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Physician-Owned Distributors in the Crosshairs: Senate Committees Call on OIG and CMS to Take Action

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In a strong signal that physician-owned distributors (PODs) may be in the line of enforcement fire, on June 9, five senators, representing the Committees on Finance, Aging, and Judiciary (Committees), signed joint letters to the U.S. Department of Health and Human Services Office of Inspector General (OIG) and the Centers for Medicare and Medicaid Services (CMS) directing them to analyze and address concerns regarding troubling trends in the medical device and hospital industries related to PODs, medical device distributors or purchasing organizations with physician owners or investors.[1] Both letters establish response deadlines within the next 60 days, requesting an OIG report by August 12, 2011 and a CMS staff briefing by July 15, 2011.

The requests to OIG and CMS were preceded by an investigation and a report of the Minority Staff of the Senate Finance Committee into PODs (Report or Hatch Report) that was released simultaneously with the joint letters.[2] In a press release announcing the Report, Ranking Member Orrin Hatch (R-UT) challenged the POD model, stating that "[t]he financial incentives created by these entities set a dangerous precedent that, as indicated in this report, can lead to serious overutilization and force unnecessary, invasive procedures for patients."[3] The Report asserted that OIG has "enabled" the growth of PODs due to a lack of clear guidance or "visible enforcement" in the area, and also implored CMS to close any potential loopholes that could permit PODs to avoid being regulated under Accountable Care

1. Letter from Senators Orrin G. Hatch (R-UT), Max Baucus (D-MT), Herb Kohl (D-WI), Bob Corker (R-TN), and Charles E. Grassley (R-IA) to Administrator Donald Berwick, CMS, June 9, 2011, available at http://finance.senate.gov/newsroom/ranking/download/?id=1e6e609a-20ae-46cf-b85e-ea567a7ecc8c (last visited June 14, 2011); Letter from Senators Orrin G. Hatch (R-Utah), Max Baucus (D-MT), Herb Kohl (D-WI), Bob Corker (R-TN), and Charles E. Grassley (R-IA) to The Honorable Daniel R. Levinson, Inspector General, U.S. Department of Health and Human Services, June 9, 2011, available at http://finance.senate.gov/newsroom/ranking/download/?id=8f1a711c-0a52-4d94-bb6d-d2a02d411cb4 (last visited June 14, 2011).

2. Minority Staff of the Senate Finance Committee, "Physician Owned Distributors (PODs): An Overview of Key Issues and Potential Areas for Congressional Oversight," June 2011, available at http://finance.senate.gov/newsroom/ranking/download/?id=274abe2e-ee0d-489e-9498-6542c0476cf5 (last visited June 14, 2011).

3. Press Release of Senate Finance Committee Ranking Member Senator Orrin Hatch (R-UT), "Hatch Releases Analysis Outlining Questionable Legality of Physician Owned Entities: Analysis Finds Overutilization of Medical Procedures By Physicians Participating in these Entities; Hatch Spearheads Bipartisan Letters Calling for Investigation," June 9, 2011, available at http://finance.senate.gov/newsroom/ranking/release/?id=126c415e-f1a3-41e9-ab49-665a71188f1c (last visited June 29, 2011).

Organization (ACO) rules or the Physician Payments Sunshine Act (Sunshine Act), enacted as part of the Patient Protection and Affordable Care Act of 2010 (ACA). Further, it emphasized the obligation of hospitals, physicians, and device manufacturers that do business with PODs to avoid running afoul of applicable fraud and abuse laws.

The existence of PODs has given rise to significant legal questions, particularly under the Anti-Kickback Statute. In 2006, a request for guidance by AdvaMed, a medical device trade association, prompted an OIG letter expressing concern about the proliferation of physician investments in medical device and distribution entities.[4] OIG's letter stated that joint ventures between physicians and device vendors and purchasers should be carefully evaluated under fraud and abuse laws such as the Anti-Kickback Statute due to the "strong potential for improper inducements" among physician investors, PODs, device vendors, and purchasers such as hospitals.[5] The California Attorney General also stepped into the debate in 2006; rather than clarifying certain legal issues involved, however, the office appeared to help fuel the growth of PODs when it issued an opinion in response to a state senator's inquiry finding that physician investments in PODs may be acceptable under the state's stringent Anti-Kickback laws.[6]

Hospitals, physicians, and other industry stakeholders should take note of the more recent developments, as they may portend increased congressional oversight, administrative audits or reviews, possible legislation, potential agency rulemaking, and potential fraud and abuse enforcement actions targeting PODs and their business partners or customers.

