

How to Handle Stark and Anti-Kickback Legal Barriers When Physicians Invest in an MSO

September 22, 2018
By Michael H. Cohen

This is a story about how Harry, a healthcare entrepreneur, worked through a proposed arrangement that was raising Stark and Anti-Kickback issues.

Chapter 1. Harry the Healthcare Entrepreneur Confronts the Stark and Kickback Puzzle

Joe, a savvy healthcare entrepreneur, has some wealthy medical doctors “lined up” to purchase investment interests in an LLC that will serve as a management company (or medical services organization, MSO, for a professional medical corporation (PMC) or medical group.

The LLC has a complex structure where it is going to be 50% owned by the doctors and 50% owned by Harry.

Harry proposes that the MSO operate as a typical MSO, providing management and marketing services at fair market value to physicians and professional medical corporations that operate medical groups.

CORPORATE PRACTICE OF MEDICINE ON STEROIDS: HOW YOUR MSO AND PROFESSIONAL MEDICAL CORPORATION COULD WORK TOGETHER WITHOUT COURTING LEGAL DISASTER

You, MSO is my own variation on I Claudius. Poor Uncle Claudius, everyone said. Ended up becoming Emperor of Rome. Through craft and careful strategy. So you have an MSO and want to operate [...]

Harry also has a number of ‘bells and whistles’ to his proposal. He is going to put a whole bunch of other entities into the mix.

Joe has an outside, diagnostic testing lab that supplies the physicians with urine collection kits, blood collection kits, and other medical supplies. The doctors will collect samples and send them to the lab for analysis. The lab also has some equipment it wants to lease to the physician practices.

The medical doctors will bill insurers for performing the screens and tests that are done within the medical groups. The labs will bill separately

Through some complicated financial scheme, the lab ends up paying the MSO a share of monies it receives from insurance, and this has something to do with the fact that the lab has sales reps on-site all the time at the medical groups.

Harry wants to be “100 compliant,” yet, he also wants to make a ton of money, and sign up the doctors while he still has their

interest (as he recently sold them on this idea at a black-tie cocktail party).

Chapter 2. Harry Gets some Stark and Anti-Kickback Legal Advice

The first thing to notice is that we've spotted an oxymoron, and it isn't "military intelligence."

Harry's concern with the potentially vanishing sales prospects from the cocktail part notwithstanding, we think Harry doeth protest too much. He really does not want to be "100% compliant." He wants to make a lot of money. If he is going to be 100% compliant then he should probably go into another business, like retail sales. There isn't too much the government can do if you simply tell someone this shirt looks great on him (or her) when trying to sell them for the store.

Also, the federal and state authorities that enforce legal prohibitions against self-referral and kickbacks / fee-splitting, don't think or act in terms of percentages of compliance. The closest they will to this is an OIG Advisory Opinion on fraud and abuse which might say that a proposed arrangement presents a risk of fraud and abuse, but has significant safeguards, such that it is unlikely that the government will initiate enforcement action.

Therefore typically, we look at the risk presented and whether we can build in some reasonable safeguards as a way to mitigate potential enforcement risk.

We hope Harry is open to the advice. First, though, Harry needs to know a lot more about what he's getting into.

Chapter 3. Harry Digs into Stark and Anti-Kickback Analysis

Can the physicians collectively own 50% in the MSO? Harry asks point-blank. He told them, at the cocktail party, that they could – he would place a call to his healthcare lawyer to double-check.

From an anti-kickback perspective, there is a safe harbor for a straight, passive investment in an entity.

Under 42 CFR 1001.952(a)(2), a safe harbor exists if the entity possesses investment interests that are held by either active or passive investors.

All of the following 8 standards must be met:

- (i) No more than 40 percent of the value of the investment interests of each class of investment interests may be held in the previous fiscal year or previous 12 month period by investors who are in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity. Equivalent classes of equity investments may be combined, and equivalent classes of debt instruments may be combined.
- (ii) The terms on which an investment interest is offered to a passive investor, if any, who is in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity must be no different from the terms offered to other passive investors.
- (iii) The terms on which an investment interest is offered to an investor who is in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity must not be related to the previous or expected volume of referrals, items or services furnished, or the amount of business otherwise generated from that investor to the entity.
- (iv) There is no requirement that a passive investor, if any, make referrals to, be in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity as a condition for remaining as an investor.
- (v) The entity or any investor must not market or furnish the entity's items or services (or those of another entity as part of a

cross referral agreement) to passive investors differently than to non- investors.

(vi) No more than 40 percent of the entity's gross revenue related to the furnishing of health care items and services in the previous fiscal year or previous 12-month period may come from referrals or business otherwise generated from investors.

(vii) The entity or any investor (or other individual or entity acting on behalf of the entity or any investor in the entity) must not loan funds to or guarantee a loan for an investor who is in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity if the investor uses any part of such loan to obtain the investment interest.

(viii) The amount of payment to an investor in return for the investment interest must be directly proportional to the amount of the capital investment (including the fair market value of any pre-operational services rendered) of that investor.

Harry is excited by this anti-kickback safe harbor. However, we've barely begun the analysis. There are other anti-, anti-kickback safeguards we would want to put in.

And, there are many parts of the arrangement Harry has put together that we will not review—for example, the whole idea of making money from the lab and the tie-in between the physicians, the lab, and the MSO. (Warning, Will Robinson!)

Among other things, there are dangers inherent in paying anything other than a flat fee for marketing services. And the tie-in between the lab, the supplies, the doctors, and the MSO raises a lot of issues.

