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Hospital Employment of Physicians: Stark Law and Anti-Kickback Statute Compliance, Physician-Hospital Alignment

TUESDAY, SEPTEMBER 25, 2018

1pm Eastern | 12pm Central | 11am Mountain | 10am Pacific

Today's faculty features:

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Buchanan Ingersoll & Rooney PC

Hospital Employment of Physicians: Legal and Business Strategies

Lorin E. Patterson, J.D.

September 25, 2018

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Why the Trend Towards Employment?

- For Hospitals:
  - Staking out/increasing market share
  - Satisfying coverage needs
  - Addressing marketing considerations using high profile and profitable specialty services
  - Increased willingness of administrations to work with physicians
  - Trend towards integration because of changing payment models

Modification in the Manner Outpatient Hospital Departments are Compensated

Effective November 2, 2015, the Bipartisan Budget Act provided that "off campus" (*i.e.*, more than 250 yards from the hospital) outpatient departments ("HOPD(s)") would not be reimbursed at hospital rates. The interim final rule published on November 1, 2016 states that:

- HOPDs in operation prior to November 2, 2015 are grandfathered but **only if they continue to operate at the same location**. The HOPD may expand services.
- Off campus clinics will be reimbursed at 50% of the OPPS.

Why the Trend Towards Employment Now?

- For Physicians
  - Concerns regarding reimbursement amid climate of political gridlock
  - Increasingly aggressive managed care environment
  - Heavy and expensive regulatory and IT burdens
  - Security/lifestyle concerns
  - Increased trust of hospital administrations
  - Evolution of payment models

Why the Current Trends Towards Employment?

- Employment arrangements are not the only means for achieving integration
  - Gainsharing
  - Management and Co-Management Relationships

    e.g. Physician groups are paid to manage service lines for a management fee consisting of two components: (i) monthly flat fee and (ii) variable bonuses conditioned on the achievement of certain benchmarks

Regulatory Framework – CPOM Doctrine

- Corporate Practice of Medicine Doctrine: State law doctrine aimed at preventing non-physicians from impairing the medical judgment of physicians through employment
  - Health law version of "Blue Sky" laws in that they vary from state to state and the law is sometimes contained in case law and not only statute
  - There is often a state law exception which allows hospitals to employ physicians
  - Even under the most stringent of corporate practice state law regimes the benefits of physician employment can usually be realized

    e.g. "Captive PC Model."

Regulatory Framework - Anti-Referral Statutes

- **Federal Stark Law Statute**: 42 U.S.C. 1395.nn. Civil federal statute which prohibits referrals of certain "designated health services" by physicians to providers with which they have a "financial relationship" unless an exception is satisfied
  - compensation relationship
  - ownership relationship
- **Strict Liability Statute**: Intent is irrelevant. Penalties for violation include heavy fines and possible exclusion from participation in federal programs

Regulatory Framework - Stark Law, cont.

- Intended to Provide a “Bright Line” regime, but ….

“ The Stark law has become a booby trap rigged with strict liability and potentially ruinous exposure.”

… concurring 4th Circuit Judge in the Toumey case

Regulatory Framework - Stark Law, cont.

- Stark Law Exceptions Applicable to Compensation Relationships:
  - Bona Fide Employment Relationships – 42 CFR 411.357(c)
    - Employment for identifiable services
    - Remuneration is (i) fair market value, (ii) commercially reasonable even if no referrals were to be made to the employer and (iii) is not determined in a manner which tracks the volume or value of referrals **but** productivity bonuses may be paid for services personally performed by the physician
  - Emphasis on Bona Fide! The Government will confirm
    - See, e.g., U.S. v. Campbell, M.D. 2011 WL 43013 (D.N.J.); (Action against physician under the False Claims Act on grounds that physician did not actually perform the full "menu" of services under his part time employment agreement and that agreement was merely a vehicle to obtain referrals)

Regulatory Framework - Stark Law, cont.

- Personal Services Arrangements – 42 CFR § 411.357(d)
  - Arrangement is set out in writing, signed by the parties and describes the services being offered
    - Stark law updates clarify that a single writing is not required. Rather, the contents of a number of documents may be combined to meet this requirement
    - 90 days are allowed for the satisfaction of the signature requirement
  - The arrangement covers all services being performed by the physician
  - The contracted for services do not exceed those which are necessary

Regulatory Framework - Stark Law, cont.

