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PHYSICIAN INVESTMENT COMPLIANCE

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INTRODUCTION

Many physicians are tempted to develop income from ancillary services. While there are many different models available, most share the common feature that physicians are offered an investment opportunity, either directly in an ancillary services provider like a pharmacy, toxicology lab, or surgical implant company, or, alternatively, in a management services organization (MSO) that services ancillary services providers. This article identifies some common pitfalls of such opportunities and

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is a former Assistant United States Attorney (AUSA). In that capacity as a federal prosecutor, Ms. Byrd prosecuted a great variety of healthcare matters on behalf of the United States including are providers and business owners in complex civil and criminal healthcare investigations.

Laws Regulating Physician Investments

There are two federal statutes that govern business relationships between physicians and non-physicians.

The Anti-Kickback Statute (AKS)
is a criminal law that prohibits payments intended to influence (i) the referral of an individual for an item or service for which payment may be made by a federal health care program or (ii) the purchase, lease, order, or arrangement for or recommendation to purchase, lease, or order any good, facility, service, or item for which payment may be made by a federal health care program. *See* 42 U.S.C. § 1320a-7b(b). The AKS is an intent-based statute so conviction requires evidence showing that the payments for referrals were knowing or willful. But the prevailing standard is that a person (including non-providers) can violate the AKS if just "one purpose" of the arrangement is to induce referrals for services or purchasing of items payable by a federal health care program. *See, e.g., United States v. Greber*, 760 F.2d 68, 72 (3d Cir. 1985), *cert. denied*, 474 U.S. 988 (1985). If an arrangement has several purposes, but one of them is illicit, the AKS is implicated. As a result, the one purpose standard sets a relatively low bar that can be especially problematic in the case of investment arrangements. However, The AKS's broad reach is limited somewhat by a number of safe harbors that can protect an arrangement that otherwise would fall within the purview of the AKS. Compliance with a safe harbor is not mandatory and an arrangement that does not meet the requirements of the safe harbors will be analyzed on a case-by-case basis. But safe harbors serve an important purpose by providing physicians and other healthcare providers with certainty and security and insulating them from nebulous intent analysis.

The Ethics in Patient Referrals Act (Stark Law)
prohibits physicians from referring designated health services (DHS) reimbursable by Medicare and Medicaid to entities with which they have a financial relationship, subject to certain exceptions. *See* 42 U.S.C. § 1395nn(a)(1). DHS includes, among others, inpatient and outpatient hospital services. *See* 42 U.S.C. § 1395nn(h)(6). In this context, a financial relationship includes both a direct or indirect compensation arrangement. *See* 42 U.S.C. § 1395nn(a)(2), (h)(1). Like the AKS, the Stark Law has exceptions that can protect an arrangement from violating the law. But unlike the AKS, the Stark Law is a strict liability statute, which means that if an arrangement is subject to Stark Law and that arrangement does not satisfy a recognized exception, the arrangement will be considered illegal—regardless as to the parties' intent.

THE ANTI-KICKBACK STATUTE SMALL INVESTOR SAFE HARBOR

The most relevant AKS safe harbor for physician investment opportunities is the safe harbor for small investments that are not publicly traded. See 42 C.F.R. § 1001.952. This safe harbor requires:

(i) No more than forty percent physician ownership;

(ii) Investment terms to non-physicians are the same as to physicians;

(iii) Investment terms to physicians are not influenced by expected referral volume;

(iv) Investors are not required to refer in order to keep their interest;

(v) The entity's goods or services must be marketed and provided to investors in the same way they are marketed and provided to non-investors;

(vi) No more than forty percent of the entity's revenue comes from investor referrals;

(vii) The entity cannot loan (or otherwise provide) the physician the funds to obtain the investment interest; and

(viii) The returns must be determined by the amount of the capital contribution.

It is important to recognize that there is no comparable exception for the Stark Law. Even if an arrangement satisfies the eight factors of the AKS safe harbor, it must still be compliant with the Stark Law. Because there is no comparable Stark Law exception, most physician-owned ancillary services providers do not take federal funds in order to avoid violation of the Stark Law.

