

Regulatory Considerations for Structuring Physician/Hospital Co-Management Agreements

By

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In the current climate of healthcare reform and decreasing physician reimbursement, physicians are evaluating innovative ways to provide efficient, quality care while still receiving adequate compensation for the services that they provide. In parallel, hospitals face similar reimbursement challenges along with a desire to improve quality while aligning with physicians and physician practice groups. Co-management arrangements are becoming an increasingly popular model for aligning incentives between physician groups and hospitals, specifically in the context of high-cost service lines such as cardiology and orthopedics. However, co-management agreements implicate a unique combination of regulatory issues. Such regulatory issues demand co-management agreement to be structured appropriately within this regulatory framework. This article discusses the regulatory considerations parties should consider when assessing the feasibility of entering into a physician/-hospital co-management relationship.

I. Co-Management Relationships Generally

A typical co-management relationship involves an agreement between a hospital and a specialty physician

group, such as a cardiology or orthopedic group, whereby either the physician group alone, or the physician group in partnership with the hospital, manages the operational and clinical activities of a hospital-based specialty service line. Generally, the co-management agreement provides for fair market value compensation in exchange for the provision of management services. Under a typical co-management agreement, the compensation includes an annual base fee and a quality-based incentive fee. The base fee is predetermined, consistent with the fair market value of the services provided, and includes compensation for management and oversight in addition to service line development activities. The incentive fee is typically structured to include a series of predetermined payments that are contingent on the achievement of specified, mutually agreed upon quantifiable targets based on quality improvement and efficiency.

II. Guiding Principles for Structuring a Co-Management Agreement

Based on the regulatory framework described below, the following principles should be implemented when structuring a co-management agreement:

- a. Compensation must be consistent with fair market value in arms-length transactions for the services provided, and not take into account the volume or value of referrals. Generally an independent appraiser should perform the fair market value compensation analysis. The co-management agreement should carefully detail the tasks to be completed by the physician group.
- b. If a 501(c)(3) tax-exempt entity is a contracting party, the compensation should be approved in advance by a disinterested board or committee, and the basis for the compensation should be well-documented.

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- c. Clinical quality and patient mix should be monitored throughout the term of the co-management agreement. Incentive payments should only be made for cost reductions where clinical quality is maintained or improved. The patient mix should not change. For example, the parties cannot reduce or eliminate care to costly patients as a way to improve the clinical quality metrics upon which the incentive payment is based.
- d. The duration of the co-management agreement should be at least one year. Additional term requirements may apply if the property used to render services to patients pursuant to the co-management agreement is financed by tax-exempt bond proceeds. If the hospital has tax-exempt bonds outstanding, some limitations may apply to the term and termination of the relationship.

III. The Regulatory Framework

Co-management agreements have the potential to implicate most of the major healthcare federal regulatory schemes. Thus, it is critical to perform a thorough analysis of these regulatory schemes within the context of the intended co-management structure, the written agreement, and the actual implementation of any co-management program. Following is a summary of the major regulatory considerations to consider when structuring a new co-management program: (a) the Civil Monetary Penalty Statute, (b) the Anti-Kickback Statute, (c) the Physician Self-Referral Act, (d) the False Claims Act, and (e) if applicable, tax exemption and intermediate sanctions considerations. Depending on the nature of a potential co-management agreement, it may also be necessary to consider whether the agreement will implicate provider-based status rules or raise anti-trust issues. Of course, state laws and regulations impacting physician relationships may also impact agreement structuring considerations.

a. Civil Monetary Penalty Statute

The Civil Monetary Penalty Statute (“CMP Statute”)¹ prohibits a hospital from knowingly making a payment, directly or indirectly, to a physician as an

inducement to reduce or limit services to a Medicare or Medicaid beneficiary. A co-management structure that incentivizes behavior to reduce costs or otherwise change physician behavior could run afoul of the CMP Statute. A physician who knowingly accepts payment in violation of the CMP Statute could be fined up to \$2,000 for each such individual with respect to whom the payment is made. In addition, violators face potential exclusion from federal and state healthcare programs.

