

@Regulatory Special Bulletin

Physician relationships under scrutiny

This issue of @Regulatory focuses on recent regulatory and enforcement actions by OIG, DOJ, CMS, as well as Congress' increased interest in and scrutiny of health care delivery systems and manufacturers and their relationships with the physicians or health care professionals with whom they do business.

Overview

An effective health care system relies upon many participants including: health care professionals, such as doctors and nurses, health care institutions, such as hospitals and clinics, and product manufacturers, such as pharmaceutical and medical device companies. All of these participants of our health care delivery system, along with other key participants, such as payors and distributors, must interact and conduct business with each other. While this concept may sound simple and obvious, the nature of their interactions, the competition for revenue dollars, contractual relationships, reimbursement mechanisms, and multiple regulatory oversight parties creates a complex inter-organizational business model.

In the best of circumstances, the participants work together in a manner that ensures health care consumers receive safe and effective care. In the worst of circumstances, the participants engage in conduct that the largest payor of health care, the U.S. Federal Government, considers abusive or fraudulent because the products or services provided to the consumer were never delivered, were not necessary or were unduly influenced through kick-back relationships.

This issue of @Regulatory focuses on the Federal government's current intense scrutiny of physician relationships within the health care system and highlights the focus of the government's concerns.

Although physician relationships are subject to significant regulation, arrangements with physicians and other licensed health care professionals are essential to the health care delivery system. Thus, engaging in appropriate relationships with physicians should be a top priority.

The current climate of regulatory scrutiny and how to respond

At the heart of the scrutiny are the relationships both hospitals & health systems and manufacturers have with physicians or other health care professionals who can prescribe or recommend health care services, prescription drugs or medical devices. There are many concurrent activities surrounding this issue and we have summarized some of these developments in the following articles:

- **Disclosure of financial relationships reporting** discusses the announcement by the Centers for Medicare and Medicaid Services (CMS) of a disclosure process for select hospitals, requiring the submission of information related to the hospital's financial relationships with physicians.
- **Deferred prosecution agreements with medical device companies** summarizes the September 27, 2007 settlements by the United States Department of Justice (DOJ) of claims relating to the alleged payment of improper inducements to physicians in exchange for using the products of five companies in the hip and knee replacement industry.
- **New Stark and other physician self-referral regulations** provides an overview of how CMS' issuance of final and proposed regulations modifies the requirements imposed under the physician self-referral prohibition commonly known as the "Stark Law."
- **A recap of the 2008 OIG work plan** discusses the stated intent of the Office of the Inspector General of the U.S. Department of Health and Human Services (OIG) to invest in significant enforcement efforts relating to the potential application of the Anti-Kickback Statute and Stark Law to physician arrangements in a variety of settings.
- **In Congressional inquiry for information relating to physician payments**, we discuss the Senate Finance Committee's request for information relating to all payments made by a medical device manufacturer to physicians.

- The summary entitled **Compensation arrangements for tax-exempt providers** reviews the continuing regulatory scrutiny of the operation of tax-exempt hospitals, including, increased emphasis on compensation arrangements with physicians who are in a position to influence control over the operation of tax-exempt entities.
- Finally, in **Practical tips to demonstrate proper interactions with physicians** the underpinnings of the legal requirements are examined and readers are provided several initiatives they should consider undertaking to help demonstrate their compliance with the laws.

The recent developments demonstrate the increased interest of various regulatory agencies in ensuring relationships with physicians are appropriate by establishing mechanisms to make the relationships transparent. There are many steps organizations can take to establish compliance standards, to train their employees on the “do’s and don’ts” regarding physician relationships and to demonstrate their need for physician involvement in their day-to-day operations.

Disclosure of financial relationships reporting

On September 14, 2007, CMS announced an information collection program that will require approximately 500 hospitals to disclose information relating to the hospital’s financial arrangements with physicians¹. Approximately 290 of the hospitals designated to participate in the disclosure process were selected based on their failure to respond to CMS’ 2006 voluntary request to physician-owned specialty hospitals and their competitor community hospitals. CMS circulated the 2006 voluntary request in an effort to learn more about the impact of physician ownership on hospitals.