- The term is for at least one year
  - The requirement that a term be at least one year no longer requires that the term be set out in the agreements. It is enough if the agreement actually lasts for more than one year.
  - Holdover requirements have been considerably liberalized – holdovers can be indefinite if all other requirements of the exception are met.
- Compensation is set in advance, does not exceed FMV and is not calculated in a manner that takes into account volume or value of referrals
- The arrangement does not violate the federal anti-kickback statute

Regulatory Framework - Stark Law, cont.

- The requirements around what constitutes a "writing" have been significantly liberalized
- The types of documents that can evidence a written agreement will vary depending on the type of arrangement and the circumstances. These could include:
  - Board meeting minutes; documents authorizing payments for specified services; hard copy and electronic written communications between the parties; fee schedules for specified services; check requests or invoices identifying items or services provided, relevant dates and/or rate of compensation; time sheets documenting services performed; call coverage schedules or similar documents providing dates of services to be provided; or accounts payable or receivable records or checks issued for items, services or rent.

Regulatory Framework - Stark Law, cont.

- Hospitals must ensure that their written agreements with physicians are easily accessible and maintained in a centralized database, for the purposes of identifying all the services provided by a physician
- The exception for personal services arrangements requires that an entity maintain a "master list" of contracts, updated in a central database, which can be provided to CMS upon request
- The master list of contracts must be maintained in a manner that "preserves the historical record of contracts"
- Additionally, centralized record keeping permits easier review and updating of agreements and easier responses to any inquiries by regulatory authorities

Regulatory Framework - Stark Law, cont.

- Stark Law Exceptions Applicable to Ownership Relationships:
  - In states where the corporate practice of medicine imposes barriers to employment, "captive practices" may remain intact, and an exception for ownership relationships as well as compensation relationships must be identified
- Stark Law Cases Raise the Red Caution Flag!
  - U.S. ex rel. Drakeford v. Tuomey Healthcare System
    - $237 million judgment awarded against South Carolina hospital as a result of Stark non-compliant part-time employment contracts
    - Settled for $72.4 million
    - Tuomey facts:
      - The hospital's outpatient surgery center ("OSC") and a competing physician-owned ASC received CONs at approximately the same time

Regulatory Framework - Stark Law, cont.

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Regulatory Framework - Stark Law, cont.

- Tuomey facts (cont.):
  - Hospital engaged a consultant to assist it in evaluating the potential loss from competition and to design a plan to make up the difference. The result was a part time employment arrangement involving 19 local specialists who were all:
    - only employees of the hospital when they performed outpatient procedures
    - contractually bound to bring all of their outpatient procedures to the hospital's OSC and to not otherwise compete within a wide radius of the OSC
    - compensated through base salaries and productivity bonuses of 80% of net collections. The package resulted in the physicians receiving approximately 131% of the professional revenue generated by them on the cases performed at the OSC
    - given full time benefits

Regulatory Framework - Stark Law, cont.

- The Tuomey situation was very "heavy" with experts
  - Numerous lawyers gave conflicting advice. The hospital seemed to be "opinion shopping." The defendants lost the protection of the Advice of Counsel Defense when they rejected opinions that they did not like
  - The consultant issued a cursory fair market value analysis which did not square with the pertinent facts
- Liability stemmed from a qui tam action filed by a physician with whom the hospital was unable to contract

Regulatory Framework – Stark Law, cont.

- Toumey "lessons learned"
  - Potential liability for Stark missteps can be astronomical; consider being proactive in identifying problems with even existing contracts and self reporting
  - Physician compensation must not be based upon the volume or value of anticipated referrals
  - Physician compensation must meet both the fair market value and commercial reasonableness tests
  - Not all fair market analyses are created equal. In Tuomey the fmv report was deficient in its face
  - STOP! and RETHINK! your arrangement when confronted with conflicting legal opinions
  - Use "new and improved" structures cautiously. The "elastic" and over generous Tuomey structure appeared to the government to be merely a "case buying scheme"

Regulatory Framework, cont.