Since 2001, the U.S. Department of Health and Human Services Office of Inspector General (“OIG”) has issued favorable advisory opinions on several proposed co-management arrangements. The favorable advisory opinions generally include the following elements: (1) verifiable cost savings tied to specific protocol/cost lowering activity; (2) assurances that quality is measured and maintained; (3) monitoring of changes in case mix to ensure that more costly patients continue to receive treatment; (4) disclosure of the co-management arrangement to patients; and (5) reasonable, fair market value compensation. It is important to note that under the Patient Protection and Affordable Care Act (Pub. L. 111-148), as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111-152) (together, “PPACA”), the CMP Statute is amended to except from the definition of “remuneration” any other remuneration which promotes access to care and poses a low risk of harm to patients.²

b. Anti-Kickback Statute

The Federal Anti-Kickback Statute (“Anti-Kickback Statute”)³ is a criminal statute that generally prohibits the offering, payment, solicitation, or receipt of any remuneration in order to induce referrals to another person or entity for the furnishing, or arranging for the furnishing, of any item or service that may be paid for in whole or in part by Medicare, Medicaid, or any other federally funded health care program. The Anti-Kickback Statute ascribes criminal liability to both sides of an impermissible “kickback.” An arrangement could violate the Anti-Kickback Statute if “any one purpose” of the arrangement is to induce referrals. An improperly

¹ 42 U.S.C. § 1320a-7a.

² 42 U.S.C. § 1320a-7a(i)(6)(F).

³ 42 U.S.C. § 1320a-7b(b)(2).

structured co-management arrangement could be interpreted as an agreement to provide remuneration to physicians in exchange for referrals.

The OIG, however, has promulgated Safe Harbors to the Anti-Kickback Statute. If an arrangement complies with the requirements of a Safe Harbor, individuals and entities are insulated from prosecution under the Anti-Kickback Statute for conduct which would otherwise violate the Anti-Kickback Statute. However, arrangements which do not fit within a Safe Harbor may nevertheless be lawful under the Anti-Kickback Statute. The OIG has recognized in its commentary to the Safe Harbor regulations that many arrangements which may not fall within a Safe Harbor nevertheless operate without the type of abuses the Anti-Kickback Statute is designed to prevent (i.e., increased costs to the programs, over-utilization of services, and reduced quality).

The Personal Services and Management Contracts Safe Harbor is the most applicable Safe Harbor to a co-management relationship. In order to qualify for Safe Harbor protection, the arrangement must: (i) be set out in writing and signed by the parties, (ii) specify the services to be provided, (iii) if the agreement is intended to provide for services on a periodic, sporadic or part-time basis, the agreement must specify the exact schedule of such intervals, their precise length, and the exact charge for such intervals, (iv) the term must be for not less than one year, (v) the compensation must be set in advance, consistent with fair market value, and not determined in a manner that takes into account the volume or value of referrals, and (vi) the services performed under the agreement must not involve the counseling or promotion of a business arrangement or other activity that violates any state or federal law.

We offer this option: “. . . the arrangement must (i) be set out in writing; (ii) be signed by the parties; (iii) specify the services to be provided; (iv) set the compensation in advance, consistent with the fair market value, without taking into account the volume or value of referrals; and (v) not involve the counseling or promotion of a business arrangement or other activity that violates any state or federal law. If the agreement is intended to provide for services on a periodic, sporadic or part-time basis, the agreement must have a term of not less than one year and must specify the exact schedule of such intervals, their precise length, and the exact charge for such intervals.”

A co-management arrangement utilizing a percentage-based compensation structure (for example, with an incentive fee that varies based on achievement of certain clinical quality improvement metrics) likely would not satisfy the Personal Services and Management Contracts Safe Harbor. The Personal Services and Management Contracts Safe Harbor requires “aggregate compensation” to be set in advance and the OIG’s position is that percentage compensation is not “set in advance.” However, a co-management arrangement can meet many of the other elements of this Safe Harbor. Specifically, a co-management agreement should be set forth in writing and include all of the services to be provided, the term of the agreement should be for a duration of one year or greater, any contracted services should be reasonably necessary to accomplish the business purposes of the agreement, and the compensation should be consistent with fair market value in arms-length transactions and not take into account the volume or value of referrals.

It is recommended that compensation paid pursuant to a co-management arrangement be supported by an independent third-party fair market valuation. The compensation and incentive payment structure should be revisited throughout the course of the relationship to ensure that incentive payments are only being provided for performance improvements and to ensure that the compensation is still fair market value. If compensation provided is not commensurate with fair market value, such compensation could be construed as a kickback from the party paying greater than fair market value for the services actually provided.

c. Physician Self-Referral Act (“Stark Law”)

The Stark Law⁴ generally prohibits a physician from making referrals for certain designated health services to entities with which he or she has a financial relationship, unless an exception applies. Designated health services include, among others, inpatient and outpatient hospital services. Payments to physicians under a co-management agreement constitute a financial relationship. Therefore, an exception to the Stark Law must be satisfied since this law is a strict liability statute, and no intent to

⁴ 42 U.S.C. § 1395nn.

violate the law is necessary for a party to be in violation of the Stark Act.

