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FRAUD AND ABUSE

OIG APPROVES PHYSICIAN COMPENSATION FOR ON-CALL SERVICES

by Lisa Pierce Reisz, Esq.

Introduction

On May 14, 2009, the OIG issued Advisory Opinion No. 09-05 advising that a non-profit hospital, the sole provider of acute care, inpatient hospital services in its geographic area, could pay their staff physicians for on-call services performed for their uninsured patients without violating the Medicare anti-kickback statute (the “Proposed Arrangement”). In this opinion, the OIG recognized that legitimate reasons exist for compensating physicians for on-call emergency room services, including EMTALA obligations, scarcity of physicians within a service area, or access to trauma services. Nevertheless, the OIG advised that such arrangements potentially create considerable risk that physician demand for such compensation may be a condition for doing business with the hospital, even when neither the services provided nor any external market factor support it. Thus, the OIG cautioned that such compensation be set in an arm’s length transaction at the services’ fair market value, and not determined in any manner that takes into account the volume or value of referrals or other business generated between the parties.

Factual Background

The hospital’s current Bylaws require its active medical staff to provide on-call coverage for its Emergency Department. The hospital, however, does not compensate its physicians for on-call services provided to indigent and uninsured patients, which has resulted in one of its physician groups reducing its weeks of Emergency Department coverage to the minimum required by hospital policy. As a result, there are weeks each month when the hospital does not have needed specialists on-call, and is forced to outsource emergency care to other hospitals.

Under the Proposed Arrangement, the hospital’s Bylaws will be amended to allow participating physicians to submit claims to the hospital for payment for services rendered to eligible indigent and uninsured patients in the emergency room. Patients are deemed eligible if they have no sponsoring insurance plan and their eligibility is verified by the

This newsletter contains information necessarily of such a general nature that it cannot be regarded as legal advice. Vorys, Sater, Seymour and Pease LLP is available to provide additional information and to discuss matters contained herein as they may apply to specific situations.

hospital's accounting department. Physicians are eligible to participate if the physician (1) is an active member of the Hospital's medical staff, (2) signs a letter agreement consenting to participate and follow the program's policies (including a 30-minute response time, patient evaluation and follow-up, and compliance with the claims process), and (3) provides on-call coverage in the emergency room as part of the established on-call schedule. Compensation is to be paid after the physician has completed the care for an eligible patient and submitted a completed claim request form. Participating physicians also agree to waive all billing or collection rights against any third-party payers for services rendered. Compensation is based on a set schedule, and the hospital has certified that payments will be made solely on the basis of services actually needed and provided, and without regard to referrals or other business generated. The hospital has also certified that payment amounts fall within the range of fair market value for services rendered.

Analysis

The anti-kickback statute makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive remuneration either in return for or to induce referrals for, or purchases of, services, if those services will be paid for by Medicare or other federally funded health care programs. 42 U.S.C. § 1320a-7b(b). Where remuneration is paid purposefully to induce or reward referrals of items or services payable by a Federal health care program, the anti-kickback statute is violated. *United States v. McClatchey*, 217 F.3d 823 (10th Cir. 2000); *Hanlester v. Shalala*, 51 F.3d 1390 (9th Cir. 1995). HHS has promulgated safe harbor regulations that define practices that are not subject to the anti-kickback statute because they would be unlikely to result in fraud and abuse. See 42 C.F.R. § 1001.952. The safe harbors set forth conditions that, if precisely met, assure entities involved of not being prosecuted or sanctioned for the arrangement qualifying for the safe harbor.

The OIG initially analyzed the Proposed Arrangement under the safe harbor for personal services and management contracts, but determined that the Proposed Arrangement failed to satisfy every condition of the safe harbor because aggregate annual compensation is not fixed in advance. However, the OIG acknowledged that the failure to meet all conditions of the safe harbor was not fatal, and determined that under the totality of the facts and circumstances identified below, the Proposed Arrangement presented a low risk of fraud and abuse:

1. The hospital certified that the payments are within the range of fair market value for the services rendered, without regard to referrals or other business generated.
2. The hospital has a legitimate rationale for revising its on-call coverage policy.

3. The Proposed Arrangement is offered uniformly to all physicians and imposes tangible responsibilities upon them. Scheduling is based on the hospital's medical staff Bylaws. The claims process promotes transparency and accountability.
4. The Proposed Arrangement facilitates better emergency on-call and related uncompensated care physician services at the hospital.

