

HEALTH CARE REGULATORY COMPLIANCE

PERSONAL SERVICES ARRANGEMENTS WITH REFERRING PHYSICIANS

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As part of our Health Care Law practice, we are often asked to help structure or advise on the legality of various compensation arrangements between physicians and hospitals or other providers of health care items or services. Among these arrangements, there are medical directorship agreements, professional services agreements, independent contractor agreements, physician employment agreements and many others. The arrangements between referring physicians and the entities to which they refer present a host of health care regulatory compliance, business and legal issues and must be structured, or restructured, to comply with Federal and State laws and regulations, including Stark prohibitions on self-referrals, the Anti-Kickback Statute, and their State counterparts and prohibitions on fee splitting.

In August 2018, William Beaumont Hospital ("Beaumont"), a subsidiary of Beaumont Health, one of the largest hospital systems in Michigan, agreed to pay \$84.5 million, primarily to resolve allegations of improper financial relationships with eight referring physicians.¹ Among other things, the Beaumont settlement resolves allegations that between 2004 and 2012, Beaumont provided compensation substantially in excess of fair market value and free or below-fair market value office space and employees to certain physicians to secure their referrals of patients in violation of the

Anti-Kickback Statute and the Stark Act, and then submitted claims for services provided to these patients, in violation of the False Claims Act. We note that the claims resolved by this settlement are allegations only, and there has been no determination of liability. However, this settlement once again demonstrates that the Office of Inspector General and the Department of Justice are serious about the legality of these types of arrangements. Also, the physicians who were allegedly involved in these financial relationships are not parties to the Beaumont settlement, and it is possible that the Office of Inspector General and the Department of Justice may still pursue them.

This article provides an overview of the provisions of the Stark Act and the federal Anti-Kickback Statute, with emphasis on personal service compensation arrangements with referring physicians who are not employed by the entities to which they refer. The next article will address Stark and Anti-Kickback Statute issues related to leases of space and equipment.

1. STARK ACT AND ANTI-KICKBACK STATUTE

Under Stark Act, if a physician has a financial relationship with an entity, then the physician may not refer patients to that entity for designated health services ("DHS") and the entity may not bill for any DHS furnished pursuant to a prohibited referral.² DHS include,

among others, diagnostic testing services, physical therapy and occupational therapy services, DME, home health services, outpatient prescription drugs, and inpatient and outpatient hospital services.³ A financial relationship could be a direct or indirect ownership or investment interest in the entity that provides DHS; it could also be an arrangement involving any payment or other benefit between the physician and the entity.⁴

The federal Anti-Kickback Statute ("AKS") prohibits anyone (that is, health care providers and non-providers) to knowingly and willfully solicit, receive, offer or pay any remuneration (including any kickback, bribe or rebate) to induce or reward referrals or orders of items or services reimbursable by a federal healthcare program.⁵ It is a criminal statute which requires proof of intent to induce referrals through the payment of remuneration in one form or another. The AKS has been interpreted to cover any arrangement where one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals.⁶

There are many exceptions to the prohibitions of the Stark Act and the AKS, which allow certain arrangements with referring physicians.^{7,8} For purposes of Stark, if a physician has a financial relationship with a hospital, diagnostic testing facility or another DHS entity, the physician may refer patients to that entity for DHS only if the arrangement complies with an

applicable exception. The Stark Act imposes strict liability, meaning that an arrangement that does not meet all of the requirements of a relevant exception is illegal, regardless of whether the parties intended to violate the statute. For purposes of the AKS, although compliance with a safe harbor is not mandatory, if an arrangement complies with all of the elements of a safe harbor, such compliance creates a presumption that the parties are meeting the requirements of the AKS.

A. PERSONAL SERVICE ARRANGEMENTS AND FAIR MARKET VALUE COMPENSATION EXCEPTIONS TO STARK ACT

There are two exceptions to Stark that potentially apply to compensation for services performed by a non-employed referring physician: Personal Service Arrangements and Fair Market Value Compensation.⁹ Under the Personal Service Arrangement exception, a DHS entity may pay compensation for the referring physician's services if, among other things, the arrangement is for a term of at least one year, is set out in writing and signed by the parties, and specifies the services covered by the arrangement. Importantly, the aggregate services must be reasonable and necessary for the legitimate business purposes of the arrangement, and the compensation to be paid over the term of the arrangement must be set in advance, may not exceed fair market value ("FMV"), and may not be determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.¹⁰

The requirements of the Fair Market Value Compensation exception are substantially the same as those under the Personal Service Arrangements exception, except

that the arrangement may cover the provision of items or services, as opposed to just services, and the term of the agreement can be for any period of time, as opposed to a period of at least one year, provided that the parties enter into only one arrangement for the same items or services during the course of a year.¹¹

For purposes of these exceptions, FMV compensation is the compensation that would be included in bona fide service agreements with comparable terms at the time of the agreement between the parties, where the compensation has not been determined in any manner that takes into account the volume or value of anticipated or actual referrals.¹² Compensation is considered to be "set in advance" if the aggregate compensation, a time-based or per-unit of service-based amount (whether per-use or per-service, known as "per click"), or a specific formula for calculating the compensation is set out in writing before the furnishing of the items or services for which the compensation is to be paid. Per click compensation may not vary during the course of the arrangement in any manner that takes into account referrals of DHS or other business generated by the referring physician, including private pay health care business.¹³

B. PERSONAL SERVICES AND MANAGEMENT CONTRACTS SAFE HARBOR TO AKS

A Personal Services and Management Contracts safe harbor to the AKS also applies to compensation for referring physician's services.¹⁴ Most of the requirements of this safe harbor are substantially the same as those under the Personal Service Arrangements exception to Stark, with two notable deviations. If a

physician intends to provide the services on a periodic, sporadic or part-time basis, rather than on a full-time basis, the agreement must specify exactly the schedule of such intervals, their precise length, and the exact charge for such intervals. Also, the aggregate compensation paid to the physician over the term of the agreement must be set in advance, must be consistent with fair market value in arms-length transactions and may not be determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties. Importantly, this safe harbor does not protect any unit-based compensation (i.e., per procedure or "per click" payments) or compensation based on a formula (i.e., percentage of collections or billings).

