Guidance for Hospitals (Original 1998 and Supplemental 2005)
- OIG 2003 Special Advisory Bulletin on Contractual Joint Ventures
- OIG October 6, 2006 Letter regarding Response to Request for Guidance Regarding Certain Physician Investments in Medical Device Industries



OIG 1989 Special Fraud Alert On Joint Ventures – Questionable Features

- Investor
 - Investors chosen because of a position to refer
 - Large physician referrers offered greater opportunity
 - Physician investors encouraged to refer to JV and to divest if not refer
 - JV tracks sources of referrals
 - Physician investors required to divest if cease to practice in service area (move or retire)
 - Investment interests may be nontransferable



Questionable Features, cont'd

- One ongoing entity may be already engaged in line of business and provide that line of business to JV (e.g., DME supplier, lab services)
- Ongoing entity may provide lab testing or own DME or other capital equipment
- Ongoing entity may be responsible for day-to-day operations
- JV entity is shell



Questionable Features, cont'd

- Amount of capital invested by physicians may be small compared to ROI (versus typical business investment)
- Physicians may invest only nominal amount
- Physician investors may be permitted to borrow their investment from JV entity and pay off loan via profit distributions
- Investors may be paid high returns with little risk to them



OIG Compliance Program Guidance For Hospitals

1998 Hospital Compliance Guidance

- Included among risk areas:
 - Joint ventures
 - Stark law
- Policies and procedures for anti-kickback and self-referral law compliance
 - All contractual arrangements with referral sources must comply



2005 Supplemental Guidance

- “Chief concern is remuneration from a joint venture might be a disguised payment for past or future referrals to the joint venture or one or more of its participants” (e.g., dividends, profit distributions, or economic benefit under contract)

OIG Compliance Program Guidance For Hospitals, cont'd

- Factors to examine:
 - Are investors selected based on referrals?
 - Is a JV participant already in the business?
 - Do JV participants invest reasonable amount of own funds and receive reasonable profits?
 - Are large portion of revenues from referrals of JV participants?
 - Attempt to fit JV in safe harbors for “small entity,” medically underserved areas, etc.
 - Repeats Advisory Bulletin on Contractual Joint Venture concerns



OIG 2003 Special Advisory Bulletin on Contractual Joint Ventures

- Joint Venture is “any common enterprise with mutual economic benefit” and includes contractual arrangements
- Five Questionable Features:
 1. New Line of Business. Owner expands into a service provided to Owner’s existing patients, (e.g., hospitals expanding into DME services, DME companies expanding into the nebulizer pharmacy business, or nephrologists expanding into the home dialysis supply business)



OIG 2003 Special Advisory Bulletin On Contractual Joint Ventures – Indications Of Suspect Joint Venture

2. Captive Referral Base. New business serves Owner's existing patient base (or patients under the control or influence of the Owner) and not new customers
3. Little or No Bona Fide Business Risk. Owner's primary contribution to the venture is referrals; it makes little or no financial or other investment in the business, delegates the entire operation to the Manager/Supplier but retains profits generated from its captive referral base



OIG 2003 Special Advisory Bulletin On Contractual Joint Ventures – Indications Of Suspect Joint Venture

4. Status of the Manager/Supplier. The Manager/Supplier is a would-be competitor of the Owner's new line of business and would normally compete for the captive referrals. It has the capacity to provide virtually identical services in its own right and bill insurers and patients for them in its own name



Indications Of Suspect Joint Venture, cont'd

5. Scope of Services Provided by Manager/Supplier.
The Manager/Supplier provides all, or many, of the following key services:

- Day-to-day management;
- Billing services;
- Equipment;
- Personnel and related services;
- Office space;
- Training;
- Health care items, supplies and services



Indications Of Suspect Joint Venture, cont'd

6. Remuneration. The practical effect is to provide Owner the opportunity to bill insurers and patients for business otherwise provided by the Manager/Supplier. The remuneration from the venture to the Owner (i.e. the profits of the venture) takes into account the value and volume of business the Owner generates
7. Exclusivity. The parties may agree to a non-compete clause, barring Owner from providing items or services to any patients other than those coming from Owner and/or barring the Manager/Supplier from providing services in its own right to Owner's patients





OIG October 6, 2006 Letter Re: Response To Request For Guidance Regarding Certain Physician Investments In Medical Device Industries (And Group Purchasing Agents)

- Confirms 1989 Special Fraud Alert on Joint Ventures and other guidance on physician investment at oig.hhs.gov is current and applies to all types of joint ventures
- Confirms that amount of revenues generated directly or indirectly by a physician investor is a relevant factor in analyzing a joint venture (e.g., small entity investment safe harbor applies if no more than 40% of gross revenues from investors such as physicians)
- Confirms fact that if substantial portion of a venture's gross revenues is derived from participant-driven referrals is potential indicator of a problematic joint venture (see Supplemental Hospital Compliance Guidance)



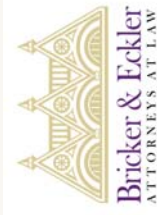
Hospital-Physician Ventures (The Good, the Bad, and the Ugly)

- MOBs
- Ambulatory Surgery Centers
- Imaging
- Equipment Leasing
- Ambulatory Surgery Suites
- Oncology Joint Ventures
- GPOs
- Hospitals
- Under Arrangements



Contractor Arrangements

- Co-Management
- Gainsharing
- Employment
- Recruitment/Stark Work-Arounds
- Malpractice Assistance
- Call





VI. Questions – Discussion?

