



FRAUD AND ABUSE LAW IMPLICATED BY COMPENSATION ARRANGEMENTS

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Real Quick Overview

False Claims Act

- Any person who—
 - knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval
 - is liable to the United States Government for a civil penalty... plus 3 times the amount of damages which the Government sustains because of the act of that person. 31 USC 3729(a).

Anti-Kickback Statute

- The federal anti-kickback statute prohibits the knowing and willful solicitation, offer, payment or acceptance of any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind:
 - (1) for referring an individual for a service or item covered by a federal health care program, or
 - (2) for purchasing, leasing, ordering, or arranging for or recommending the purchase, lease, or order of any good, facility, service or item reimbursable under a federal health care program. 42 U.S.C. § 1320a-7b(b).

Exception—Compensation Arrangements

Personal services and management contracts—42 CFR 1001.952(d)

•(d) *Personal services and management contracts.* As used in section 1128B of the Act, “remuneration” does not include any payment made by a principal to an agent as compensation for the services of the agent, as long as all of the following seven standards are met—

- The agency agreement is set out in writing and signed by the parties.
- The agency agreement covers all of the services the agent provides to the principal for the term of the agreement and specifies the services to be provided by the agent.
- If the agency agreement is intended to provide for the services of the agent on a periodic, sporadic or part-time basis, rather than on a full-time basis for the term of the agreement, the agreement specifies exactly the schedule of such intervals, their precise length, and the exact charge for such intervals.
- The term of the agreement is for not less than one year.
- The aggregate compensation paid to the agent over the term of the agreement is set in advance, is consistent with fair market value in arms-length transactions and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs.
- The services performed under the agreement do not involve the counselling or promotion of a business arrangement or other activity that violates any State or Federal law.
- The aggregate services contracted for do not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the services.

Employee—42 CFR 1001.952(i)

•(i) *Employees.* As used in section 1128B of the Act, “remuneration” does not include any amount paid by an employer to an employee, who has a bona fide employment relationship with the employer, for employment in the furnishing of any item or service for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs. For purposes of paragraph (i) of this section, the term *employee* has the same meaning as it does for purposes of 26 U.S.C. 3121(d)(2).

Stark....Manufacturers are generally not
covered

BUT....

Stark Law

- Prohibits physicians from referring Medicare patients for designated health services (DHS) to an entity in which the physician or immediate family member has a financial interest. 42 U.S.C. § 1395nn.
- DHS:
 - Clinical laboratory services.
 - Physical therapy, occupational therapy, and outpatient speech-language pathology services.
 - Radiology and certain other imaging services.
 - Radiation therapy services and supplies.
 - Durable medical equipment and supplies.
 - Parenteral and enteral nutrients, equipment, and supplies.
 - Prosthetics, orthotics, and prosthetic devices and supplies.
 - Home health services.
 - Outpatient prescription drugs.
 - Inpatient and outpatient hospital services.
- There are exceptions, including compensation arrangements.

Exception—Compensation Arrangements

Bona Fide Employment Exception—42 CFR §411.357(c)

The following compensation arrangement does not constitute a financial relationship:

- (c) *Bona fide employment relationships.* Any amount paid by an employer to a physician (or immediate family member) who has a *bona fide* employment relationship with the employer for the provision of services

Personal Services Arrangement Exception. General.—42 CFR §411.357(d)(1)

The following compensation arrangement does not constitute a financial relationship:

- (d) *Personal service arrangements.* (1) *General*—Remuneration from an entity under an arrangement or multiple arrangements to a physician or his or her immediate family member, or to a group practice, including remuneration for specific physician services furnished to a nonprofit blood center

Exception—Compensation Arrangements

Non-Monetary Compensation Arrangement Exception—42 CFR §411.357(k)

The following compensation arrangement does not constitute a financial relationship:

- (k) *Nonmonetary compensation.* (1) Compensation from an entity in the form of items or services (not including cash or cash equivalents) that does not exceed an aggregate of \$300 per calendar year, as adjusted for inflation in accordance with paragraph (k)(2) of this section

Fair Market Value Exception—42 CFR §411.357(l)

The following compensation arrangement does not constitute a financial relationship:

- (l) *Fair market value compensation.* Compensation resulting from an arrangement between an entity and a physician (or an immediate family member) or any group of physicians (regardless of whether the group meets the definition of a group practice set forth in §411.352) for the provision of items or services (other than the rental of office space) by the physician (or an immediate family member) or group of physicians to the entity, or by the entity to the physician (or an immediate family member) or a group of physicians

Old Dog – New Tricks

Basically, it comes down to legitimacy and
FMV

Fair Market Value

- **Fair Market Value**
 - The term fair market value means a lot of different things to a lot of different people
 - In essence...
 - The value in an arms-length transaction that someone would reasonably pay for the services or items being provided/received

So, what are some of these new novel ideas
being considered?