Therefore, the OIG concluded that, as structured, the Proposed Arrangement contains safeguards sufficient to reduce the risk that the remuneration is intended to generate referrals of federal health care business in violation of the anti-kickback statute.

CMS Clarifies “Stand In The Shoes” Questions In Proposed 2010 Medicare Physician Fee Schedule Update

by Andrea Ebreck, Esq.

The Stark II, Phase III rule, released September 5, 2007, introduced Stark's “Stand in the Shoes” provision to the health care community. Under this provision, for purposes of an arrangement between a designated health service (“DHS”) entity and a physician organization, a physician who has a direct financial relationship with a physician organization will be deemed to have a direct compensation arrangement with the DHS entity if the only intervening entity between the physician and the DHS entity is the physician organization. According to CMS, the purpose of requiring physicians to “stand in the shoes” of their physician organizations was to close an unintended loophole in the definition of an indirect compensation arrangement by deeming more arrangements to be direct compensation arrangements.

In the 2009 Hospital Inpatient Prospective Payment System (“IPPS”) Final Rule published on August 19, 2008, CMS narrowed the Stand in the Shoes provision to require only those physicians who have an ownership interest in their physician organizations to stand in the shoes of their organizations. The 2009 IPPS rule further clarified that physicians with only a “titular” ownership interest (i.e., those without the ability or right to receive the financial benefits of ownership or investment, including but not limited to, the distribution of profits, dividends or proceeds from any sale of the entity) are permitted, but not required, to stand in the shoes of their physician organizations.

On July 13, 2009, the 2010 Medicare Physician Fee Schedule Update (“MPFS”) (74 Fed. Reg. 33520) was published. In the 2010 MPFS, CMS clarifies the following questions regarding the application of the Stand in the Shoes provision.

Signed By The Parties

- Most Stark law compensation exceptions require that financial relationships between covered entities be in writing and signed by all parties to the agreement. Because the Stand in the Shoes provision states that all physician members of a physician organization are “parties” to the physician organization’s compensation arrangements, a question arose as to whether all members of the physician organization must also sign compensation arrangements with DHS Entities in order to satisfy the applicable Stark exceptions. In the proposed 2010 MPFS, CMS clarifies that only a single authorized signatory must sign an agreement.

Volume or Value

- Most direct Stark compensation exceptions also require that the compensation paid under the arrangement not be determined in a manner that takes into account the volume or value of referrals or other business generated between the parties. Following the 2009 IPPS revisions, a question arose with respect to whether referrals for purposes of applying the “volume or value” standard were limited to the referrals of those physician members standing in the shoes of the physician organization, or whether the referrals of all of the physician organization’s physician members were relevant. In the proposed 2010 MPFS, CMS clarifies that if the applicable compensation exception prohibits compensation that is determined in a manner that takes into account the volume or value of referrals “between the parties,” the compensation paid to the physician organization by a DHS entity may not take into account the volume or value of referrals by any of the physician organization’s members, employees, or independent contractor physicians (even the non-owners).

If CMS finalizes the Stark changes proposed in the 2010 MPFS, physician organizations will only be required to obtain the signature of one representative to comply with the requirement that agreements between DHS entities and physician organizations be “signed by the parties.” Additionally, all of a physician organization’s physician members (not just owners) will be “parties” to a compensation arrangement between the physician organization and a DHS entity for purposes of determining whether the compensation takes into account the volume or value of referrals between the parties.

ENFORCEMENT ACTIVITY

Permanent Exclusion of Nursing Home Executive

by Paul Coval, Esq.

The Office of Inspector General for the Department of Health and Human Services (“OIG”) announced on July 13, 2009, that Emanuel Bernabe, President and Chairman of the Board of Pleasant Care Corporation, a California-based nursing home operator, agreed as part of a settlement reached with the OIG, to be permanently excluded from all federal health care programs. The settlement that resulted in Mr. Bernabe’s exclusion also resolved accusations that the Pleasant Care Corporation had been putting nursing home residents at risk by providing sub-standard care such as inadequate hydration and nutrition, poor wound care and failing to maintain adequate staffing levels. Although he agreed to permanent exclusion from participation in federal health care programs, Mr. Bernabe did not acknowledge the validity of the OIG’s allegations, and specifically denied liability.