- Federal Anti-Kickback Statute: 42 U.S.C. 1320a-7b. Criminal statute which provides for the imposition of severe fines and possible imprisonment if "illegal remuneration" is paid or received in exchange for the referral of services covered by Medicare or Medicaid
  - Intent based statute but threshold for intent is very low. Statute may be violated if only one purpose of the payment is to steer referrals
- Safe harbors exist which will insure participants in a transaction that they will not be prosecuted if all elements of the safe harbor are satisfied
  - Failure to satisfy all of the elements of a safe harbor will expose an arrangement to a "facts and circumstances" test

Regulatory Framework, cont.

- **Safe Harbor for Payments to Employees**: 42 CFR 1001.952(i). Payments by employers in a bona fide employment relationship are exempt
  - "Employees" is defined using the common law definition of the term:
    (i) ability to direct,
    (ii) exclusivity during the periods of employment, etc.
  - OIG Advisory Opinion No. 08-22: OIG has acknowledged that the safe harbor is applicable for part time physician employees

Regulatory Framework, cont.

- **Safe Harbor for Personal Services**: 42 CFR 1001.952(d)
  - Agreement set out in writing covers all the services to be offered
  - Periods of time in which the services to be offered are spelled out with precision
  - The term of the agreement is not for less than one year
  - The aggregate compensation to be payable over the term is set in advance and is consistent with fair market value
  - The services which are performed do not violate state or federal law
  - The services performed do not exceed those which are reasonably necessary

Regulatory Framework, cont.

- Government on Alert For Sham Contractual Joint Ventures and/or Quasi Employment Relationships
  - OIG Advisory Opinion No. 08-10: OIG declined to "bless" an arrangement under which urology groups would enter into part time leases of space, equipment and personnel services from another physician group to provide intensity-modulated radiation therapy
  - OIG concluded that the arrangement bore the hallmarks of a suspect contractual joint venture referenced in Special Advisory Bulletin – 68 Fed.R. 23146, April 20, 2003
    - One party expands into a related business by contracting with an existing provider to provide services to the first party's existing patients
    - The second party essentially provides all services on a turnkey basis to the first party's patient base
    - The profits which the first party receives from referring its existing patients to the second party under the turnkey arrangement would comprise kickbacks

Regulatory Framework, cont.

- Under both Stark and the AKS "Fair Market Value" is absolutely key
  - Stark Definition: "…. the compensation that would be included in a service agreement, as the result of bona fide bargaining between well informed parties … who are not … in a position to generate business for the other party."
    - comparables are very useful
    - third party valuations highly recommended
  - Must also consult state anti-referral and AKS statutes!

