Arnall Golden Gregory LLP

Client Alert

Contact Attorneys Regarding This Matter:

R. Michael Barry
404.873.8698 - direct
404.873.8699 - fax
michael.barry@agg.com

Jennifer Downs Burgar
404.873.8194 - direct
404.873.8195 - fax
jennifer.burgar@agg.com

OIG Responds to Senators' Request for Guidance on Physician Owned Distributorships—PODs Remain Risk-laden Ventures

On September 13, 2011, the Department of Health and Human Services Office of Inspector General (OIG) responded to previously presented concerns from Senators Hatch (R-Utah), Kohl (D-WI), Grassley (R-IA), Baucus (D-MT), and Corker (R-TN) regarding the proliferation of physician owned distributorships (PODs) and the lack of discrete guidance regarding their utilization. The Senators had requested specific guidance from the OIG in a letter dated June 9, 2011.[1] In that letter, the Senators were highly critical of PODs and raised concerns that PODs were areas of significant fraud and abuse risk. In a similar letter to CMS Administrator Donald Berwick, also dated June 9, 2011,[2] the Senators had requested specific regulatory guidance regarding PODs.

PODs are entities owned and operated by physicians for the sale of medical devices. In most instances, the PODs will purchase the medical devices directly from the manufacturer and then sell those devices to either a hospital or surgery center, where some or all of the physicians will use those devices in surgery. Many PODs have little or no overhead, little or no actual business operation outside of that generated by its physician investors, and little or no actual business risk. The Senators had raised issues of conflicts of interest, patient safety, and negative impacts on healthcare costs, as some of the reasons why additional, direct regulatory guidance is necessary. The Minority Staff of the Senate Finance Committee issued a report[3] in June 2011 that detailed significant concerns with regard to PODs and the lack of specific guidance regarding their use.

In its response, the OIG stated that it is initiating a review of PODs, though it did not provide a timeline for a final report. The review will include a national analysis of hospitals that bill Medicare for spinal surgery to determine to what extent PODs provide the spinal implants used by such hospitals. The analysis will also focus on whether the PODs save hospitals money on the purchase of spinal implants, how widespread the use of PODs has become, and what services PODs offer to hospitals. Answers to these questions will help the OIG address at least one of the Senators' concerns—that of cost increases, which may be attributable to PODs. While this analysis may take some time, the OIG

1 http://finance.senate.gov/newsroom/ranking/download/?id=8f1a711c-0a52-4d94-bb6d-d2a02d411cb4
2 http://finance.senate.gov/newsroom/ranking/download/?id=1e6e609a-20ae-46cf-b85e-ea567a7ecc8c
3 http://finance.senate.gov/newsroom/ranking/download/?id=274abe2e-ee0d-489e-9498-6542c0476cf5

Arnall Golden Gregory LLP
Attorneys at Law

171 17th Street NW
Suite 2100
Atlanta, GA 30363-1031
404.873.8500

2001 Pennsylvania Avenue NW
Suite 250
Washington DC 20006
202.677.4030

www.agg.com

clearly noted that there is existing guidance regarding physician-vendor relationships under the Anti-Kickback Statute. Re-stating its 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", the OIG further noted that its considers other, specific elements when reviewing questionable relationships:

- The terms under which a physician may invest in the entity;
- The terms under which a physician owner may be required to divest his or her ownership;
- The actual return or projected return on the physician's investment;
- The amount of revenues generated for the entity by the physician-investors.

The OIG's letter is important because it highlights the continued scrutiny that will be applied to PODs. While PODs may have proliferated over the last few years, their use continues to be anything but risk-free.

Physician-vendor relations have long been targets of significant scrutiny. It appears that even as health-care reform evolves, regulatory guidance will unfold to anticipate and address the new and varied means of healthcare delivery and service. It is clear from the OIG's letter that physicians can expect more, not less, enforcement and regulation of physician-vendor relationships—particularly where the physician controls or influences the amount of business generated.