

## Monitoring Hospital – Physician Contractual Arrangements to Comply with Changing Regulations

By Gary Keilty





The vast majority of physicians are hard-working, ethical healers who seek and promote the appropriate use of medical care and treatment for their patients. Similarly, most hospitals are committed to providing high-quality health care at affordable rates to patients. But with regulatory agencies estimating the scope of overall healthcare fraud being as much as \$200 billion a year – and Medicare and Medicaid costs continuing to grow rapidly – a series of recent regulatory developments underscore the increased interest of regulatory agencies in examining contractual arrangements between hospitals and physicians in a position to refer patients.<sup>1</sup> When the ultimate payer is a government program – like Medicare or Medicaid – the government has an interest in ensuring that hospitals don't enter into or maintain contractual arrangements with physicians that could allow for potential kickbacks, unnecessary referrals, or outright fraud.

This article reviews briefly two federal statutes that are frequently used by regulators in enforcement efforts in this area, recently issued regulations that may affect how hospitals structure their contractual arrangements with physicians who are in a position to refer patients and suggested approaches for hospitals and their outside counsel when investigating such existing contractual agreements from a regulatory compliance perspective.<sup>2</sup>

The two main federal laws used by enforcement agencies in connection with this area are:

- An anti-kickback statute<sup>3</sup>, which is a criminal law with criminal penalties, enforced by the Office of the Inspector General, and
- The physician self-referral statute<sup>4</sup> (the "Stark Law," named for its Congressional sponsor), which is a civil statute with civil penalties, generally enforced by state attorneys general.

Congress enacted these statutes in large part to ensure that doctors' health care decisions were based upon their professional judgment pursuant to the doctor-patient relationship – without financial influence in the form of compensation or other remuneration of others, including hospitals, health systems, medical suppliers or drug or device manufacturers.

Briefly, the anti-kickback statute prohibits providing or offering anything of value, either directly or indirectly, in exchange for the referral of products or services that are paid for by government programs such as Medicare or Medicaid. Meanwhile, the Stark Law prohibits physicians from referring certain goods or services where they have a financial relationship in the company providing those specific services. Because the anti-kickback statute is a criminal law, establishing a violation requires proof of intent to induce referrals. By contrast, the Stark Law is not an intent-based statute; referring a single patient for a service where the physician (or an immediate family member) has a financial interest is sufficient to violate Stark.

In addition to the federal anti-kickback and self-referral statutes and their underlying regulations, hospitals and other health systems face a maze of other state and

<sup>1</sup> Regulators are also focused on other life science and health care companies, including pharmaceutical and medical device companies. Although many regulatory issues with these companies are similar, this article emphasizes hospital and physician relationships.

<sup>2</sup> In addition to the two federal laws discussed in this article, regulators may rely on other federal and state laws, including those relating to false claims acts.

<sup>3</sup> Found at 42 U.S.C. 1320a-7b(b).

<sup>4</sup> Found at 42 U.S.C. 1305nn.

federal regulations enforced by different agencies. For example, tax-exempt hospitals face special constraints, and the National Institutes of Health, the agency that awards large grants to research hospitals, has its own rules regarding the use of grant funds and against conflicts of interest. Prohibitions against referrals are continually expanding, and now cover referrals from physicians that involve inpatient and outpatient hospital services, radiology, home health and durable medical equipment and supplies.<sup>5</sup> In addition, many enforcement efforts are based on violations of statutes that relate to the improper quality or excessive utilization of goods or services.

During the last three years, at least a dozen hospitals or health systems have reportedly entered into settlements with the Office of Inspector General (OIG) to resolve alleged questionable physician arrangements. The hospital systems entered into either a Corporate Integrity Agreement (CIA) or a Certification of Compliance Agreement (CCA) with significant compliance requirements. Many of these settlements resulted from an OIG investigation prompted by an internal whistleblower. Under “qui tam” statutes, whistleblowers can get up to 30% of any penalties the government collects as a “bounty” for turning in offending parties.