Hospital Employment of Physicians: Legal and Business Strategies

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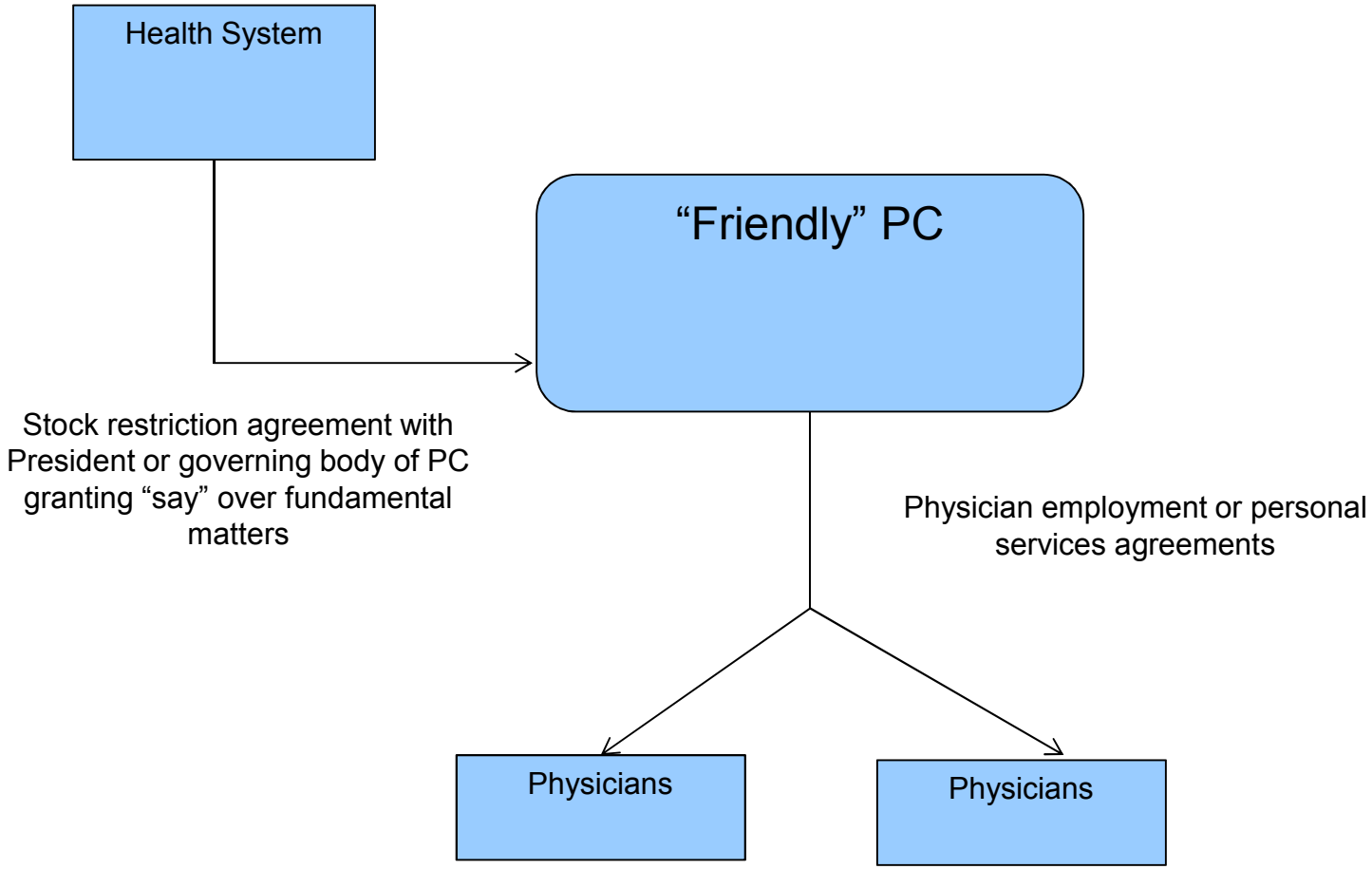
The business of relationships.™

“Captive PC Model”



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Direct Employment – No CPOM

- Simplest model
- Generally, easy to structure to not implicate, or to comply with exceptions/safe harbors to, kickback and self-referral laws
  - Stark Law, 42 U.S.C. § 1395nn
  - Federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)
  - State laws (kickback, self-referral, medical licensure)
- Compensation – use of a valuation consultant
  - Protection from future regulatory scrutiny
  - Bargaining chip with physicians
- Consistency in form

Direct Employment and Practice Purchase

- Hospital's strategy and market may drive decision to choose purchase/employment rather than only employment
- Immediate integration of a service line/patient base
- Asset purchase vs. stock purchase
  - Exposure associated with the practice's prior acts
  - Considerations for agreement's representations and warranties
- Conducting thorough due diligence is key
- Valuation Methodology
  - Tangible and financial assets
  - Intangible assets