Example of Some Recent Novel Compensation Arrangements that Were Alleged to Violate Fraud and Abuse Laws

Trips

New Jersey Investigation of Hip and Knee Device Manufacturers

- Alleged that companies provided financial incentives in the form of consulting arrangements, lavish trips, and “perks” to induce physicians to use company products.
- Consulting agreements:
 - Companies paid consultants a fee, typically \$5,000, for each quarterly report that included information on market trends, activity in the operating room, and product issues, but quarterly reports were of little or no value to the companies.
 - Consultant panels at luxury resorts. Consultants were compensated for the whole day although most of the day was available for recreational act.
- Royalty payments:
 - Companies entered into product development agreements with consultant physicians, offering them royalty payments once the products were launched. These agreements provided for annual payments of hundreds of thousands or millions of dollars for up to 20 years.

Company-Sponsored Adult Entertainment

Medtronic, Inc.

- Kickbacks of various forms to choose Medtronic devices:
 - Consulting and royalty agreements for little actual work performed
 - Trips for doctors and their families/spouses/girlfriends
 - Company sponsored adult entertainment
 - Consultant meetings held at lavish venues
- Settlement:
 - Medtronic paid \$40 million to settle FCA case and entered into 5 year CIA.

Payment of Front Office Staff

- Settlements with 12 individual physicians who entered into impermissible medical directorship and office staff agreements
- Office staff agreements included another entity paying the salaries of the physicians' front office staff.
 - This constitutes improper remuneration in violation of AKS because “it relieved the physicians of a financial burden they otherwise would have incurred.”
- Compensation paid to physicians under the medical directorship arrangements constituted improper remuneration under AKS because:
 - Payments took into account the physicians' volume or value of referrals
 - Did not reflect fair market value for the services to be performed
 - The physicians did not actually provide the services called for under the agreements.
- Cite:
http://f.datasrvr.com/fr1/015/37117/Fraud_Alert_Physician_Compensation_06092015.pdf

Free Use of Private Jet

- Company allegedly provided the physicians with valuable compensation, including free use of the corporate jet, pursuant to medical directorship agreements, requiring limited services in return.
- The agreements were allegedly for redundant services and encouraged physicians to refer their patients to company's facilities.
- Cite:
<http://oig.hhs.gov/compliance/physician-education/03providers.asp>.

This is all bad!
So, what else is new?

Not everything is outlawed

- Drug and Medical-Device manufacturers paid \$6.5 billion to prescribers and hospitals in 2014
 - <http://www.wsj.com/articles/drug-and-medical-device-makers-paid-6-49-billion-to-doctors-hospitals-in-2014-1435694053>
 - <http://www.reuters.com/article/2015/06/30/usa-healthcare-payments-idUSL1N0ZG2Z920150630>
- In 2013, almost 1/3 of all sunshine reported general payment expenses were for royalty and licensure payments
 - <http://www.npr.org/sections/health-shots/2014/10/01/352978027/5-things-we-learned-from-new-database-of-payments-to-doctors>

Stock Options/Royalty Agreements

- Testimony before the Senate Special Committee on Aging, Gregory E. Demske, assistant inspector general for legal affairs
 - http://highline.huffingtonpost.com/miracleindustry/americas-most-admired-lawbreaker/assets/documents/8/demske_testimony_financial_ties.pdf.
- His testimony stated that interactions between manufacturers and health care professionals “can be especially valuable because physicians play an essential role in the development, testing, and extensive training involved in producing effective and safe medical devices...”
 - “Device companies can legitimately compensate physicians for their actual time and intellectual contributions to product innovations and training in the appropriate use of devices.”

So, What's the Issue?

- “[I]n an environment where physicians routinely receive substantial compensation from medical device companies through stock options, royalty agreements, consulting agreements, research grants, and fellowships, evidence suggests that there is a significant risk that such payments will improperly influence medical decision making.”
- Personal Services and Management Contract Safe Harbor
 - Stock Option and royalty arrangements would have to: (among other things)
 - ensure that the aggregate compensation paid is set in advance
 - consistent with fair market value
 - not determined by the volume or value of any referrals or business otherwise generated between the parties
- “We found that during the years 2002 through 2006, four manufacturers (which controlled almost 75 percent of the hip and knee replacement market) paid physician consultants over \$800 million under the terms of roughly 6,500 consulting agreements. Although many of these payments were for legitimate services, others were not.”

So, What's the Issue?

- ...Sometimes industry payments are not related to actual contributions, but instead are kickbacks designed to influence medical decision making
 - Key takeaways
 - FMV
 - When
 - How
 - Legitimate services

Analyzing Agreements

- Test the propriety of any proposed relationship by asking yourself the following questions:
 - Does the company really need the particular expertise or input?
 - Is the amount of money the company is offering fair, appropriate, and commercially reasonable for what it is asking to be done?
 - Is the compensation set and fixed?
 - <http://oig.hhs.gov/compliance/physician-education/04vendors.asp>

Lessons Learned

- Review all compensation arrangements not just novel arrangements
 - Just because it is novel, does not mean it is wrong
- Make sure the arrangements provide value and are based on legitimate services
- Obtain a Fair Market Value opinion
- Use exceptions wisely

QUESTIONS?

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