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## Dept. of Justice scrutiny of physician-owned distributorships: Implications for physician investors

--By Matthew Fornataro, Arnold & Porter LLP

In a development that many predicted, federal authorities recently initiated what is likely to be the first of many investigations into a physician-owned distributorship (POD). PODs sell devices for use in procedures at hospitals and ASCs, and many focus on implantable devices, including orthopedic and cardiac devices. A POD's physician-owners or investors typically perform procedures using devices sold by the POD to a limited number of hospitals or surgical facilities. The medical community has seen a rapid growth in PODs during the past several years, and these entities are reportedly operating in more than half of the states as either traditional distributors or as group purchasing organizations.

### Government puts PODs on notice

PODs have come under increasing scrutiny in recent years at both the state and federal levels. Proponents of PODs assert that the entities can negotiate better pricing and reduce costs for hospitals, however, the government has always taken the position that PODs are inherently suspect under the federal anti-kickback statute (AKS).

For example, the Senate Finance Committee issued a [report](#) in June 2011 that concluded that PODs "create financial incentives for physician investors to use those devices that give them the greatest financial return." More pointedly, the Department of Health and Human Services Office of Inspector General (OIG) issued a [Special Fraud Alert](#) in March 2013 indicating that PODs pose a "substantial fraud and abuse risk" and that such entities are "inherently suspect" under the AKS. The OIG indicated that PODs incentivize the corruption of medical judgment, overutilization of products and services, increased costs to the federal health care programs, and unfair competition. Several states, including California, are considering or have passed legislation aimed at curbing the reach and operation of PODs.

### DOJ pursues enforcement

Although the government's suspicions about PODs are well-documented, proceedings currently underway in Michigan demonstrate that the DOJ is willing to pursue enforcement. Specifically, the DOJ went to court in February 2014 to enforce a civil investigative demand (CID) seeking documents relating to financial relationships between a neurosurgeon and Apex Medical Technologies, a subsidiary of Reliance Medical Systems.

The government's inquiry appears to be focused on whether the physician's investment in Apex resulted in his performing unnecessary procedures using Reliance products. Specifically, the DOJ's [February filing](#) to enforce its CID stated that the physician "made a \$5,000 initial 'investment' [in Apex] and started using Reliance implants on his patients" at the same time. The DOJ then asserted that Reliance paid the physician-investor more than \$30,000 per month in return and that the "rates at which [he] performed

surgeries that involve implanted spinal devices ... increased dramatically ... ” The DOJ noted, for example, that the physician’s use of one Reliance product on Medicare patients increased more than 400% during the time he had a financial relationship with Apex.

### **Compliance Considerations for POD Investors**

Given the recent government guidance on PODs, physicians with existing POD relationships, or those considering entering into similar arrangements, should proceed with caution. Current POD owners or investors should review their entity’s organization and operation for compliance with OIG’s guidance. For example, arrangements with a limited number of investors who perform procedures using the products distributed by the POD may be a red flag for government investigators. The government also will view relationships that provide physician-investors with a generous return on investment in exchange for a minimal financial risk as inherently suspect. Since POD owners and investors may need to restructure or unwind existing relationships to mitigate any risks of kickback liability, physicians who are active in this space should engage qualified legal counsel to help work through this complicated process.

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