Physician Leasing Arrangements

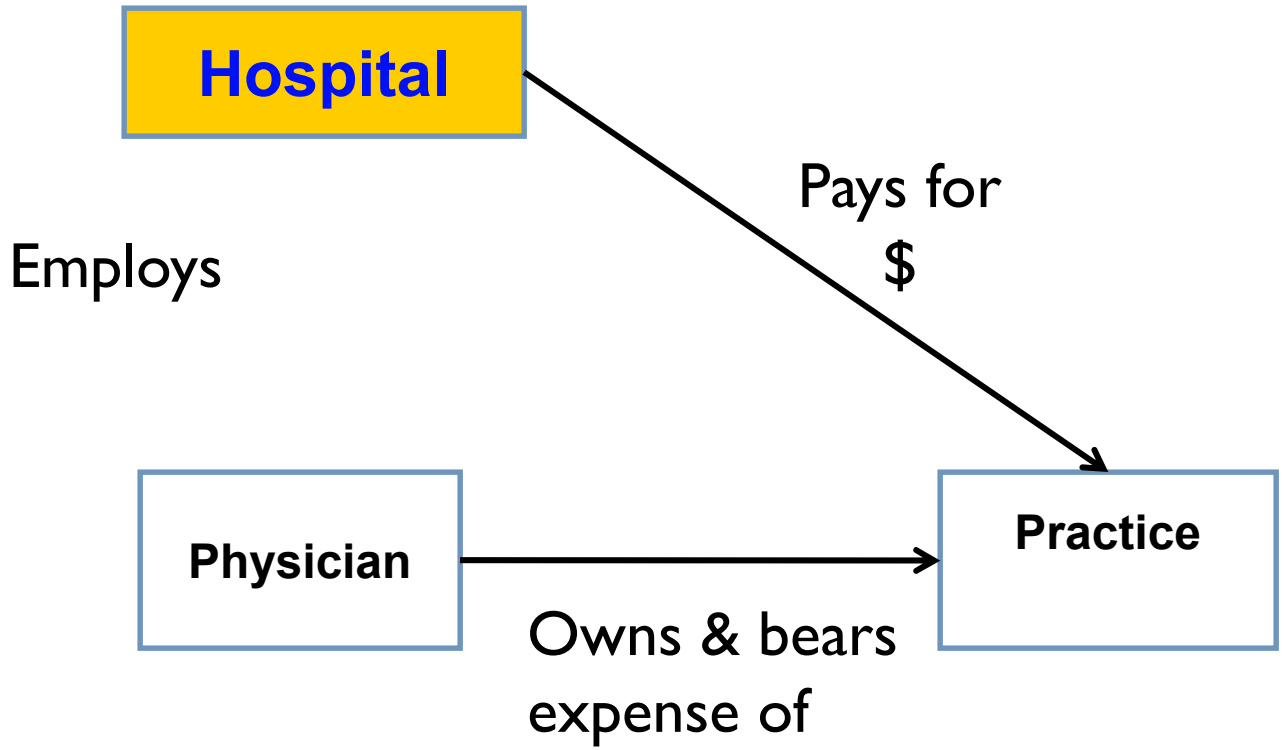
- Services can be leased by Hospital from a physician group, or by a physician group from a Hospital
- Provides for low-level integration in the context of higher level of relationship development
  - May lead to future high-level integration
- Legal Considerations
  - Stark Personal Services Exception
  - AKS Personal Services Safe Harbor
  - OIG Advisory Opinion 08-10 (Aug. 26, 2008)
  - New Stark Law Timeshare Exception
- As with most of the various relationships between Hospitals and physicians, FMV is critical
  - In its purest form, a leasing arrangement is mostly dependent on the parties agreeing on what the leased services are worth from a FMV perspective

FMV Issues to Keep in Mind

- Asset/service line being purchased
  - What is being valued?
  - Does having a “value” necessarily translate into FMV?
  - Will referrals from the Seller be necessary post-purchase

- Practice lease/PSA
  - Is payment based on $/wRVU?
  - How is amount determined?
  - Upside/downside risk?
  - Methodology the same for both?

Physician Enterprise Model (PEM)



Practice becomes an MSO and enters into a management agreement with the Hospital. Staff (and possibly mid-levels) remain employees of the Practice.

Physician Enterprise Model

- Often considered a step toward more fulsome integration (e.g., direct employment)
- Provides for low-level integration in the context of higher level of relationship development
  - May lead to future high-level integration
  - Potential challenges with lower level of integration?
- Can be unwound more easily than employment/purchase model – Practice entity (the new MSO) remains intact and ready to be re-converted to a medical practice

Physician Enterprise Model continued

- May be financially lucrative for participation physicians
  - Incentive based compensation
  - Hospital negotiated rates
  - Guaranteed revenue stream for physicians
- Less administratively burdensome to Hospital
- Less costly to Hospital than purchasing assets (thought he ultimate savings may be lower than expected depending valuation methodology utilized to value a practice)

Physician Enterprise Model

- Fair market value
  - Management services
  - Physician compensation
  - Office space and equipment

- Employment of physicians
  - Employment Safe Harbor/Exception

- Management Services
  - Personal Services Safe Harbor/Exception
  - Office Rental Safe Harbor/Exception
  - Equipment Lease Safe Harbor/Exception

