U.S. Department of Justice Files False Claims Action Against 3 PODs and Physician Investors for Physician and Hospital Claims

On September 8, 2014, the U.S. Department of Justice (DOJ) filed a False Claims Act (FCA) case in the Central District of California against Reliance Medical Systems, two related distributors (Apex Medical Technologies and Kronos Spinal Technologies), and several of their physician owners, based on the theory that investment returns from these physician-owned distributors (PODs) were unlawful kickbacks.

As reported in previous Ropes & Gray alerts, DOJ has been investigating Reliance and its financial relationships with investor physicians. *This new filing is significant, however, in that it represents the first time that POD investigations have led the government to file its own FCA lawsuit based on the theory that the offer to a physician of a chance to receive a financial benefit through ownership in a POD from which the physician orders implants is an unlawful kickback.*

Of special note, the government's claims that this investment opportunity constitutes a kickback are based in part on the following factual allegations in the Complaint, which track the indicia of "inherently suspect" features of PODs recognized in the U.S. Department of Health and Human Services Office of Inspector General's 2013 Special Fraud Alert on PODs:

- Kickbacks Result from Investment Opportunity and Referral. The kickbacks resulted from "offering investment opportunities in [the PODs] to physicians who agreed to use [POD] implants in their surgeries" (¶ 98);
- Choice of Investors. POD offers investment interests only or primarily to physicians who are expected to order or recommend implants sold by the POD (¶¶ 138–155);
- Investors = Customer Base. The POD exclusively or primarily serves its physician-owners' patient base (¶ 106);
- Shift in Implant Choices Coincides with Ownership. POD physician-owners shift to the POD's products on a primary or exclusive basis in connection with joining the POD (¶¶ 121–124);
- "Coercing" Hospitals. POD physician-owners condition their referrals to hospitals/ambulatory surgical centers on their purchase of implants from the POD by coercion (stating or implying that otherwise they will take their business elsewhere) or promises (stating or implying that they might refer more if the hospital does buy from the POD) (¶¶ 203–208);
- Investment Return Correlates with Referrals. Investor-physicians are few enough in number that the volume or value of a physician's own referrals correlates closely to investment return (¶¶ 111–112);
- Investment Return is based on Volume or Value of referrals when the Profits of the Business are from the Investor Physicians' Collective Referrals. The kickbacks were based on the volume or value of referrals from the investor doctors because the returns paid to physicians were based on profits generated from the owners' collective referrals (¶¶ 111–112, 119–120);

The government also relies on the extensive regulatory guidance given by OIG over the years, beginning with the 1989 Special Fraud Alert on Joint Venture Arrangements, proceeding through the safe harbor for investment interests, and concluding with the 2013 Special Fraud Alert, as evidence of the defendants' knowing and willful violations of the law (¶¶ 65–80).

In addition, factors that are often cited by POD proponents as evidence in favor of PODs' legitimacy are cited in the Complaint as further evidence of illegality. For example, the fact the PODs bought and re-sold the products ordered by their owners, as opposed to simply receiving a commission, is regarded not as an indication that the POD is "ethically" assuming the risks incident to product ownership, but as evidence that

the scope of the kickback included the "substantial markup" (¶ 84). Moreover, the fact that the PODs held the FDA 510(k) clearance for the implantable products that they sold is seen as evidence that the products in question were simply "knock-offs," indistinguishable from other products commercially available (¶¶ 82, 87, 89–90).

Simultaneously, DOJ intervened in a *qui tam* FCA suit against Dr. Aria Sabit, against whom the government had issued a civil investigative demand in February 2014. That the government also chose to file a separate lawsuit against the other POD owners and principals demonstrates that its enforcement interests extend to the ordinary business structure of PODs, and are not limited to the special circumstances of any one physician.

The Complaint also alleges that the hospital claims filed pursuant to the POD induced referrals are also false claims (¶¶ 304, 309, 312). In this case, as the Complaint points out, the ownership interests of the physicians were concealed, (¶¶ 179-193), so the government may have concluded that they should not be treated as culpable in this instance. Accordingly, that the hospitals were not sued here should not be taken as a sign that the government will not include hospitals in future enforcement against PODs.

Industry will watch the progress of this case with interest, but the fact of the lawsuit seems likely to lead to more soul searching by the doctors, hospitals, and manufacturers who are interested in or considering POD relationships.

If you have any questions, please do not hesitate to contact the authors or your usual Ropes & Gray contact.

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