Traps for the Unwary – A Review of Key Health Care Contract Provisions and Laws

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Overview

• Applicable Laws
• Types of Contracts
• Sample Provisions

NOTE: this presentation will not discuss in detail all forms of agreements related to health care (e.g. we will not discuss in detail managed care contracts).
Overview

- Health care is first and foremost an industry, not a legal discipline
- Because so much health care is paid for by the Federal and state governments, and the individuals and facilities who provide health care are licensed by governmental agencies, it is highly regulated and subject to close scrutiny by enforcement agencies
- Contracting in health care implicates many of the laws that are specific to the health care industry
Hospitals/Providers – Laws

- Stark Law
- Anti-Kickback Statute
- Tax-Exemption for Nonprofits/Bond IRS Revenue Ruling
- HIPAA
- Licensing Statutes
- Corporate Practice of Medicine
- False Claims Act
- Antitrust Laws
- EMTALA
Hospitals/Providers – Laws (Cont.)

- Many business arrangements that are appropriate and commonplace in other contexts are prohibited in the health care industry
- Typical goals of health care fraud and abuse laws
  - Prevent over-utilization of health care items and services
  - Control health care costs
  - Preserve health care quality
  - Discourage unfair competition
Self-Referral Laws

• A major consideration in all physician contracting
• Federal stark law—Prohibits physicians from ordering “Designated Health Services” for Medicare patients from entities with which physician has a financial relationship
  – “Designated health services” include inpatient and outpatient hospital services, clinical laboratory, various therapies and imaging services
  – “Financial relationship” includes ownership, compensation, lease, etc.
• Violations—Denial of payment, Civil Monetary Penalties, exclusion from Medicare program
• State analogs
Self-Referral Laws (Cont.)

• **All** physician contract situations must fall within at least one exception to the Stark Law prohibition
• Important contracting exceptions:
  – Space/equipment leasing
  – Personal service arrangements
  – Fair market value transactions
  – Group practice exception
  – Physician recruitment
  – In office ancillary services
Self-Referral Laws (Cont.)

• Standard Contract Requirements:
  – In writing and signed by both parties
  – Specify all services to be provided
  – ≥ One year term
  – All payments at fair market value
  – Commercially reasonable
  – Compensation set in advance, not varying with volume or value of referrals
  – Other specifics depending upon nature of the agreement
Self-Referral Laws (Cont.)

• Common Stark problems:
  – Free items and services
  – Undocumented or expired arrangements
  – Failure to adhere to contract terms
  – Lack of fair market value

• State laws:
  – Similar intent, often different specifics
  – *Must* pay attention to specific differences
Anti-Kickback Statute

• Federal Anti-Kickback Statute – Criminal penalties for individuals who knowingly and willfully offer to pay, solicit, or receive remuneration to induce business paid under a state or federal health payment program.

• Unlike Stark, the Anti-Kickback Statute is also an issue in other health care contracts, not just physician contracts
Anti-Kickback Statute (Cont.)

• Safe Harbor Regulations
  – Often similar to Stark exceptions
    • Space/equipment leasing
    • Personal service arrangements
  – But there are differences
    • No free-standing FMV exception
    • *Bona fide* employee rules differ
Inurement/Private Benefit

• Tax issue affecting nonprofits
• IRC §501(c)(3)
  – "organized and operated exclusively" for religious, charitable, scientific, literary or educational purposes (no private benefit)
  – "no part of the net income of which inures to the benefit of any private shareholder or individual“ (no inurement)
• Payment provisions between nonprofits and individuals/for profits require care
Patient Consent & Privacy

• HIPAA
  – Health Insurance Portability & Accountability Act of 1996,
    • Privacy Rule, Security Rule, Breach Notification Rule
    • Business Associate Agreements

• State privacy laws
  – Data security and breach notification laws
  – Health care privacy laws for specific providers

• State/Federal discrepancies
Licensing/Certification/Accreditation

- Licensing
  - State (usually) prerequisite to operation

- Certification
  - Certified for participation in programs, e.g., Medicare, Medicaid

- Accreditation
  - The Joint Commission, etc.

- Watch for all three
Corporate Practice of Medicine

• Prohibits lay corporations from practicing medicine
  – General policy is that medical decisions should not be influenced by economic considerations
• State specific
  – Some states strongly enforce the doctrine by statute, medical board and/or Attorney General enforcement actions.
  – Other states do not actively enforce the doctrine.
• Scope of services
  – What constitutes “practice of medicine” can be uncertain.
  – Key to consider services for management agreements.
• Corporate practice restrictions for other licensed providers
Corporate Practice of Medicine (Cont.)