In its announcement, CMS indicated that the disclosure requirements are being implemented under provisions of the Deficit Reduction Act of 2005 (DRA). CMS is also considering whether to expand the disclosure requirements to include the establishment of an ongoing process that would require similar disclosures from all hospitals in the future.

The requested information is required to be submitted to CMS in a mandatory disclosure reporting format (Disclosure of Financial Relationships Report” or “DFRR). The broad disclosure obligations require the submission of information related to, among other items: (i) hospital ownership, (ii) real property and capital leases and (iii) compensation and other arrangements with physicians, including, leases, personal services, recruitment, medical directorships, on-call stipends, gifts and gratuities.

The DFRR must be certified by a senior hospital official and is required to be submitted to CMS within 45 days following the receipt of the request. The hospitals face penalties of up to \$10,000 per day if the information is not timely filed.

CMS intends to use the information to analyze each hospital’s compliance with the Stark Law. Under the Stark Law, a financial arrangement by and between a hospital and a physician must meet an exception to the self-referral prohibitions. Failure to fall within an exception could result in severe consequences to a hospital, including: (i) denial of reimbursement for certain designated health services

(including inpatient, outpatient, radiology and other imaging, DME and supplies, therapy and/or clinical lab services) and (ii) exposure to significant penalties and fines.

CMS estimates that the DFRR will take each hospital approximately 6 hours to complete. Most industry experts, however, believe that compliance with the disclosure obligations will require far greater administrative effort by hospitals and their legal counsel and professional advisors. In addition to document production and/or other processing issues, many hospitals will be required to evaluate existing physician arrangements in order to prepare accurate disclosures that can be certified by management. The evaluation of agreements may also be necessary to identify other actions that may be required to minimize exposure to penalties and fines that may result from inaccurate disclosures or if the physician arrangements are not in compliance with the requirements imposed under Stark.

The DFRR is currently under challenge by various trade industry groups. For example, the American Hospital Association (AHA) notes that the DRA does not authorize CMS to collect information relating to physician compensation arrangements with community hospitals. Instead, the AHA asserts that the DRA authorizes CMS only to evaluate physician investment in specialty hospitals.

Deferred prosecution agreements with medical device companies

The DOJ recently entered into settlement agreements with five companies related to improper payments to physicians. These five companies represent nearly 95% of the hip and knee surgical implant market.

As a condition of the settlement, four of the companies entered into a Deferred Prosecution Agreement (DPA)². The DPAs provide for the dismissal of criminal complaints filed against the companies after eighteen (18) months if the parties satisfy the requirements imposed by the DPA.

The terms of the settlements also provide for the appointment of an independent federal monitor for each company with broad authority to evaluate the company’s compliance practices and performance under the DPA. Among other items, the monitor is required to review existing and new arrangements between the company and orthopedic surgeons, health care professionals and other consultants for compliance with the Anti-Kickback Statute.

The settlements also required each company to enter into a Corporate Integrity Agreement (CIA) that imposes additional comprehensive compliance-related obligations for a five (5) year term. The CIA’s require each company to create and/or maintain a database of all contractual and non-contractual arrangements with physicians. The database is required to include information that is necessary to assist the company in determining whether the arrangement violates the Anti-Kickback Statute, including:

- The identify of each party
- The type of arrangement (e.g., physician employment contract, medical directorship, lease agreement)
- The term of the arrangement, including the effective and expiration dates and any automatic renewal provisions

¹ 72 FR 52568 (September 14, 2007)

² Based on its cooperation with the U.S. Attorney’s Office, no criminal complaints were filed against one of the hip and knee implant companies that entered into a settlement agreement. The company, however, executed a Non-Prosecution Agreement that requires the company to implement all reforms imposed on the other companies under the DPA.