Physician Recruitment Arrangements

- Recruitment Arrangements facilitate a strong high level relationship, but with low level integration
- Stark Law exception and AKS safe harbor (42 CFR 411.357(e), 42 CFR 1001.952(n))
- Key compliance considerations
  - Community Needs Assessment
  - Distance requirements/fresh out of schooling
  - Arrangement can cover only net new costs directly attributable to the recruited physician
  - Treatment of Medicaid/indigent patients

Physician Recruitment Arrangements

- Compliance considerations continued
  - Employment agreement noncompetition provisions – not necessarily impermissible – but should be carefully drafted to allow the recruited physician to continue practicing in the community if employment with the Practice ends.
- Practical considerations
  - Review budgets at early stage of discussions
  - Be frank about expectations from day 1
  - Point person at both Hospital and Practice
- Repayment of the forgivable loan if the arrangement is terminated

Physician Recruitment Arrangements

- New Stark Law exception (42 C.F.R. § 411.357(x)) permits remuneration from hospitals to a physician to assist in the bona fide employment of, or contracting with, a NPP by that physician to provide primary care or mental health services within the geographic area served by the hospital
  - Generally tracks the existing physician recruitment exception.
  - "Substantially all" (i.e., 75%) of the patient services provided by a NPP must be primary care or mental health services.
  - Payment must be passed through directly to the NPP Generally, a hospital, FQHC, or RHC may only
- Time limits on assistance

Practical Stumbling Blocks

- Regardless of model – know as much as you can about your potential "partners"
  - Diligence is key
- Do the Hospital's goals match up with the actual day-to-day activities of the physician/practice?
  - Research
  - Labs
  - Other ancillary services

Practical Stumbling Blocks continued

- Leases
  - Who owns the space? Who is the landlord?
  - FMV rent?
  - If it's not the physician/group, does the lease term enable the Hospital to move forward with larger strategic considerations
  - Are there subleases? To/with whom?

- Who really owns the assets?
  - UCC search
  - Serving as collateral to a loan or line of credit?

- HR considerations
  - Mid-levels
  - Administrative staff
  - Benefit plans (particularly if stock purchase)

Hospital Employment of Physicians: Legal Strategies

Arnall Golden Gregory LLP

Attorneys at Law

Physician Employment Agreements and Ancillary Agreements

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Topics to be Addressed

- Duties and Responsibilities
- Autonomy
- Term and Termination
- Compensation and Benefits
- Incentive Pitfalls to Avoid
- Restrictive Covenants

Duties and Responsibilities

- Why do the parties care?
  - Employer: Maintain Flexibility
  - Employee: Achieve Certainty
- Duties and Responsibilities may differ significantly from the historical medical practice employment agreement

Duties and Responsibilities

- Hours (patient / clinical hours); FTE, PTE?
- Services
- Administrative Responsibilities
- Billing and Compliance
- Compliance with professional standards, employer's policies, rules and regulations
- Non-Employer Based Activities
- Patient Selection
- Fee Establishment
- Facilities; Location; Referrals
- Equipment

Autonomy

- What does “Autonomy” encompass?
  - At the Hospital
  - During “off hours”?
- Who controls decision making
  - Clinical?
  - Administrative?
- Where, how and how strong is the physician(s) voice?
  - Governance?
  - Deadlock?

Term and Termination

- Term
  - 1, 3 or 5 year terms
  - Conditions to Effective Date?
  - Patient care obligations contemporaneous with Effective Date?
- Renewals
  - Automatic?
  - Notice requirements
  - Ties to other obligations

