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Senators Criticize OIG for Lack of Guidance on Physician Joint Ventures: Request Study on Physician Owned Distributorships

A bipartisan U.S. Senate committee has asked both the Centers for Medicare & Medicaid Services (CMS) and the Office of Inspector General (OIG) for the U.S. Department of Health and Human Services to study the proliferation of physician owned distributorships (PODs), citing a lack of regulatory guidance on how these arrangements square with existing federal law. PODs, arrangements in which physicians purchase ownership shares in entities that serve as a distributorship for products used in surgeries, can save hospitals millions of dollars in supply costs, and allow physicians to share in the savings. At the same time, critics of PODs claim they cause an increase in utilization, especially in spinal fusion surgeries. The Senate's action will focus regulatory and legislative attention on this rapidly evolving development in the healthcare industry.

Senators Cite OIG Confusion

U.S. Senator Orrin Hatch (R-Utah) in June 2011 released a report compiled by the Senate Finance Committee that examined the complicated issues surrounding PODs. The report blamed the proliferation of PODs – which now exist in at least 20 states – on the lack of regulatory guidance. Over 40 PODs have been identified in California, and in particular there seems to be a marked increase in rural areas where PODs are being used very aggressively.

The OIG in 2006 was asked to rule on the legality of PODs, but declined to explicitly address the issue, stating that its prior guidance on physician joint ventures might chart a path to compliant operation of PODs.[1] Two years later, an OIG representative articulated in Congressional testimony concerns that "physician ownership of medical device manufactures and related businesses appear to be a growing trend in the medical device sector. These business ventures raise substantial concerns that a physician's return on investment from the venture may influence the physician's choice of device." [2]

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1 Letter from Vicki Robinson, Chief, Industry Guidance Branch, HHS Office of Inspector General (Oct. 6, 2006), available at http://www.oig.hhs.gov/fraud/docs/alertsandbulletins/GuidanceMedicalDevice%20%282%29.pdf

2 Testimony of Gregory E. Demske, Office of the Counsel of the Inspector General, U.S. Department of Health and Human Services, before the U.S. Senate Special Committee on Aging Examining Relationships Between Medical Device Industry and Physicians (Feb. 27, 2008), available at http://www.oig.hhs.gov/testimony/docs/2008/demske_testimony022709.pdf

The Senate Report also pointed out that the OIG's office had not handled this healthcare development properly stating, "[t]here is as much confusion in your office [the OIG] as there is in the community about how to arrange these [PODs] in a legal manner."[3] The letter stated that PODs present issues under the Federal Anti-kickback Statute[4] and Physician Self Referral Law (commonly known as the "Stark Law")[5] that need clarification. The Senate Report went further, stating that past OIG guidance did "not appear to address all of the new permutations of the POD model and many of the models are being set up in a way to purposefully circumvent the federal fraud and abuse law designed to curb such behavior."

Senators Ask for Guidance from OIG and CMS

The Senate Report concludes by stating it must take a leadership role in addressing the multiple issues presented by PODs in the absence of clear guidance from OIG and CMS. It also asks both CMS and OIG whether additional legislation and or regulation is needed to ensure that PODs are fully compliant with federal law. In doing so, the Senate Report repeatedly states that some POD models may be appropriate in helping reduce healthcare costs.

The Senate Report asks whether payments to physicians under POD models should be disclosed pursuant to the Physician-Payment Sunshine Law,[6] and whether PODs should be allowed to participate in Accountable Care Organizations. The OIG was asked to provide feedback on several questions regarding PODs including:

- Are physician investors threatening hospitals that they will lose patient referrals if they refuse to deal with PODs?
- Is there evidence of overutilization of medical services or inappropriate choice of products by physician investors?
- Do PODs serve as a vehicle for physicians to solicit remuneration from manufacturers?
- How could any POD pass the anti-kickback statute "one purpose" test, under which the law is violated if even one purpose (as opposed to a sole or primary purpose) of an arrangement is to pay remuneration in return for referrals?

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3 Letter from U.S. Senate Committee on Finance to the Hon. Daniel R. Levinson, Inspector General, U.S. Department of Health and Human Services, June 9, 2011, available at http:/finance.senate.gov/newsroom/ranking/release/?id=126c415e-f1a3-41e9-ab49-665a71188f1c

4 42 U.S.C. § 1320a-7b

5 42 U.S.C. § 1395nn

6 The Physician Payment Sunshine Protection Act was included in the Patient Protection and Affordable Care Act, P. Law 111-148, Section 600

In conclusion, the Senate Report found that some POD models appear to have appropriate frameworks designed to ensure their activities are legally compliant, but there are far more which are operating in a manner that appear to be unethical and illegal. The Senate is concerned that such entities are allowed to operate without guidance, and more importantly, without enforcement actions from the OIG. The Senate Report is designed to spur the OIG and CMS to action. Those individuals and entities that have relationships with PODs are encouraged to monitor the activities of the PODs they deal with and to monitor the Senate's actions in response to the OIG and CMS reports, which will be delivered later this summer.