- The amount of compensation to be paid pursuant to the arrangement and the means by which compensation is paid
- The methodology for determining the compensation under the arrangement, including the methodology used to determine the fair market value of such compensation
- Whether the amount of compensation to be paid pursuant to the arrangement is determined based on the volume or value of referrals between the parties
- Whether each party is required to comply with the company's compliance program, code of conduct and policies and procedures related to the Anti-Kickback Statute
- Whether the arrangement satisfies the requirements of an Anti-Kickback Statute safe harbor

The recent settlements with the hip and knee replacement companies reflect the increasing use of DPAs and CIAs. Recent examples of physician arrangements and/or other improper payment practices that violate the Anti-Kickback Statute and/or Stark Law and resulted in DPAs and/or CIAs include:

- Payment of excessive compensation and other improper financial arrangements between a hospital and physicians
- Failure to properly reflect rebates and credits paid to a manager of a hospital's outpatient clinics
- Payment of excessive compensation to a manager of a hospital's specialty unit
- Payment of improper marketing and promotion of pharmaceuticals for off-label uses
- Switching of drugs to avoid Medicaid upper payment limits

The broad review rights of monitors and Independent Review Organizations (IRO's) granted under DPAs and CIAs also create exposure for additional claims. A monitor recently identified alleged violations of the Anti-Kickback Statute relating to improper payments by an academic medical center that were intended to induce referrals. The monitor was originally appointed under the terms of a 2003 DPA related to alleged double billings for services provided in outpatient clinics.

New Stark and other physician self-referral regulations

On September 5, 2007, CMS issued the third phase of final regulations for the Stark Law³. The final regulations are effective December 4, 2007 and include changes that may require modification of certain physician contracting or payment practices including:

- **Standing in the Shoes.** Under current Stark Law regulations, an individual physician is generally deemed to have an "indirect" financial relationship as a result of a contract between the physician's medical group and an entity that bills for a designated health service (DHS) subject to Stark. However, with implementation of the new regulations, an individual physician is deemed to have a direct financial relationship with the DHS billing entity (i.e., the physician is deemed to "stand in the shoes" of his/her physician organization). Thus, the broad exception for indirect compensation arrangements will no longer be available for such arrangements and

the relationship will have to meet the exception criteria for direct financial relationships. The new regulations do provide limited relief (i.e., a grandfather clause) for existing arrangements that comply with the indirect compensation arrangement.

- **Compensation:** The new Stark regulations also change the scope of permitted medical group practice compensation arrangements, including clarifications relating to services and supplies provided "incident to" a physician's professional services and the computation of productivity bonuses. The new regulations also eliminate a safe harbor relating to the measurement of fair market value of compensation for hourly rates. In connection with the elimination of the safe harbor, CMS emphasized that (i) one of the surveys listed in the safe harbor no longer exists, (ii) the determination of fair market value is dependent on the specifics of the transaction, and (iii) "the use of multiple, objective independent sources of fair market value remains a prudent practice."

CMS also issued proposed regulations on July 12, 2007 that include certain provisions that would restrict business arrangements that are permitted under the current regulatory framework⁴. The proposed rules include significant revisions that would require the restructuring (or termination) of many physician contracts. Although certain of the significant proposed changes were not included in the final rules, CMS continues to evaluate whether such rules may be advisable to safeguard against over-utilization or other abusive practices. If adopted, the proposed changes would eliminate or otherwise restrict certain common contracting arrangements such as:

- Services performed under "an arrangement" between an entity that furnishes DHS and an entity that bills Medicare for the DHS
- Percentage compensation arrangements that are not related to the provision of physician services (e.g., leases)
- Mark-up of certain diagnostic testing procedures
- Unit of service (i.e., "per-click") lease arrangements
- Block leasing of independent diagnostic testing facilities

The final physician fee schedule rule issued by CMS on November 1, 2007, adopted certain restrictions relating to the mark-up of certain diagnostic testing procedures⁵. Based on the significance and complexity of the issues involved in physician self-referral issues, CMS did not finalize the other proposed changes included in the July 12 proposed regulations. The preamble to the final November 1 regulations, however, indicates that CMS intends to issue additional changes to the physician self-referral rules through the issuance of final regulations in the future. Accordingly, health care and life sciences companies and their legal counsel should carefully evaluate the final and proposed regulations relating to the Stark law and other physician self-referral prohibitions. In addition, companies should ensure that existing agreements, and applicable compliance policies, procedures and guidelines are properly updated to reflect such changes.