As a consequence of his exclusion, Mr. Bernabe cannot participate directly or indirectly in any health care endeavor which would receive payment of federal health care dollars for services furnished or ordered by him, or own or manage any entity that participates in, or receives funds from, a federal health care program. Violation of the terms of this exclusion could subject Mr. Bernabe to criminal prosecution, and any claims resulting from such a violation would be considered false claims.

Covenant Medical Center: Stark and False Claims Act Settlement

by Stephanie Angeloni, Esq.

Covenant Medical Center in Waterloo, Iowa has agreed to pay the United States \$4.5 million to resolve allegations that it violated the Stark Law and False Claims Act.

This settlement resolves allegations that Covenant submitted false claims to Medicare by having financial relationships with five physicians that violated the Stark Law. Stark is a federal law that governs certain referral based transactions involving physicians. Generally, Stark prohibits a physician from making referrals for designated health services payable by Medicare to an entity with which the physician has a financial relationship unless an exception is satisfied. One available exception allows referral based transactions under a direct compensation arrangement so long as the physician is paid fair market value for services rendered and compensation is commercially reasonable. Overall, Stark is intended to ensure that physician’s medical judgments are based solely on the best interest of the patient and not compromised by improper financial incentives.

In the Covenant Medical Center matter, the United States alleged that Covenant violated the Stark Law by paying commercially unreasonable compensation, far above fair market value, to five employed physicians who referred their patients to Covenant for treatment. These physicians were among the highest paid hospital-employed physicians in the country, some making more than double what the physicians could have made elsewhere in Iowa.

Tony West, Assistant Attorney General for the Department of Justice's Civil Division, stated, "Health care providers must act in the best interests of their patients. The Justice Department will protect patients by pursuing hospitals that have improper financial relationships with physicians."

"This payment is the largest ever related to claims of health care fraud in the Northern District of Iowa," said U.S. Attorney Matt M. Dummermuth of the Northern District of Iowa. "We are actively working with our investigative partners to ensure Medicare funds are properly spent, and we will continue to aggressively pursue all types of fraud in order to protect federal health care dollars."

Pfizer Pharmaceutical Qui Tam Settlement

by Stephanie Angeloni, Esq.

In the largest health care fraud settlement in the Justice Department's history, Pfizer, Inc. has agreed to pay a \$2.3 billion penalty for illegally promoting its pharmaceutical products. This settlement originated as a qui tam action under the False Claims Act ("FCA"). The FCA allows a private citizen with knowledge of fraud to assist the Government in recovering ill-gotten gains and additional civil penalties. Specifically, the Government can collect up to three times the amount it was defrauded, in addition to civil penalties between \$5,500 and \$11,000 per false claim.

In this case, Pfizer's fraudulent activity included the improper branding and marketing of Zyvox, Bextra, and several other drugs.

Zyvox is an antibacterial agent that is approved by the FDA to treat certain types of infections. In marketing this drug, Pfizer ignored a 2005 FDA Warning Letter accusing Pfizer of misbranding Zyvox, making misleading and unsubstantiated superiority claims, and omitting important safety information from its ads. Bextra is an anti-inflammatory drug approved to treat arthritis, rheumatoid arthritis and menstrual pain. Pfizer's subsidiary Pharmacia & Upjohn Co., Inc. agreed to plead guilty to a felony violation for misbranding Bextra with the intent to defraud or mislead by marketing Bextra for unapproved, off-label uses.

The government also discovered that Pfizer offered and paid illegal compensation to health care professionals. Pfizer treated doctors to meals, paid them for speaking engagements, and subsidized their travel to induce them to

prescribe various drugs for off-label use, including Zyvox, Bextra, Geodon, Lipitor, Lyrica, and eight others. All of this was done while Pfizer was subject to a corporate integrity agreement stemming from prior misbranding and improper marketing activities.

Out of the \$1 billion settlement, the federal share of the civil settlement is \$668.51 million and the state Medicaid share is \$331.49 million. Six whistleblowers will also receive payments totaling more than \$102 million from the federal share of the civil recovery.

Learn More!

We represent clients in Ohio, across the country and around the world in litigation and business transactions involving virtually every legal subject. To find out how Vorys can help your company's legal needs, contact a member of our Health Care Group:

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