Term and Termination

- Termination
  - For Cause – by the Employer
    - If the Employer is unable to obtain malpractice insurance covering Employee;
    - If the Employee's license to practice medicine is revoked, terminated, limited, conditioned, suspended, restricted in any way;
    - If the Employee's license to prescribe or dispense controlled substances is revoked, terminated, limited, conditioned, suspended, restricted in any way;
    - If the Employee is found guilty of professional misconduct by any professional organization having jurisdiction;
    - If the Employee is excluded, terminated, suspended or declared ineligible to participate in Medicare, Medicaid, or any other governmental program providing compensation for services rendered to patients;
    - If the Employee is charged with the commission [conviction] of a felony crime, or a crime involving moral turpitude.
    - If the Employee's medical staff membership or clinical privileges at the Hospital are revoked, terminated, limited, conditioned, suspended, restricted in any way;
    - The Employee's failure or refusal to faithfully and diligently perform the duties of, or adhere to the provisions of this Agreement.
    - If the Employee's board certification is restricted, limited, suspended or revoked;
    - If the Employee commits or engages in any act or practice, including without limitation the abuse of alcohol or drugs, which is detrimental to the care and treatment of the Employer's patients or otherwise detrimental to the Employer.
    - If the Employee fails to commence services hereunder on the Commencement Date.
  - Change in Control – By the Employer or Employee

Term and Termination

- Termination
  - For Cause – By Employee
    - Employer's licensure, certification or accreditation expires or is revoked, terminated, limited, conditioned, suspended, restricted in any way or not renewed;
    - Employer is excluded, terminated, suspended, or declared ineligible to participate in Medicare, Medicaid, or any other governmental program providing compensation for services rendered to patients;
    - Employer fails or refuses to perform or fulfill any of Employer's duties, obligations or covenants under the Agreement;
    - Employer files for bankruptcy, is adjudicated bankrupt, takes advantage of applicable insolvency laws, make an assignment for the benefit of a creditor, or a receiver or its equivalent has been appointed for Hospital's property.

Term and Termination

- Termination
  - Without Cause
    - Implications of the “no-cut”
    - Mutual?
      - Might this change at a renewal period?
    - What notice?
    - Accelerated Removal Options by the Employer?
  - Death or Disability

Term and Termination

- Impact on other obligations
  - Tail coverage
  - Bonus payments
  - Restrictive Covenants
  - Severance Pay
  - Any unwind of a related purchase transaction
- Access to Medical Records
- Return of Property
- Due Process

Compensation

- Typical Arrangements
  - Base for the entire term
  - Base + Productivity
  - Productivity, less expenses (periodic reconciliation)
  - Compensation for administrative duties, research?
- Typical Adjustments
  - Base adjustments if fail to meet a minimum productivity threshold
  - Conversion Factors
  - “Soft” factors – patient satisfaction, quality measures
  - Outside income?

Compensation and Benefits

- Issues:
  - Fair market value measurement
  - Base salary or pure production
  - Some measure other than wRVUs (what about quality?)
  - Credit for “other services” at the Hospital? Cash or Credit?
  - Ancillaries
  - How / when does the formula adjust?
  - Audit rights

Compensation and Benefits

- Typical Benefits:
  - All standard benefits provided to similarly situated employees
  - Retirement
  - Paid Time Off
  - Medical Insurance
- Unique Benefits
  - Signing Bonus
  - Moving Expenses; Housing Allowance
  - Professional Society Fees and Dues
  - Professional Liability Insurance
  - CME (time and money)
  - Business Expenses
  - Payment of Student Loans
  - Severance Payments
  - Athletic Facilities
  - Educational Expenses (non-CME)
  - Child Care
  - Life Insurance

Incentive Pitfalls to Avoid

- Commercially reasonable? Watch for “overnight successes” (moving from 65th percentile to 95th percentile)
- 1+1=1.5
- No ties to productivity + a long “no cut” term
- Failure to obtain a fair market value analysis of the compensation
- Overextending the employee = overpayment of compensation
- Failure to reconcile and collect shortfalls or offset against future payments

Restrictive Covenants

- Not to Compete
  - Generally valid during the term of the employment agreement (e.g., moonlighting, teaching, research)
  - Vary State by State
    - Consider reasonableness of term, scope and duration
    - Whether the Court will blue-pencil?
    - In conjunction with the purchase of the Practice?
  - To which of the specific duties might the restrictive covenant apply? (e.g., patient care, ownership in competing ancillary?)
  - Variances based upon termination
  - Sunset provisions

Restrictive Covenants

- Non-Solicitation
  - Patients
  - Employees
- Confidentiality
  - Generally enforceable
- Intellectual Property
  - Who owns what?
  - Does the participation terminate with the Agreement?
- Sunsets, carve-outs and limited exceptions are less prevalent
- Ability to address competition indirectly through these provisions

Thank you.

Arnall Golden Gregory LLP

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