A recap of the 2008 OIG work plan

In October 2007, the Office of the Inspector General released its work plan for FY 2008⁶. The OIG work plan is regarded as an important indicator of enforcement policy and demonstrates the OIG's intent to scrutinize anti-kickback and physician self-referral issues. The work plan contemplates the OIG's review of the following items:

3 72 FR 51012 et. seq. (September 5, 2007)

4 72 FR 3822 et. seq. (July 12, 2007)

5 See <http://www.cms.hhs.gov/center/physician.asp>. To be published in the Federal Register on November 27, 2007.

6 See <http://oig.hhs.gov/publications/workplan.html>

- Services provided by nonphysician 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 magnetic resonance imaging services, including financial relationships among physicians, billing providers and others involved in providing imaging services and the effect of such relationships on the levels of utilization of services
- 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

Congressional inquiry for information relating to physician payments

On September 20, 2007, Senator Charles Grassley (R-IA), Ranking Member of the Senate Committee on Finance, requested a major medical device manufacturer to provide information relating to the manufacturer’s alleged practices of “providing physicians with inordinately high consulting fees, free travel and other perks [that] distort decision making among physicians and obscure the best interest of patients.”

The Senator’s information request constitutes part of an ongoing Senate investigation into financial ties between the medical device industry and practicing physicians. Additional investigation by Congress is expected to continue with respect to payment practices that may violate the Anti-Kickback Statute, Stark Law or related laws.

Compensation arrangements for tax-exempt providers

The scrutiny of physician arrangements is also a key component of the ongoing regulatory examination of the practices of tax-exempt entities. For example, the proposed Form 990 information return issued by the Internal Revenue Service (IRS) in June, 2007 includes revised compensation disclosure requirements that are intended to further the IRS objectives of enhancing transparency and promoting tax compliance with respect to compensation arrangements.

The IRS is also conducting a comprehensive study of the compensation practices of tax-exempt providers. As part of the study, the IRS requested information in 2006 from over 500 hospitals related to compensation practices and procedures used to determine compensation for executives, physicians and others with the potential to influence or control the affairs of the tax-exempt entity. The IRS is expected to issue a final report on its findings next year. The results of the study will likely play a large role in determining the scope of any further changes to compensation and other tax-exemption requirements that may be imposed by the IRS and/or Congress.

Practical tips to demonstrate proper interactions with physicians

The Anti-Kickback Statute and Stark Law were enacted as a means to ensure health care decisions were based upon a physician’s professional judgment pursuant to the doctor-patient relationship without improper influence from hospitals, health systems, medical suppliers or drug or device manufacturers. In short, 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 the federal health care program, Medicare or Medicaid. The Stark Law, prohibits a physician from referring patients for specific services where the physician has an ownership interest in the company providing those specific services. While the Anti-Kickback prohibitions require an intent to induce referrals, simply the referral of a single patient for a service where the physician has an ownership interest is sufficient to violate Stark. While both laws have a series of safe harbors or exceptions that allow certain relationships or transactions, any person or entity who participates in the health care delivery system should have a compliance program that includes policies and procedures, training programs, and auditing plans that guide their day-to-day processes and systems regarding how they interact with the physicians with whom they work (hereinafter “Physician Arrangement Compliance Program”).

A physician arrangement compliance program should be able to readily respond to the following questions:

- Do we have policies and procedures that define appropriate and inappropriate interactions with physicians?⁷
- Have we identified all of the business activities in our organization where we enter into arrangements with physicians?
- Have we determined the need for services the physicians provide (e.g. Medical Directors, Instructors or Trainers, Research Grants, Advisory Boards)?
- Do we have a record of all the physicians that provide services to our organization or on our organization’s behalf?
- Have we established the Fair Market Value for any payments that are made to physicians when the physician is providing services to or on our behalf?
- Have we trained all of our employees, at all levels in our organization, on the risks regarding violations of the Anti-Kickback Statute or Stark Law and the policies and procedures we have in place to prevent such violations?
- Have we conducted audits to ensure our policies and procedures are being followed?
- Have we taken corrective action when we have identified violations of our policies and procedures?

Even if this is an area that historically has not been the focus of an organization’s compliance activities, all of the recent scrutiny warrants placing this as a high priority for the organization’s 2008 Compliance Program Plan.

⁷ Physicians include any health care professional who prescribes products or services such as Nurse Practitioners in some states.

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