

# United States Senate

COMMITTEE ON FINANCE

WASHINGTON, DC 20510-6200

June 9, 2011

The Honorable Daniel R. Levinson  
Inspector General  
U.S. Department of Health and Human Services  
Room 5541 Cohen Building  
330 Independence Avenue, S.W.  
Washington, D.C. 20201

Dear Inspector General Levinson:

We are writing to you in our roles as Chairman and Ranking Members of the Senate Finance, Special Committee on Aging and Judiciary Committees to raise an issue which is an area of mutual concern given our collective mandate to protect Medicare beneficiaries and the Federal health care programs. We are increasingly concerned about the proliferation over the past few years of what are known as physician owned distributorships (PODs), also sometimes known as physician owned intermediaries, and the lack of guidance being provided to physicians, patients and the health care community on how these arrangements square with existing federal law. Specifically, Congress passed the Federal Anti-Kickback law to protect patients and the federal health care programs from the potential influence of financial arrangements on health care decisions. Congress also established exceptions to that law for certain types of business or payment practices, including investments in small health care joint ventures.

A POD is an arrangement where a physician investor purchases ownership shares in an entity that then purchases or serves as a medical device distributor for the products the physician utilizes in surgery. There are a variety of models which are utilized, some of which may indeed be appropriate, but the potential for conflicts of interest in this physician ownership model, the safety concerns for patients, and the potential impact on costs to the healthcare system raise a number of troubling issues about PODs and other similar arrangements which we believe merit further inquiry.

Your office previously issued written guidance in 2006<sup>1</sup> expressing the need for careful review of these types of entities because of “the strong potential for improper inducements between and among the physician investors, the entities, device vendors, and device purchasers” which necessitates these arrangements being “closely scrutinized under the fraud and abuse laws.” Additionally, in Congressional testimony two years later<sup>2</sup>, an Office of Inspector General (OIG) representative articulated

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<sup>1</sup> 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>.

<sup>2</sup> Testimony of Gregory E. Demske, Office of 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

ongoing concerns that “physician ownership of medical device manufacturers 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.” Despite the strong concerns voiced in these statements that a physician’s financial interest in physician-owned implant supply chain companies, including PODs, could inappropriately influence the physician’s choice of implantable medical device or the facility where those procedures will be performed, there is abundant evidence that PODs have proliferated in the last several years. In particular, it appears that over the last 18-24 months there has been substantial growth of PODs in the spine and total joint arena. Curiously, this follows a study published last year in the Journal of the American Medical Association which noted there had been a marked fifteen fold increase in the number of spinal fusion surgeries from 2002-2007 and that there was a significant financial incentive to both hospitals and surgeons to perform these complex fusions.<sup>3</sup> Further analysis is required to determine whether the growth in the number of surgeries and the increasing utilization of PODs are related.

The continued increase in the number of PODs and the extent to which the medical community remains deeply divided as to the legality of the POD model indicates that previous OIG guidance on this topic is not sufficient. There is as much confusion in your office’s stance on PODs as there is confusion in the health care community about how to arrange these in a legal manner. Until there is clarity, inappropriate versions of these entities could continue to proliferate, potentially driving up medical device costs to the Medicare and Medicaid programs and putting patient safety at risk. In fact, the use of PODs may have been enabled by the absence of policy statements, guidance or visible enforcement proceedings that demonstrate, with sufficient clarity and emphasis, the extent of the government’s concerns with the ways that PODs differ from physician joint ventures to provide legitimate health care services and the risks of abuse posed by some PODs. Further, questions have been raised about whether PODs serve any legitimate value. Many of the physicians, hospitals and medical device companies that the Finance Committee minority staff spoke to as part of their review on this issue indicated that they are uncertain about what guidance to follow when determining whether or not to participate in or do business with a POD. One surgeon who was pushing back against his colleagues pressuring him to join a POD wrote that those colleagues were citing the absence of any prevailing guidance specifically on point on this topic as a reason for joining a POD like venture and that “ this sort of thought is what prevails unless the OIG takes a stand.”

Given the trends noted above, we are worried that OIG’s existing guidance, which is largely focused on physician-owned providers of ancillary healthcare services, and its expressions of concern, is not adequate to protect against the risk of PODs abuse. We are also concerned that guidance alone, in the absence of any visible enforcement proceedings, may be insufficient to stop the growth of those entities that do not appear to be structured with the appropriate safeguards. Many POD proponents and

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Device Industry and Physicians (Feb. 27, 2008), available at [http://www.oig.hhs.gov/testimony/docs/2008/demske\\_testimony022708.pdf](http://www.oig.hhs.gov/testimony/docs/2008/demske_testimony022708.pdf).

<sup>3</sup> Deyo RA, Mirza SK, Martin BI; et al. "Trends, major medical complications, and charges associated with surgery for lumbar spinal stenosis in older adults." JAMA.2010;303(13):1259-1265.

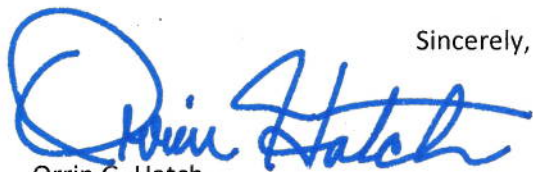


physician investors have concluded that there is, in fact, no real legal or practical impediment to their operations and some of them are being structured in very haphazard ways as a result. Therefore, we believe it is incumbent upon the OIG to address this rapidly evolving healthcare market issue by conducting an inquiry into PODs and their current structures and activities and then report to us the results of such an inquiry, along with your recommendations for further action should be taken by the OIG and Congress to effectively address the patient and program risks presented by PODs.