Failure to comply with a safe harbor to the AKS is not a prima facie case of a violation, and payment practices that do not fully comply with a safe harbor may still be lawful if no purpose of the payment practice is to induce or reward referrals of Federal health care program business.¹⁵ Any AKS analysis requires consideration of the aggregate facts and circumstances in light of available federal guidance. The fact that a referring physician may receive remuneration from a hospital or another entity, by itself, may not violate the AKS in so far as the determinative element of any AKS violation is impermissible intent. Therefore, even though remuneration to a referring physician may not comply with a safe harbor, the arrangement is not necessarily unlawful if no payment or other remuneration is intended to induce or reward the physician's referrals or orders for services, and the parties implement appropriate safeguards.

2. FEDERAL AND MICHIGAN FALSE CLAIMS ACTS

Although this topic is outside the scope of this article, it is worth noting that a violation of the AKS or the Stark Act would render the claims submitted in violation of one or both of these statutes false or fraudulent, creating an overpayment obligation, as well as may result in liability under the federal False Claims Act which carries significant penalties. We also note that Michigan Health Care False Claim Act provides, in part, that a person who offers or pays a kickback or bribe in connection with the furnishing of goods or services for which payment is or may be made in whole or in part by a health care corporation or health care insurer, is guilty of a felony, punishable by imprisonment for not more than 4 years, or by a fine, or both.¹⁶ This Michigan statute applies to commercial insurers (i.e., HAP, Blue Cross Blue Shield, etc.) and Medicaid, and there are no statutory safe harbors to this statute. Also, under the Michigan physician licensing statute, any violation of the Stark Act or its implementing regulations by a physician may result in the loss of that physician's license.¹⁷

3. RECOMMENDATIONS

Potential "red flags" that a compensation arrangement with a referring physician does not comply with the applicable requirements could be any of the following:

- Total compensation exceeds FMV.
- Excluding pay for on-call services, directorships or other duties when evaluating total compensation.
- Payment for unnecessary services.
- Examining the value or volume of

past or future referrals when determining compensation.

- Lack of documentation supporting administrative or other services provided.
- Provision of space, equipment or personnel to a referring physician for free or below FMV.

The referring physicians and entities to which they refer should jointly implement safeguards to ensure that their compensation arrangements not only make business sense, but also comply with the applicable health care regulatory compliance requirements. We recommend the following:

- Prior to entering into any compensation arrangement with a referring physician, obtain an independent third-party FMV valuation, which must include sufficient supporting documentation and explanation of the methodology behind the valuation.
- Retain internal documentation to support the FMV nature of the compensation, which should include the manner in which the compensation was determined, the surveys utilized and whether a FMV opinion was sought, as well as an analysis and record of why the physician's services are reasonably necessary.
- All compensation arrangements must be in writing.
- Compile a list of all personal services (and other) arrangements between referring physicians and entities, and reconcile payments to specific physician contracts.
- Physicians must timely complete time sheets and other documentation of services rendered, and health care entities should review this documentation for completeness and accuracy.
- Examine for legal compliance, and restructure where necessary, any formula, percentage-based or

"per click" compensation arrangements.

- For arrangements that extend for more than one year, re-evaluate on an annual basis whether the compensation to a referring physician still represents FMV.
- For any part-time arrangements, make sure the agreement specifies the schedule when the services will be provided.
- Be wary of requesting or offering a change in compensation or compensation structure during the term of the arrangement based on the value or volume of past or anticipated future referrals.
- Physicians should use their own legal counsel who is knowledgeable in health care regulatory compliance issues.

THIS ARTICLE IS FOR EDUCATIONAL PURPOSES ONLY AND SHOULD NOT BE INTERPRETED OR RELIED UPON AS LEGAL ADVICE. EACH ARRANGEMENT IS UNIQUE AND SHOULD BE REVIEWED WITH THE ASSISTANCE OF COMPETENT PROFESSIONALS.

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1 <https://www.justice.gov/opa/pr/detroit-area-hospital-system-pay-845-million-settle-false-claims-act-allegations-arising>;
The claims resolved by the settlement are allegations only, and there has been no determination of liability.

2 42 U.S.C. §1395nn(a)(1)

3 42 C.F.R. §411.351

4 42 C.F.R. §411.354(a)

5 42 U.S.C. §1320a-7b(b); The terms “recommending” and “arranging” are not defined in the AKS or its implementing regulations.

6 *United States v. Kats*, 871 F.2d 105 (9th Cir. 1989), emphasis added

7 Exceptions to Stark Act: 42 C.F.R. §§411.355, 411.356, 411.357

8 Safe harbors to the AKS: 42 U.S.C. §1395nn(b) - (e)

9 42 C.F.R. §411.357(d), (l)

10 42 C.F.R. §411.357(d)

11 42 C.F.R. § 411.357(l)

12 42 C.F.R. §411.351

13 42 C.F.R. §411.354(g)

14 42 C.F.R. §1001.952(d)

15 64 F.R. 63519

16 M.C.L. §752.1004

17 M.C.L. §333.16221(e)(iv)(B)