Here are some other brief considerations, basics Harry will want to know about:

- If no Medicare (or other federal healthcare) reimbursement is involved, then federal law will not apply. Technically speaking, this means that we are not looking at Stark which is federal self-referral law, and not looking at the federal anti-kickback statute (AKS).
- However, federal law is worth review as it may be persuasive to state authorities. Thus, we might look at OIG opinions.
- There is an issue of cross-referrals among the physicians who are investors in the MSO. These could potentially trigger fraud and abuse consideration. We can deal with this later, but first, let's lay out some more background Harry should understand.
- One thing Harry should consider is that self-referral law often is, like Stark, black and white. In other words, it is what we call a strict liability statute. Intent is not required.

Under Stark, either you meet an exception or not. Whereas, in contrast, the anti-kickback statute is intent-based. And failing to meet the safe harbor does not in itself create liability.

Chapter 4. Harry learns more about Stark than he wanted to know

Let's step back to get a more birds'-eye view of Stark. Stark, the federal self-referral law, prohibits physicians from ordering "designated health services" (DHS) for Medicare and Medicaid patients from entities with which the physician (or an immediate family member) has a "financial relationship."

KICKBACKS, FEE-SPLITTING, CORPORATE PRACTICE OF MEDICINE, STARK, MSOS: GUIDING HEALTHCARE VENTURES THROUGH THE MAZE

Fundamentally, you're worried about legal rules prohibiting kickbacks, fee-splitting, corporate practice of medicine, as well as Stark law; you don't know whether the MSO or management structure [...]

CAN AN MSO CONTROL PHYSICIANS GIVEN CORPORATE PRACTICE OF MEDICINE?

Can a medical management company or MSO control physicians given corporate of medicine concerns, especially in a strong corporate practice of medicine state? Whether the MSO can control [...]

The term, “financial relationship” includes both compensation arrangements, and investment and ownership interests.” The term “referral” under the Stark Law is defined more broadly than merely recommending a vendor of designated health services (DHS) to a patient. Instead, the term “referral” means, for Medicare Part B services, “the request by a physician for the item or service” and, for all other Medicare and Medicaid services, “the request or establishment of a plan of care by a physician which includes the provision” of the DHS.

DHS includes, among other things, clinical laboratory services, which makes it relevant to what Harry is trying to put together.

Stark contains several exceptions. The exceptions that are typically relied upon by physicians and MSOs include:

- Physician Services.
- In-Office Ancillary Services (IOAS).
- Rental of Office Space and Equipment.
- Bona fide Employment Relationships.
- Personal Services Arrangements.
- Payments for Items and Services.
- Fair Market Value.
- Indirect Compensation.

However, **Stark does not have an exception for investments in group practices.**

This is an important limitation, because Stark expanded the definition of the performing “entity” to go beyond the entity in whose name bills were submitted to Medicare (the billing)—i.e., to include also the entity performing the services (i.e., the MSO can be deemed the performing entity under Stark). This complicates things. There is no in-office ancillary services (IOAS) exception available where the performing entity is the MSO, because the physicians do not provide services in the name of the MSO. All the physicians are essentially referring to one another, and financially benefitting from these referrals, by virtue of their equity interest in the MSO.

So that knocks out the investment in group practices exception.

As mentioned above, though, Stark has an “indirect compensation arrangement” exception where the compensation meets certain requirements, including that it is at fair market value, in writing, and does not violate the anti-kickback statute.42 CFR 411.357(p).

However, a physician “stands in the shoes” of his or her physician organization for purposes of determining the physician’s compensation arrangements, and thus has a “direct” compensation arrangement with the entity receiving the referral (i.e., this means that the physician does not meet the indirect exception).

And a physician is “a physician (including a professional corporation of which the physician is the sole owner), a physician practice, or a group practice that satisfies the Stark ‘group practice’ definition.”

When determining whether a direct or indirect compensation arrangement exists between a referring physician and a DHS entity, the referring physician would stand in the shoes of: (1) another physician employing the referring physician, (2) the physician’s wholly owned professional corporation, (3) a medical practice that employs or contracts with the referring

physician, or (4) a group practice of which the referring physician is a member or independent contractor.

While an MSO may or may not technically be subject to these rules (i.e., a physician may not necessarily “stand in the shoes” of the MSO contracting with a lab), CMS has stated that such arrangements “may involve illegal kickbacks” even if not within Stark.72 Fed. Reg. at 51030.

Also to consider, a “referral” under Stark includes a request for an item or service by the physician. Thus, when the physician orders a lab test, the physician has made a “referral.” If the physician has an ownership interest in the MSO, then the physician is receiving compensation from the referral. At the least, this triggers anti-kickback review. There is no corresponding anti-kickback safe harbor to the Stark indirect compensation exception. As well, there is no Stark exception comparable to the safe harbor available under anti-kickback statute (AKS) for certain investment interests.

Harry is starting to understand that it’s a bad idea to make promises at cocktail parties about complicated schemes or thinking that his lawyer has some magical “workaround” to these nuanced legal prohibitions. He doesn’t necessarily have to wade through every exception nested within an exception to an exception to a rule; but he must learn enough of the nuances to know that isn’t necessarily to get a green light simply by pulling the right lever.

Stark and self-referral law have many nuanced exceptions and anti-kickback and fee-splitting rules have many potential safe harbors. While an MSO provides an established legal vehicle to accomplish many revenue-producing goals for non-physician healthcare entrepreneurs, throwing physician investment and lab-related fees into the mix can complicate matters. [Contact](#) an experienced healthcare lawyer for legal advice relevant to complex proposed compensation arrangements involving physicians or physician investors.



[Contact](#) our [healthcare law](#) and [FDA attorneys](#) for legal advice relevant to your healthcare venture.