

Compliance Flash



Topic: Physician Owned Distributorship July 2022

What is a Physician Owned Distributorship?

Also known as PODs, these are physician owned entities that obtain revenue by selling or arranging for the sale of implantable medical devices ordered and used by the physician owners in the performance of surgery on their own patients.

How may PODs implicate the Federal Anti-Kickback Statute?

When a referring physician earns profit through their investment in the entity for which he or she generates business, this could constitute illegal remuneration under the Anti-Kickback Statute. The anti-kickback statute is violated if even one purpose of the remuneration is to induce referrals.

What is the cost of non-compliance?

[Reliance Medical Systems LLC](#), a distributor of spinal implant devices, its owners and two physician-owned distributorships agreed to pay \$1 million to resolve violations of the Anti-Kickback Statute and False Claims Act. This is in addition to previous civil recovery of over \$9.25 million.

Can a POD not violate the Federal Anti-Kickback Statute?

Maybe. The U.S. Department of Health and Human Services Office of the Inspector General (OIG) recently issued its first favorable analysis of a POD medical device company. [OIG Advisory Opinion No. 22-07](#)

Concerns

Government Concerns:

- Potential for Improper Inducement
- Illegal Remuneration
- Risk of Fraud and Abuse
- Corruption of Medical Judgment
- Patient Safety
- Medical Necessity & Overutilization
- Increased Cost to the Federal Health Care Program and Beneficiaries
- Unfair competition

Questionable Features of PODs?

- Selecting investors based on their position to generate business for the entity.
- Requiring investors to divest their ownership for failure to refer.
- Paying returns on investment that are not in proportion to ownership interest.
- Size of investment offered to each provider varies with expected or actual volume or value of the devices used.

For more information, please review the

- [OIG Special Fraud Alert: Physician Owned Entities](#)

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