- Problems and Penalties
  - Government enforcement
  - Loss of Licensure
  - Unenforceability of Contracts
  - “Illegality” defense
False Claims Act

• **What is prohibited?**
  – Submitting claims for services that were never provided
  – Providing medically unnecessary or duplicative services
  – “Double billing” (submitting two bills for the same service or billing two payors for the same service)
  – Failing to repay a Medicare or Medicaid overpayment within 60 days
  – Submitting claims pursuant to conduct that violates the AKS or Stark

• **Penalties = Civil monetary penalties; treble damages; reasonable attorney’s fees**
False Claims Act (cont.)

• Private citizens, called “relators” or whistleblowers, may bring FCA actions in the name of the Government
• Whistleblowers have a significant financial incentive to file an FCA action—they receive up to 30% of the FCA settlement
• Oftentimes, relators are employees of the health care provider that is submitting the claims!
• The FCA protects whistleblowers from retaliatory action
Antitrust Issues

• Price fixing, tying arrangements, group boycotts, division of markets
• Careful review of otherwise competing providers
• Hart Scott Rodino Antitrust Improvements Act
• State Attorney General scrutiny
EMTALA

• Emergency Medical Treatment & Active Labor Act
  – Watch for issues in transfer agreements and other agreements between providers
  – Evolution of call coverage agreements
Hospitals/Providers – Types of Agreements

- Professional Services Agreements
- Physician Recruitment
- Hospital-Based Services
- Call Coverage
- Administrative Services
- Co-Management
- Telemedicine
- Transfer Agreements
- Student Training
Hospitals/Providers – Types of Agreements

• Vendor Contracts
  – Supply Chain
  – IT Software
  – HIPAA Business Associate
  – Consultants
  – Temporary Staffing Agreements
• Leases
• Ambulance Transport Services
• Settlement Agreements
Hospitals/Providers – Types of Agreements

• Merger and Acquisition Agreements
• Management Agreements
• Managed Care Agreements
• Financing Agreements
• Joint ventures

NOTE: the following is from my point of view as a hospital/health system attorney.
Basic Contract Review Questions

• Who is providing the health care service?
  – Entity choice
  – Is a license required?

• What is the setting in which the service is delivered?
  – Hospital, skilled nursing facility, or other institution
  – Private physician office

• Was there a referral of the patient?

• Does the referring physician have a financial relationship with the facility provider?
  – Loan
  – Lease
  – Employment or independent contractor agreement

• Who is paying for the health care service?
  – Government payor, insurer, HMO, etc.?
Hospitals/Providers – General Terms

• Recitals
  – Maybe cross-reference other agreements between the parties

• Duties

• Payment
  – Fair Market Value requirement in physician arrangements
  – Invoices
  – Reimbursement of expenses

• Indemnity

• Insurance

• Term and Termination
  – Include effect of termination
Hospitals/Providers – General Terms

• Not excluded from Federal Health Care Programs
• Exclusivity??
• Relationship of parties – e.g., independent contractors
• Compliance Program/Hospital Policies/Medical Staff Bylaws
• Compliance with Laws
• No referrals
• Agree to cooperate (e.g., litigation)
Hospitals/Providers – Boilerplate

- Dispute Resolution (e.g., Arbitration)
- Attorneys Fees???
- Choice of Law
- Non-discrimination
- Marketing
- Force Majeure
- No third party beneficiary
- Notice for addresses
- Counterpart signatures/e-signatures
- Entire Agreement (incorporate exhibits)/Modification/Assignment/Binding on Successors/Severability/Waiver/Headings/Ambiguities
Hospitals/Providers - Confidentiality

• Non-Disclosure Agreements
• Trade Secrets
• Intellectual Property/Research/Inventions
  – Work for hire/ownership
• HIPAA
  – Business Associates (agency; brother’s keeper)
  – Organized Health Care Arrangements
  – Follow appropriate policies
  – Access to electronic health record
  – Managed Care Delegated Duties (limit definition of PHI)
Hospitals/Providers – Access to Records for Medicare Purposes

• Important language to include in agreements:
  – “Until the expiration of four years after the furnishing of Services pursuant to this Agreement, <Contractor> shall make available, upon request, to the Secretary of Health and Human Services, or to the Comptroller General, or any of their duly authorized representatives, this Agreement, and books, documents and records of <Contractor> that are necessary to certify the nature and extent of the costs claimed to Medicare by Hospital with respect to the Services provided under this Agreement. If <Contractor> carries out any of the duties of this Agreement through a subcontract with a related organization ("Subcontractor"), with a value or cost of Ten Thousand Dollars ($10,000) or more over a twelve (12) month period, such subcontract shall contain a clause to the effect that until the expiration of four (4) years after the end of the term of such subcontract, the related organization shall make available, upon written request from the Secretary of Health and Human Services, or the Comptroller General of the United States, or any other duly authorized agent or representatives, the subcontract and Subcontractor’s books, documents and records of such organization that are necessary to verify the nature and extent of such costs.”