But, as important as whistleblowers have been to the enforcement process to date, the government is trying other ways to identify potential violations of the Stark or anti-kickback laws, as a flurry of new regulations reveal.

## **New disclosure rules for some hospitals**

Last September, the Centers for Medicare and Medicaid Services (CMS) – the agency charged with administering the Medicare and Medicaid programs – announced a new information-collection program that will require approximately 500 hospitals to disclose their financial arrangements with physicians.<sup>6</sup> About 60 percent of those hospitals were named as mandatory participants in the disclosure process based on their failure to respond to CMS’s prior voluntary requests to physician-owned specialty hospitals and their competitor community hospitals. The new information must be submitted to CMS in a “Disclosure of Financial Relationships Report” (DFRR), including details about: (a) hospital ownership, (b) real property and capital leases and (c) compensation and other arrangements with physicians, including leases, personal services, recruitment, medical directorships, on-call stipends, and gifts. The DFRR must be certified by a senior hospital official and must be submitted to CMS within 45 days after receiving the request. Hospitals face penalties of up to \$10,000 per day for delays. Although the issuance of the DFRR rules is currently under regulatory review, many legal analysts believe that final, expanded disclosure requirements for hospitals are on the horizon.

## **New Stark-related regulations**

Last September, CMS also issued final regulations implementing the Stark Law.<sup>7</sup> Based on the complexity of the regulations and the identification of potential unintended consequences that would result from implementing them, CMS has issued several technical

<sup>5</sup> See 42 U.S.C. 1395nn(h)(6).

<sup>6</sup> 72 FR 52568 (September 14, 2007); for details, see Deloitte’s November 2007 Regulatory Special Bulletin, at [http://www.deloitte.com/dttr/da/doc/content/us\\_lshc\\_atregulatoryspecialbulletin\\_nov07.pdf](http://www.deloitte.com/dttr/da/doc/content/us_lshc_atregulatoryspecialbulletin_nov07.pdf).

<sup>7</sup> 72 FR 51012 et. seq. (September 5, 2007).

corrections, including a delay in the effective date for rules relating to arrangements between physicians and academic medical centers and nonprofit entities. CMS also issued Stark-related rules in July and November of 2007, and recently announced a one-year delay (until January 1, 2009) in the effective date of a final rule relating to prohibitions on the markup of technical and professional components of some diagnostic tests.

This raft of new rules includes numerous changes to the scope of permitted arrangements that may require hospitals to change their physician contracting or payment practices.

### **The 2008 OIG Work Plan**

The OIG issued its "Work Plan" in October 2007, indicating that it will focus its enforcement efforts on certain physician arrangements, including, the following:

- Services provided by non-physician staff members "incident to" physician professional services, including a review of qualifications of staff, medical necessity, documentation and quality of care
- Business relationships and the use of MRI services, including financial relationships among physicians, billing providers, and others involved in providing imaging services and how those relationships affect how often services are used
- Services and billing patterns in geographic areas with a high concentration of independent diagnostic testing facilities or high utilization of ultrasound services
- Fraudulent and abusive activity relating to physicians' reassignment of their rights to receive Medicare payments to other entities

### **Department of Health & Human Services' open letter to providers**

The Inspector General can impose significant Civil Monetary Penalties (CMPs) under the Stark Law and anti-kickback statutes: up to \$15,000 for each service billed and up to \$50,000 for each kickback. The OIG can also impose damages of up to three times the kickback or the amount claimed for such services.

In April 2006, Inspector General Daniel Levinson issued an open letter to health care providers. In it, he announced an initiative intended to promote the use of OIG's Provider Self-Disclosure Protocol (SDP) to resolve CMPs. To encourage voluntary disclosure and compliance, the letter states that the OIG will generally settle SDP matters near the lower end of the continuum of potential damages and penalties. In legal terms, health care providers can get lower penalties – and face less onerous ongoing compliance burdens – if they turn themselves in.

