



SEP 13 2011

The Honorable Orrin G. Hatch
Ranking Member, Committee on Finance
United States Senate
Washington, DC 20510

The Honorable Max Baucus
Chairman, Committee on Finance
United States Senate
Washington, DC 20510

The Honorable Herb Kohl
Chairman, Special Committee on Aging
United States Senate
Washington, DC 20510

The Honorable Bob Corker
Ranking Member, Special Committee on Aging
United States Senate
Washington, DC 20510

The Honorable Charles E. Grassley
Ranking Member
Committee on the Judiciary
United States Senate
Washington, DC 20510

Dear Senators:

I am writing in response to your June 9, 2011, letter in which you expressed concerns regarding the recent proliferation of physician-owned distributorships (PODs) and the potential adverse impact these entities could have on Medicare beneficiaries and the Federal health care programs. You requested that my office conduct an inquiry into, and analyze a number of legal and operational issues about, PODs. You also asked my office to assess the adequacy of the guidance we have issued addressing the legality of PODs and other physician-owned entities under the Federal Anti-Kickback Statute and to indicate whether we believe further guidance, legislation, or enforcement actions are required to address this growing trend.

On July 19, 2011, we met with your staff to discuss your request. Based on that discussion, we are initiating a review of PODs that will seek to determine the extent to which PODs provide spinal implants purchased by hospitals. The study will be nationally representative of hospitals that bill Medicare for spinal surgery. We will review information from hospitals and other sources to establish how widespread PODs are, what services PODs offer to hospitals, and whether PODs save hospitals money in the acquisition of implants. We also will analyze Medicare claims data to determine whether the PODs we identify in our review are associated with high use of spinal implants.

We expect that our study will produce important information about PODs. We will consider this information in determining whether to issue additional guidance addressing physician-owned entities, including PODs. However, as we have discussed with your staff, a wide variety of POD

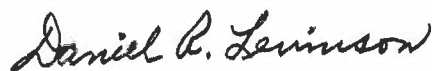
models are being utilized, and different POD models can raise varying levels of legal concern; thus, the answers to many of the important legal questions you posed about PODs depend on the specific facts of the case. The Federal Anti-Kickback Statute is a criminal, intent-based statute that plays a central role in addressing improprieties in physician-industry relationships. The legality of any individual physician-owned entity under the Federal Anti-Kickback Statute is highly dependent on each entity's particular characteristics, including the details of its legal structure; its operational safeguards; and, importantly, the actual conduct of its investors, management entities, suppliers, and customers during the implementation phase and ongoing operations. For these reasons, OIG's ability to issue guidance about the application of the statute to these business structures is limited.

OIG's current guidance explains key factors that OIG continues to consider when evaluating advisory opinion requests, potential investigation targets, and other matters falling within OIG's jurisdiction. For instance, it has been OIG's longstanding view that the opportunity for a referring physician to earn a profit, including through an investment in an entity for which he or she generates business, could constitute an illegal inducement under the Federal Anti-Kickback Statute. When evaluating the legality of a such an investment, OIG would consider, among other factors, the terms under which a physician may invest in the entity and, conversely, the terms under which a physician-owner may be required to divest his or her ownership interest; the actual return or projected return on the physician's investment; and the amount of revenues generated for the entity by its physician-investors. OIG has repeatedly expressed this view, and listed these factors, in various guidance documents, including Special Fraud Alerts, advisory opinions, and published letters to the industry.

OIG is committed to the ongoing monitoring of physician-owned entities and to taking enforcement actions when appropriate. For example, in July 2010, OIG entered into a settlement agreement and corporate integrity agreement in a case involving United Shockwave Services, United Urology Centers, and United Prostate Centers, which OIG alleged had violated the Federal Anti-Kickback Statute by soliciting and receiving remuneration from various hospitals in exchange for the referral of Medicare beneficiaries controlled by the entities' physician-owners.

If you have further thoughts or questions, please call me or have your staff call Chris Hinkle, Director of Congressional and Regulatory Affairs, at (202) 401-2206 or christina.hinkle@oig.hhs.gov.

Sincerely,

A handwritten signature in cursive script that reads "Daniel R. Levinson".

Daniel R. Levinson
Inspector General