• Failure to include such language may result in Medicare not reimbursing the hospital/provider for the costs for such services. (2003 Provider Reimbursement Review Board decision of VNA of Rhode Island, Inc. – Portuguese translators; costs were disallowed by Medicare Intermediary).
Hospitals/Providers – Special Provisions for Physician Contracts

- Not retroactive (Stark)
- Physician qualifications – representations (e.g. licensure, DEA registration, Board certification)
- Credentialing
- Billing for professional services
  - Limitation on use of collection agencies
- Use of Hospital Premises only for services under the agreement – no private use – hospital licensing issue
- Hospital not involved in practice of medicine
- Coverage if physician is absent
Hospitals/Providers – Special Provisions for Physician Contracts

- Ability to add/remove physician to/from providing services
  - Try to avoid “fair hearing” rights
- Medical record compliance – timely and accurate (legible too!)
- Performance standards
  - Joint Commission is keen on these
- Master list of other agreements with physician to meet Stark exception requirement
- Warranty from physician group that its financial arrangements are Stark compliant
- Include list of physicians providing the services
Hospitals/Providers – Special Provisions for Vendor Contracts

• Business license
• Non-solicitation of employees
• Health screening
  – OSHA Bloodborne Pathogens Standards
• Criminal background checks
• Who is the employer?
  – Payroll requirements
• Sentinel event reporting
• Avoid limitation of liability provisions
• Ability to remove vendor employee from providing services
Hospitals/Providers – Supply Chain and Medical Device Agreements

- Identify products and introduction of new products
- Change in products
- Avoid minimum orders
- Quarterly management meetings
- Own use
- Discounts/Rebates under Anti-Kickback Statute
  - Must be based on actual purchases
  - Beware free equipment
  - Beware “prebates” or signing bonuses
- Conflict of Interest
  - Beware gifts, education trips, PhRMA Code
- Vendor credentialing
- Safe Medical Devices Act
  - Sequester products involved in serious injury or death
Hospitals/Providers – Supply Chain and Medical Device Agreements

• Delivery
   – Incorrect shipment; defective product; recall; returns of unused goods
   – Cover damages (hospital can obtain product from alternate and receive difference in cost from vendor)

• Warranty
   – Avoid “as-is”; OK to say warranty is fit for the purpose stated on the labeling
   – Avoid short warranties (e.g. 30 days)
   – OK to agree that warranty not apply if we do not use product per vendor’s instructions
   – OK to agree that there are no implied warranties, e.g. merchantability and fitness for a particular purpose

• Avoid limitation in liability
   – Avoid indemnity limited to repair or replace
   – At the very least, carve out indemnity for third party claims and for recall of products
   – OK to say vendor not liable for proximate, incidental or consequential damages
Hospitals/Providers – Other Contracts

• IT Software
  – Updates/upgrades and training at no additional cost
  – Be clear about support services
  – Special indemnity of software violates a third party’s intellectual property (make software non-infringing or replace software or reimburse fees)

• Telemedicine
  – Credentialing by Proxy

• Ambulance Services
  – Who is financially responsible for trips? (Charity program)
  – Maintenance of vehicles
  – Call Center
  – Disaster plan (special language on force majeure) – commercially reasonable and good faith efforts to transport patients
Hospitals/Providers – Other Contracts

• Student Agreements
  – See vendor contracts (e.g. health screen, background checks, removal of student)
  – Liability insurance; workers’ compensation insurance
  – Health insurance
  – No compensation
  – HIPAA workforce; but still have student sign a Confidentiality Agreement

• Settlement Agreements
  – Waiver of all claims, known or unknown
  – Reliance only on what is included in written agreement
Managed Care Contract Issues

• Unique issues
• Payment mechanism (fee for service, preferred provider organization, capitated)
• Shared risk pools
• Utilization review
Contract Management

• Consider having a contract database
• Make sure contracts are dated
• Track expiring contracts
• With regard to physician agreements, make sure fair market value documentation is linked to agreement (in case government comes knocking on your door!)