Recent settlement agreements indicate that the SDP may in fact reduce the compliance burden for hospitals who report themselves. For some hospitals that were the subject of investigations commenced by the OIG, the ongoing compliance requirements under many of the negotiated CIAs are significant. Conversely, many hospitals that identified a violation through an internal investigation and disclosed the findings to the OIG themselves were able to enter into CCAs with significantly fewer compliance requirements.

Some of the more-burdensome negotiated CIAs included the following compliance requirements:

- Creating and maintaining a database of all existing and new or renewed

- physician arrangements that included details on the terms and conditions of the agreement, including the identity of the parties, a description of goods and services provided under the arrangement, and compensation methodology and amount
- Tracking remuneration to and from physicians
- If the arrangement involves services, then tracking service and activity logs
- If the arrangement involves space or equipment, then monitoring the use of leased space or equipment
- Implementing a review and approval process that includes: (a) legal review by experienced counsel and (b) documentation of all internal controls
- Requiring the compliance officer to review the arrangements database and arrangements procedures and report to the Compliance Committee
- Implementing effective responses, including investigation, corrective action, and disclosure, when suspected violations are discovered

## Challenges

Many hospitals focus on the initial physician contract development itself, ensuring appropriate provisions are included and that the contract is fully reviewed by the legal department of the hospital or by outside counsel. But many hospitals lack appropriate monitoring procedures to ensure continued contract compliance. The 2006 Report on Medicare Compliance outlined the most common violations hospitals are discovering during internal investigations of their physician arrangements:

- Expired contracts
- Financial relationships where no written contract ever existed
- Undocumented modification of financial terms

- Terms modified during the first year in violation of safe harbors and exceptions available under the anti-kickback statute and Stark Law
- Agreements that incorrectly describe the service
- Hospital gifts or benefits to a doctor that exceeds Stark's minimum exception (currently \$329)

If such systems are not already in place, hospitals should consider creating and maintaining a database of all existing and new or renewed physician arrangements, including the identity of the parties, a description of goods and services provided under the arrangement, and compensation methodology and amount.

Given the above government enforcement initiatives in this area, hospitals should consider working with outside counsel and experienced consultants to conduct an independent review of documentation available for their physician contractual arrangements to identify potential areas at risk for violations of the anti-kickback statute or Stark Law. Based on recent enforcement efforts, the review should include a focus on the following problem areas:

- Physician office space leases:** Hospitals that enter into physician office leases often struggle with getting physicians to sign new or renewed leased agreements on time. So they frequently find themselves with space occupied without an active contract. This scenario becomes particularly troublesome if a previous contract did not contain any hold-over provisions and there is confusion on the part of hospital personnel on how to bill and collect correct rent payments. Other potentially risky areas include:
  - Non-enforcement of late payments or non-payment for certain months or a lengthy period of time.

- Lack of current, appropriate fair market value documentation during contract renewal
- Increased space usage by physician tenants without amendments to the applicable lease agreement
- Payments that don't match terms of the lease agreement
- Timeshare usage different from what is stated in the lease agreement
- Failure to comply with other terms and conditions set forth in safe harbors or exceptions for lease arrangements under the anti-kickback statute and Stark Law
- **Medical directorship/Physician services/On-call agreements:** Despite agreeing to provide timely documentation of time spent providing various medical directorship duties, many hospitals are challenged in getting such documentation on a timely basis from the physician, which can lead to questions as to whether the services were indeed performed. Other potentially risky areas include:
  - Lack of current, appropriate fair market value documentation for rates of payment
  - Missing or inadequate time sheets or other documentation to support past payments
  - Payment for services reflecting renegotiated rates without timely amendments to the effective contract
  - Payments made without a current active contract
  - Changed or reduced responsibilities for medical directorships without applicable amendments to the effective contract
  - Payments that do not match the terms of the written agreement
  - Failure to comply with other terms and conditions set forth in safe harbors or exceptions for personal service arrangement under the anti-kickback statute and Stark Law
- **Recruiting agreements:** Recruiting agreements are among the most challenging agreements to monitor, because revenue guarantee and payback periods can last several years. Potential risks include:
  - Lack of current, appropriate fair market value documentation
  - Lack of appropriate community need documentation
  - Payments or re-payments to/from recruited physician not matching contract terms
  - Inappropriate financial results information provided by recruited physician to support revenue guarantee payments
  - Failure to comply with other regulatory requirements imposed on recruitment arrangement under the anti-kickback statute, Stark Law or tax-exemption requirements
- **Joint ventures and other agreements.** The review should determine whether other arrangements such as joint ventures or other partnerships between hospitals and physicians may be subject to regulatory scrutiny.

