



Medacta USA Position Statement on Physician Owned Distributorships

Medacta USA does not engage in any business activities with Physician Owned Distributors (PODs) of Medical Devices where the referring surgeons are actually owners of the distribution entity. This position follows the guidance of the Office of Inspector General and the intentions of existing legislation.

It is clear that the intention of both the Anti-Kickback Statute and the Stark Law is to prohibit remuneration in exchange for referrals and self-referrals.

The OIG's position is demonstrated by its responses to requests to provide clarification on the legality of PODs. They repeatedly warn that: "...it has been the 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."¹ The OIG's concern regarding this model is also demonstrated in the recent OIG Advisory Opinion 11-15, in which a Requestor asks the OIG to approve an arrangement that would establish a physician owned entity, which would enable physicians to earn a profit by referring business to the entity in which they have ownership. The arrangement is similar to PODs. The OIG's negative response clearly demonstrates their dismissive position on physicians establishing entities with an end goal of remuneration from referrals, again referencing the application of the Anti-Kickback Statute.

Participation in an activity which is prohibited by the Anti-Kickback Statute or the Stark Law is fraught with danger and repeatedly warned against by the OIG. To date, the government has not demonstrated that it is looking to amend the statutes, approve the POD model or implement a new Safe Harbor to allow for referring surgeons to engage in a venture with manufacturers and hospitals to the extent required for participation in PODs. In contrast, recent amendments to the Anti-Kickback Statute make it much easier to prosecute arrangements that the OIG determines violate the law. Therefore, absent any positive Advisory Opinion or clear OIG guidance allowing PODs, Medacta USA's position is to not engage in any business activities with PODs.

1. Inspector General, Daniel Levinson responds on behalf of OIG in letter dated 09-13-2011 to Senator's Hatch, Baucus, Corker, Kohl, and Grassley regarding their request for OIG to investigate PODs. This letter, copies of the correspondence sent to Don Berwick head of CMS, as well as his response, and a copy of the Report on PODs by the Senate Finance Committee Minority, can be found here: <http://finance.senate.gov/newsroom/ranking/release/?id=126c415e-f1a3-41e9-ab49-665a71188f1c>