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ARE PHYSICIAN MSOs LEGAL?

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A recent trend in structuring ancillary services transactions is the use of physician owned MSOs ("P-MSO"). This article— co-written by former federal prosecutors in charge of civil and criminal healthcare investigations at the Department of Justice— explains:

- Many of the current MSOs in use may not withstand law enforcement scrutiny.
- Physicians and healthcare executives using non-compliant MSOs may become subject to investigation.
- Compliant MSOs can be created by carefully ensuring the legal criteria outlined herein are met.

ABOUT THE AUTHORS

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has successfully represented physicians and healthcare executives in investigations before the Office of Inspector General (OIG), the Department of Defense (DOD), the Department of Justice (DOJ), the Department of Labor (DOL), the Department of Health and Human Services (DHS), the U.S. Postal Inspection Service (USPIS), the IRS, the FBI, the DEA, and the U.S. Secret Service.

THE IDEA BEHIND P-MSOS

P-MSOs are used primarily to mitigate the restrictions imposed by physician self-referral laws. Proponents argue that because physicians do not own the pharmacy or toxicology laboratory to which they refer business, their referrals are immune from Stark Law and more well protected against anti-kickback allegations. However, that view appears problematic in the sample MSOs reviewed by the authors. In many of these MSOs, the service fee does not reflect fair market value and the company itself is not in legal compliance. In such situations, all P-MSO participants should be on alert that distributions could be considered illegal kickbacks.

LACKING COMPLIANCE

Those P-MSOs reviewed cloud their operating agreements in an air of legality and artificial emphasis of regulatory compliance. A closer look reveals that references to safe harbors (such as a 40%-60% structure) or compliance efforts appear to be designed to merely create peace of mind. Participants should make sure that offered documents do not contain certain common flaws. For example, even though MSOs are by their very name "Management Services Organizations," in many cases, the physicians are not providing any tangible services to the MSO and have not been involved in its corporate affairs. Physicians who are merely passive investors are not making meaningful contributions to the MSO, which could cause investigation and liability for taking distributions.

Similarly, to be in compliance with federal law, MSOs must maintain completely separate ownership and management from their contracting pharmacies or laboratories. It is not sufficient to claim arms-length transactions and the observance of corporate formalities when those requirements only exist on paper, and not in real life. Government agencies who investigate MSOs will also expect that the P-MSO and the affiliated companies be represented by different law firms to ensure both independence and arms' length negotiation of service fees.

The method of determining compensation is also subject to close scrutiny by the federal government. A common flaw in this are that often draws anti-kickback scrutiny and has led to several fraud alerts from the OIG is a P-MSO that receives compensation from affiliated companies based on a per-referral, per-prescription, or percentage of revenue basis. Additionally, P-MSO service fees must be determined in accordance with fair market value. It is insufficient to merely claim in the operating agreements that service fees reflect market value. In most samples we reviewed, the service fees are astronomical and lack any legal foundation. To be safe, fees should be calculated objectively and reviewed by reputable third-party CPAs. Fees that are not based on fair market value and thus are not commercially reasonable are a classic red flag for the Department of Justice in kickback assessments. Vague references to safe harbors and 40%/60% ownership structures do nothing to decrease the risk of investigation if the fair market analysis fails.

CARVING OUT FEDERAL PATIENTS IS NO SOLUTION

In many cases, P-MSOs carve out federally funded business in an attempt to avoid federal scrutiny. However, contrary to common belief, the exclusion of patients covered by federal health care programs does not preclude federal law enforcement review and intervention. The following is an abbreviated enumeration of possible grounds for federal jurisdiction—despite federal patient carve-outs.

- ***SEC Violations.*** P-MSOs are typically offered through private placement memoranda or PPMs, which qualify them as securities. However, many fail to register with the Securities and Exchange Commission or give proper notice of Form D filings. In these cases, the P-MSO is subject to federal law – and violating it.

- ***DEA Jurisdiction.*** The Controlled Substances Act is a federal statute administered by the Office of Diversion Control, the Department of Justice, and the Drug Enforcement Administration. A DEA audit under this law may require pharmacy owners to disclose relevant corporate documents, including physician consulting agreements, marketing agreements, and documentation of MSO relationships to federal authorities.

- ***Secondary Coverage.*** Our firm has represented several laboratories and pharmacies that do not accept federally funded patients, yet found themselves subject to investigations and prosecutions by the Office of the Inspector General because of secondary or supplemental Medicare or Tricare plans that were processed accidentally.

- ***Mail & Wire Fraud.*** When questionable distribution checks are sent by mail, P-MSO management may be committing mail fraud, a federal felony under 18 U.S.C. § 1341. By submitting erroneous bills electronically, the MSO management may be committing wire fraud, a federal felony under 18 U.S.C. § 1343. Recent indictments have shown the use of mail and wire fraud as a basis of federal jurisdiction in otherwise non-federal healthcare prosecutions.

- ***CLIA & DEA & Medicare License.*** Physicians hold DEA licenses, making them subject to federal law. Similarly, the affiliated pharmacy or toxicology laboratory may have obtained a Medicare or Tricare number and a CLIA license issued by the Centers for Medicare and Medicaid, a federal agency, giving federal prosecutors jurisdiction over their businesses.

- ***Interstate Commerce.*** The MSO or the pharmacy or laboratory may be accepting business from more than one state. If so, they are engaging in interstate commerce, which creates jurisdiction for federal authorities. The same rationale applies to commercial insurance carriers that are located out of state.

We believe that the physician's exposure from participating in a P-MSO can be substantial. The monetary volume generated by P-MSOs and affiliated ancillary services make P-MSOs attractive targets for FBI and OIG agents. Deviations from legal standards as grave as noticed in some of the reviewed documents could trigger civil or criminal prosecutions or medical board actions against participants. Depending on the structure, executives and physicians could be subject to False Claims Act, Stark Law, and kickback investigations. To minimize their exposure, participants should request the following documentation and compliance certifications.

1. Documentation of an independent fair market value analysis that was issued prior to the PPM release and that concluded that the service fee between the MSO and affiliated entity (e.g. pharmacy, lab, implant company) reflects fair market value.

2. Detailed documentation of the MSO's past and ongoing efforts to meet each element of the safe harbor upon which it relies.

3. Documentation that proves that the syndicated MSO was registered with the SEC at the time of its formation.

4. Documentation of steps that demonstrate the company's intent to comply with state and federal law.

5. Documentation of all shareholder meetings conducted according to the MSO company agreement, including minutes and attendees.

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QUESTIONS?

Healthcare fraud is investigated by the Office of Inspector General (OIG), the Department for Health and Human Services (HHS), the Department of Justice (DOJ), and the Federal Bureau of Investigation (FBI). If you are part of an MSO or considering joining or establishing a physician-owned MSO, you should take appropriate precautions to avoid future liability. The former Department of Justice healthcare prosecutors and experienced attorneys of the Oberheiden P.C advise business owners, healthcare executives, and medical providers across the United States on regulatory compliance. We are ready to do the same for you.