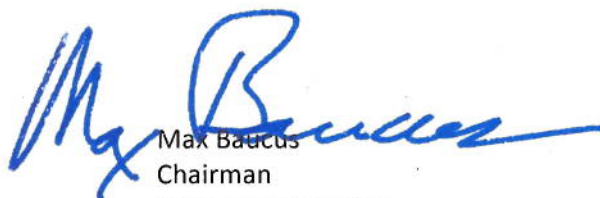
In conducting your inquiry and preparing a summary of your findings, we are especially interested in your analysis of a number of operational and legal issues related to the POD models. An inquiry conducted by the Finance Committee minority staff indicates that there are some POD models that appear to have appropriate frameworks developed to try to ensure their activities are legally compliant, but that there are far more which are operating in a manner that appears to be unethical and illegal. We are most concerned about allowing such entities to operate without additional guidance and oversight from your office and/or Congress. To assist you in your review, we have attached a number of questions that were identified during the Finance Committee minority staff review of this issue that we believe are key to better understanding what additional actions need to be taken by Congress and/or OIG to ensure these models are fully compliant with federal law. For instance, we would like to know if this is an issue that requires further legislation to enable regulatory enforcement and, if so, what kinds of legislative changes do you recommend should be made.

We look forward to receiving an initial report of your findings by August 12, 2011. Please do not hesitate to reach out to the staff of our offices if you have additional questions regarding this request. Thank you for your prompt attention to this important issue.

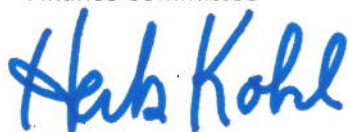
Sincerely,



Orrin G. Hatch  
Ranking Member  
Finance Committee



Max Baucus  
Chairman  
Finance Committee



Herb Kohl  
Chairman  
Special Committee on Aging



Bob Corker  
Ranking Member  
Special Committee on Aging



Charles E. Grassley  
Ranking Member  
Judiciary Committee

## Attachment A

### Background on PODs

- o How widespread are PODs? Are they clustered in certain geographic areas? What percentage of implanting physicians are investors in PODs? Why have PODs proliferated recently?
- o Do PODs provide any function that is not available directly from manufacturers and their employees or independent sales agents? Do PODs add any material value to hospital customers that hospitals could not obtain directly in this way?
- o What is a typical level and cost of warehoused inventory that PODs maintain? What controls are in place to guarantee the safety and quality of the inventory?
- o What is a typical capital structure of a POD? What level of cost typically is associated with establishing and operating a POD? What are the key expense items?
- o Assuming that POD investors control the demand for implants carried by the POD, the choice of implantable device used in their patients, and the venue where an implant procedure will be performed, is there any material business risk for a physician to invest in a POD?
- o As a practical matter, do POD investors exert pressure on each other to utilize primarily product carried by their POD? Does this pressure and the POD investor's own financial interest influence their selection of implants?
- o Are physician investors threatening to stop using the products of manufacturers who will not pay PODs to stock their products?
- o Are physician investors threatening hospitals that they will lose their patient referrals if they refuse to deal with PODs?
- o Is there evidence of overutilization of medical services or inappropriate choice of products by physicians who are POD investors?

### **Legal Issues Concerning PODs**

#### Hospital Issues

- o Does a hospital's agreement to depart from its historical purchasing practices and acquire implants through a referring physician's POD, without obtaining more favorable pricing, service, or other terms than the hospital could obtain through open and competitive arms-length negotiation with existing suppliers, provide evidence of an intent to give remuneration to induce physicians to refer patients to the hospital?
- o Does a hospital's willingness to deal with a POD that lacks any substantial business infrastructure, distributorship experience, or operating history, and may instead outsource its operations to a third-party manager, provide evidence of an intent to give remuneration for referrals?
- o Does the opportunity to make a profit that results when a hospital agrees to purchase through a physician's POD constitute the offer or payment of remuneration that would violate the anti-kickback law if improper intent were present?

#### Manufacturer Issues

- o Do PODs serve as a vehicle for device manufacturers to pay remuneration to physician investors in return for such physicians' use or recommendation of their products?
- o Do PODs serve as a vehicle for physicians to solicit such remuneration from manufacturers?
- o Does a manufacturer's willingness to deal with a POD that lacks any substantial business infrastructure, distributorship experience, or operating history, and may instead outsource any significant operations to a third-party manager, provide evidence of an intent to give remuneration for the doctor's ordering of its products?



### Investment Issues

With respect to the financial benefits initiated by either manufacturers or hospitals and received by a physician through his/her investment in a POD:

- o How could any POD pass the anti-kickback law “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?
- o In applying the small investment safe harbor provision stating that no more than 40% of the venture’s revenues “may come from referrals or business otherwise generated from investors,” is it correct that physician investors in a POD are deemed to generate business for the POD if the hospital would not have agreed to buy, and the supplier would not have agreed to sell, any products through the POD but for the promise or understanding of the physician’s referrals? And if so, how could any POD satisfy the safe harbor without placing at least 60% of its business at hospitals where investor physicians do not practice?
- o Do the terms on which POD investment interests are offered and maintained induce physician investors to use, recommend, or arrange for the hospitals where they practice to purchase products carried by the POD?
- o Does the fact that a POD promises a return on investment that could not be achieved absent the guaranteed referrals from the physician investors, and that depends primarily on business generated by the physician investors, provide evidence of an intent to offer remuneration for referrals?
- o Does a physician’s acceptance of such a POD investment provide evidence that the physician is agreeing to accept that remuneration in exchange for his or her use of POD products?
- o Does a physician’s sudden switch in implant use to different products furnished by his/her POD provide evidence that the physician is accepting remuneration in exchange for his/her use of POD products?