Professional Service Agreements

Stark Law

- Unless an exception applies, Stark prohibits referrals to an entity for the furnishing of “designated health services,” payable under Medicare or Medicaid made by a physician with a “financial relationship” with the entity.

- An entity may not present a claim or bill for designated health services from prohibited referral.

- Congressional intent to control over-utilization of government health program reimbursed services.

- 42 USC sec. 1395nn; 42 CFR Subpart J

Designated Health Services — What Does the Law Cover?

- Inpatient and outpatient hospital services
- Clinical laboratory services
- Physical therapy services
- Occupational therapy services and speech–language pathology
- Radiology services and certain imaging services (including but not limited to x–ray, ultrasound, C.A.T., M.R.I. other services listed by HCFA)
- Durable medical equipment & supplies
- Parenteral and enteral nutrients, equipment and supplies
- Prosthetics, orthotics, and prosthetic devices and supplies
- Home health services
- Outpatient prescription drugs
- Radiation therapy services and supplies

STARK LAW

Stark Exceptions: 42 CFR sec. 411.355 - 411.357

- ***Personal services arrangements***
- Physician recruitment
- Leases
- Non-monetary compensation
- Medical staff incidentals
- In-office ancillaries
- Fair market value
- Referral services
- Obstetrical malpractice insurance subsidies
- Professional courtesy
- Retention payments in underserved areas
- Electronic prescribing items and services
- Electronic health records items and services
- Bona fide employment
- Compliance training
- Isolated transactions
- Indirect compensation
- Remuneration unrelated to DHS
- Community wide information systems

Personal Service Exceptions
(42 C.F.R. §411.357(d))

- To meet exception:
- ✓ Arrangement is set out in writing, signed by parties and specifies services covered;
- ✓ Arrangement covers all of the services to be furnished by the physician (if multiple arrangements in multiple agreements, the agreement may reference a centralized list);
- ✓ Aggregate services do not exceed those that are reasonable and necessary for legitimate business purposes;
- ✓ The term must be at least one year, or if terminated during the first year the parties may not enter the same or substantially same arrangement during that first year;
- ➢ Compensation of each arrangement is “set in advance,” does not exceed “fair market value,” and is not determined in a manner that takes into account the “volume or value” of any referrals or other business generated between the parties.

Fair Market Value

- Narrow regulatory definition for Stark (42 CFR §411.351)
- ✓ Value in arm's-length transactions, consistent with general market value
- ✓ General market value means compensation as result of bona fide bargaining between well informed parties not otherwise in position to generate business for other party
- ✓ Compensation does not take into account volume or value of anticipated or actual DHS referrals
- ✓ Should establish policies/procedures for making and documenting reasonable, consistent determinations of FMV

Anti-Kickback Statute

- The federal Anti-Kickback Statute ("Anti-Kickback Statute") is a criminal statute that prohibits the exchange (or offer to exchange), of anything of value, in an effort to induce (or reward) the referral of federal health care program business
- See 42 U.S.C. 1320a–7b

Anti-Kickback Statute

- Both payor and recipient at risk
- Intent–based statute
  - “One Purpose” test – Is any one purpose to induce referrals?
- Criminal and Civil Penalties
  - 5 years imprisonment/$25,000 fine
  - Civil monetary penalties
  - Exclusion

Anti-Kickback Statute

- The anti-kickback statute excepts “any amount paid by an employer to an employee (who has a bona fide employment relationship with such employer) for employment in the provision of covered items or services.” 42 U.S.C. 1320a–7b(b)(3)
- The OIG safe harbor regulations provide that the term “remuneration,” does not include any amount paid by an employer to a bona fide employee for employment in the furnishing of any item or service for which payment may be made in whole or in part under Medicare or a State health care program. 42 C.F.R. § 1001.952(i).

Anti-Kickback Safe Harbor

- Remuneration does not include payment for compensation if the following requirements are met:
  - Agreement is in writing and signed by the parties
  - Agreement specifies and covers all services
  - Agreement the term, which should not be for less than one year
  - Aggregate compensation to be paid is “set in advance,” consistent with “fair market value” and does not take into account the “volume or value” of referrals or other business between the parties.
- Unlike Stark, it is not a violation to not meet all of the elements of the Safe Harbor, but you don’t get the full legal protection.

False Claims Act

- Whistleblower or “qui tam relators” have used both the anti-kickback Statute and the Stark law as predicate offenses to claim False Claims Act (FCA) violations.
- Federal Courts have held that violations that since these constitute Medicare payment rules, violations of the FCA arise when entities certify that they are in compliance of such rules as a condition of payment.
- The False Claims Act (FCA), 31 U.S.C. § 3729 provides for liability for triple damages and a penalty from $5,500 to $11,000 per claim

Other Legal Issues

- Anti-trust
  - **Sherman Act §1:** Prohibits contracts, combinations and ***conspiracies that unreasonably restrain*** competition
  - **Sherman Act §2:** *Prohibits* ***Monopolization***, Attempts to Monopolize, and ***Conspiracies To Monopolize***

If an agreement provides "exclusivity" does that unreasonably restrain competition in the marketplace?

"Rule of Reason" Analysis

May depend on rationale for exclusivity and other providers within the market

Other Legal Issues

- Peer Review
  - Ensure processes consistent with the HCQIA (Health Care Quality Improvement Act) which provides immunity from antitrust and common law claims, and protects professional review actions under privilege
- CMS Hospital Conditions of Participation
- State Licensing Laws
- Joint Commission (Accreditation)
- HIPAA
  - Will all services be “treatment’ or will the physician or group also provide administrative services necessitating a Business Associate Agreement?

Agreement Considerations

- Very common to have a third party group provide hospital-based services where your client does not employ the physicians
- Typical professional services agreements include:
  - Hospital-based contracts such as emergency services, radiology, anesthesiology, pathology, hospitalist, neonatologists and intensivists
  - Emergency Department call coverage agreements
  - Medical Director arrangements

Agreement Considerations

- Representations and Warranties
  - Licensure and qualifications of physicians providing the services (e.g. do you require board certification?)
  - Absence of sanctions or limitations on ability to provide services (e.g. Medicare exclusion)
- Term and termination
  - Do you include a “without cause” provision?
  - If agreement is with group, how do you remove an individual provider?
- For Agreements between a hospital and group, should the parties define a person with accountability to address issues?

Agreement Considerations

- Should Group have exclusivity
  - Is exclusivity necessary to ensure availability and continuity of care?
- Are there activities other than the provision of services that should be accounted for in the Agreement? (e.g. administrative services, committee participation, consultation with other providers, cooperation with administration and nursing staff)
- Do you need to define hours, staffing, scheduling?
- Insurance coverage requirements and risk allocation for claims (e.g. indemnities)

Agreement Considerations

- Payment
  - Does group or physician bill independently for professional services from the hospital?
  - Should the hospital provide a subsidy to ensure availability of the physicians?
    - If so, how do you determine fair market value?
  - Should the group participate with the same payers (e.g. Blue Cross, Aetna, Cigna) as the hospital to have the same network for patients?
  - Should you include either extra pay or put some compensation “at risk” for meeting defined goals (e.g. clinical quality, patient satisfaction, achievement of goals)