### **When conducting an internal investigation**

Based on significant privilege and other issues that an internal investigation may trigger, hospitals should work with their outside counsel to determine the appropriate scope of an internal investigation of existing physician arrangements. Initial steps may include:

- Allocating enough personnel and other resources (such as a contract management system) to conduct the review,
- Determining the review period, and
- Identifying the scope of the review, including the number of arrangements to review in detail (that is, deciding between sampling vs. total review).

## **Other potential work steps include:**

- Gathering initial relevant information
  - Obtaining vendor accounts payable and accounts receivable data during the identified review period to identify payments made to or received by physicians or physician groups
  - Obtaining available contracts for all physician/physician groups that were effective during the review period
  - Obtaining information collected during the contract negotiation and approval process (e.g., fair market value documentation)
  - Interviewing hospital personnel to gain an understanding of how documents and other information for physician arrangements are collected on an ongoing basis
  - Reviewing hospital policies and procedures related to the collection of documentation and the payment for services for physician arrangements
- **Reviewing and noting whether the following exists for the applicable review period:**
  - Signed, written contracts as well as applicable amendments for contractual arrangements to which payments were made or received
  - Appropriate documentation of fair market value (developed either internally or provided by a third party consultant) for compensation, income guarantees (e.g., reasonableness of guaranteed compensation levels), loans, and purchase or lease of items or other services (if applicable)
  - Documentation of community need for recruited physician(s)
  - Documentation indicating payments made to the physician(s) match the written terms of agreement (e.g., review of accounts payable runs)
  - Documentation indicating payments received from physician(s) match written terms of agreement (e.g., review of accounts receivable runs for leases)
  - Documentation provided by physician(s) supporting payments made to physician(s) from hospital (e.g., incurred expenses for recruitment agreements, time sheets for services agreements)
  - Evaluation of the hospital's current system for management and administration of physician contractual arrangements, including the use of a centralized data base
- **Additional review tasks:**
  - Reviewing the individual contracts and noting whether or not the responsibilities are listed and are unique in nature compared to the other contracts the physician/physician group might have with the hospital (i.e., each contract "stands on its own" from a responsibility standpoint)
  - Reviewing the monthly time sheets for the review period for each contract provided to the hospital for payment to confirm that the hours worked are within the terms of the individual agreement and that the hours submitted for payment don't "overlap" with other time sheets submitted for the physician's/group's other contracts
  - Identifying instances (if applicable) where multiple contracts are in place related to the same services (e.g., multiple medical director agreements for the same department and responsibilities)
  - Securing other required documentation unique to the specific contract

## Conclusion

Recent additions to the already-crowded list of federal regulations affecting how hospitals contract with physicians make it more important than ever for hospital management to have rigorous compliance processes in place to avoid both intentional and unintentional violations. The internal investigation approach outlined above may help hospitals, their compliance officers, and their outside counsel in identifying key risk areas that may need further attention. Depending on the findings, this initiative can help enhance the hospital's current compliance program – or identify potential violations of the Stark or anti-kickback laws that may need corrective action and an OIG self-disclosure.

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