The Stark Law personal service arrangements and fair market value exceptions are potentially applicable to co-management agreements. Both of these exceptions contain a requirement that the compensation must be consistent with fair market value, set in advance, and that it not vary with the volume or value of referrals. The “set in advance” requirement permits a specific formula that is set in advance, can be objectively verified, and does not vary with the volume or value of business generated. For example, an incentive fee based on achievement of objectively verifiable clinical quality improvement metrics should be acceptable. In 2009, the Centers for Medicare and Medicaid Services (“CMS”) proposed a new Stark Law exception⁵ for incentive plans/shared service plans. However, the exception was never finalized.

d. False Claims Act

Liability under the False Claims Act (“FCA”)⁶ occurs when a person or entity (1) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; (2) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; or (3) conspires to commit a violation of any of certain provisions of the False Claims Act (including the two listed above). Violations of the FCA are punishable by penalties of not less than \$5,500 and not more than \$11,000 per claim, plus treble damages for the amount of damages the government sustains. FCA actions can be based on Anti-Kickback Statute and/or Stark Law violations. If a claim that a hospital submits to Medicare was improperly induced or violated the Stark Law, then it may also be a false claim. Any co-management relationship should be structured to comply with the Stark Law and the Anti-Kickback Statute, and include a variety of prophylactic measures to ensure that the relationship does not induce or in any way contribute to the submission of a false claim.

⁵ 73 Fed. Reg. 38,502, 38,604–38,605.

⁶ 31 U.S.C. §§ 3729–3733.

e. Tax Exemption and Intermediate Sanctions

Assets of a 501(c)(3) tax-exempt entity cannot be used for private inurement, private benefit, or excess benefits. Payments by a tax-exempt entity to physicians under a co-management agreement could be construed to create private or excess benefits. If an organization meets the following three requirements, payments made to a disqualified person (any person who was in a position to exercise substantial influence over the affairs of the tax-exempt organization) under a compensation arrangement are presumed to be reasonable. That is, if the three requirements are met, the burden of proof shifts to the IRS and the IRS must prove that the compensation was unreasonable. The three requirements for establishing the rebuttable presumption are that (1) the compensation is independently approved by an authorized body of the tax-exempt organization, which is composed of individuals who do not have a conflict of interest concerning the transaction; (2) prior to making its determination, the authorized body obtained and relied upon appropriate data as to comparability; and (3) the authorized body adequately and timely documented the basis for its determination concurrently with making that determination. Finally, if the co-management agreement involves the use of tax-exempt bond-financed space, the arrangement must meet the durational requirements set forth by Internal Revenue Service Revenue Procedure 97-13 (“Rev. Proc. 97-13”).

Rev. Proc. 97-13 establishes a “safe harbor” under the Internal Revenue Code for management agreements that meet certain requirements. A management contract will fall within the safe harbor if (i) the compensation is reasonable; (ii) the compensation is not based in whole or in part on the net profits from the operation of the tax-exempt entity; and (iii) the contracting party is not a non-exempt related party. Rev. Proc. 97-13 sets forth certain permissible term and compensation combinations. The maximum term of a contract pursuant to which a vendor is paid up to a fifty-percent fixed fee is five years. Whereas, the maximum term for a percentage-based contract (e.g., percentage of revenues or expenses) is two years, and the maximum term for a per-unit contract (e.g., a billing agreement between a physician and a hospital) is three years. Commonly, co-management arrangements are structured as five-year agreements with a three-year termination clause.

IV. Conclusion

Properly designed co-management agreements have the potential to create strong alliances between hospitals and physician groups. Moreover, co-management agreements can facilitate the improvement of patient outcomes, decrease operational costs and improve a hospital's "bottom line," and increase patient and employee satisfaction. However, co-management relationships must be structured to comply with the myriad of statutes, regulations, and interpretive

guidance potentially implicated by such an arrangement. Therefore, the parties to such an arrangement should ensure that the planning, contracting, and implementation of any co-management relationship are handled appropriately. The issues involved in co-management arrangements cross a large number of regulatory schemes. Therefore, it is important to engage knowledgeable legal counsel and independent fair market value experts to ensure compliance with all applicable laws and regulations.