THE OIG'S POSITION

The Office of the Inspector General (OIG) has issued a special fraud alert and advisory opinions on physician-owned entities (POE). Its fraud alert, available at http://oig.hhs.gov/fraud/docs/alertsandbulletins/2013/POE_Special_Fraud_Alert.pdf,expresses concerns regarding POE arrangements that: (1) select investors in a position to generate business for the entity; (2) require investors who cease practicing in the service area to divest; (3) distribute extraordinary returns; (4) include few physician owners so referrals closely correlate to the return; (5) result in physician owners altering their referral patterns; and (6) have only physician owners as users of the items or services.

In the special fraud alert, the OIG also identified certain "suspect characteristics" of POEs, including: (1) investment size or distribution amount varies with the volume/value the investor's referrals; (2) investors are coerced, encouraged, or required to refer or promised benefits if they refer; (3) the POE can repurchase shares for failure to refer; (4) the company is a shell entity and does not oversee distribution functions; and (5) the POE and investors fail to disclose ownership when requested.

Although the OIG stated that an unlawful arrangement may not necessarily exhibit any of the characteristics above, minimizing these identified factors likely reduces the risk involved. And physicians should be wary opportunities that exhibit multiple features listed above.

COMPLIANCE RECOMMENDATIONS

Physicians who want to invest in a healthcare entity should be proactive in assuring that the investment they are making is compliant. Many offerings are not, and the consequences of entering a non-compliant agreement can be catastrophic. The following are a few steps that any physician should take before making an investment in a healthcare company:

- **Retain an attorney to review the arrangement.** The laws and regulations surrounding physician investment are complex and mistakes can be very costly. Your attorney will help you take the following steps and make sure you are making an informed decision.
- **Understand the ownership**. Make sure that at least sixty percent of the POE will be owned by non-physicians.
- **Understand how and why the POE will receive revenue**. A major compliance concern with many POEs (particularly those that are related to an ancillary service provider, but are not the provider itself) is whether the payments the entity receives are legitimate and fair market value. Make sure the POE has appropriate fair market valuations, and make sure that at least sixty percent of revenue will come from non-invested physician referrals.
- **Confirm that the POE provides real services**. Sometimes, POEs provide the right services for the right price on paper, but in fact subcontract every service to a third-party (or otherwise do not provide the services) and are just a shell to make payments to physicians.
- **Make sure that distributions are for ownership based on capital contribution not for referrals.** Too often, when physicians are approached with investment opportunities, the discussion immediately turns to referral volume and capital contributions are an afterthought. Compliant distributions are for your capital contribution, not your referrals.

- **Ensure that the POE does not accept federal reimbursement.** The Stark Law does not have a small investment safe harbor. POEs that accept federal reimbursement are very often out of compliance with federal law.
- **Ask about the POE's repurchase rights.** A POE's ability to repurchase your investment for failure to refer is a red flag.
- **Make sure you get copies of the executed documents.** Some unscrupulous owners intentionally fail to provide physician investors with finalized documents. Then, if the physician fails to refer, the lack of documentation is used as leverage to terminate the relationship and potentially to ask for repayment of past distributions. Failure to provide the documents may also be an indication that the POE owners know there is something wrong with the arrangement.
- **Don't let your investment affect your independent medical judgment.** Do not over-utilize, and do not make drastic changes in your referral patterns that are inconsistent your medical judgment.
- **Disclose your investment interest when asked and whenever required by state or federal law.**

FIND OUT MORE

Oberheiden & McMurrey is a healthcare defense firm with significant experience in the areas of regulatory compliance, corporate structuring, litigation, government investigations, and criminal defense. Among our attorneys are the former Chief Health Care Fraud Coordinator at the U.S. Attorney's Office, former senior Department of Justice trial attorneys, former lead prosecutors of the elite Medicare Fraud Strike Force, and other talented attorneys with years of relevant experience and education from the country's leading schools such as Harvard Law School and Yale Law School.

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