Hatch Report Raises Concerns About Legitimacy of POD Models

The Report makes Senator Hatch's distrust of PODs clear, stating that the POD model "on its face . . . appears to be entirely inconsistent with the fundamental tenets of healthcare compliance that have shaped the medical device industry," and that there are "inherent suspicions about whether they serve any legitimate value." Despite these misgivings, the Report recognizes the possibility that a prudent and legally appropriate POD structure may exist. One such example provided in the Report is a structure that is more akin to a traditional distributor model, in which the POD does not profit from doing business with its own investors, partners, or affiliated hospitals.

The primary focus of the Report is on entities operating in the spine and total joint orthopaedic implant sector of the device industry. The Report also identified the cardiac implant sector as a growth sector for PODs. Recently, federal enforcement activity in all of these sectors has been on the rise.

Compliance Concerns Identified

The Report addressed operational issues and financial incentives that pose fraud and abuse concerns. For instance, the Report raised concerns about PODs that have no operating history or experience, or do not

4. Letter from Vicki L. Robinson, Office of Inspector General, to Stephen J. Ubl, President and CEO of AdvaMed Re: Response to Request for Guidance Regarding Certain Physician Investments in the Medical Device Industries, Oct. 6, 2006, available at http://www.advamed.org/NR/rdonlyres/5ED83318-E1F1-4D34-91FB-F3C0AC55992A/0/oig_response_10606.pdf (last visited June 14, 2011).

5. *Id.*

6. Opinion of Bill Lockyer, No. 05-614, February 27, 2006, available at http://ag.ca.gov/opinions/pdfs/05-614.pdf#xml=http://search.doj.ca.gov:8004/AGSearch/isysquery/8046b231-20a0-4586-8a85-1d7eaf7f22e6/1/hilite/ (last visited June 29, 2011).

offer standard services typically provided by distributors. The Report also expressed concerns that PODs do not operate with the same licensure, federal regulation, or public oversight requirements imposed on physician-owned ancillary healthcare service providers.

In addition, the Report determined that PODs often promised physician investors potentially improper inducements, such as financial returns at rates exceeding traditional investment returns, dividends in excess of 25%, or guaranteed patient loads, all with relatively limited financial risk for the physician investors. Further, it raised concerns with POD business models in which most product sales are controlled by physician investors rather than by purchasers or physicians unaffiliated with the individual POD. This concern is consistent with the issue raised in 2006 by OIG when it stated, in its letter to AdvaMed, that "the fact that a substantial portion of a venture's gross revenues is derived from participant-driven referrals is a potential indicator of a problematic joint venture."[7]

In analyzing issues that PODs pose in the hospital setting, the Report found that arrangements involving physician POD investors who are on hospital device selection committees were "particularly troubling." It also discussed the concern that physician owners could threaten to take their practice to another facility if the hospital does not purchase a POD's products.

Anecdotal Claims of a Spike in Complex Spinal Surgeries

The Hatch Report tied the development of the POD industry to increased healthcare program costs and a spike in complex spinal surgeries. It suggested that financial incentives offered by PODs could unduly influence surgeon-investors' medical decisionmaking, causing them to perform medically unnecessary and potentially harmful procedures in order to increase their personal profit.

To demonstrate a causal connection between PODs and medically unnecessary surgeries, the Hatch Report relied on anecdotal information derived from the Minority Staff's inquiry. Citing a *Journal of the American Medical Association* study, it suggested that the growth of PODs since 2003 may correspond with a marked increase in the number of spinal fusion surgeries for Medicare patients from 2002 to 2007.[8] It also restated allegations raised by a private group claiming that a hospital experienced a dramatic increase in spinal fusion revision rates after a POD started to supply spinal implants to that hospital. The Report did not mention whether the Minority Staff of the Senate Finance Committee notified enforcement agencies of these circumstances or sought further investigation of specific fraud and abuse matters uncovered in the course of its inquiry.

Questions Raised Regarding Clarity of OIG Guidance and Loopholes in CMS Rules

The Hatch Report found that OIG's previous guidance on the legality of PODs fails to adequately address potential fraud and abuse issues with PODs. Thus, in their joint letter to OIG, the senators requested that OIG conduct an inquiry into the current structures and activities of PODs and report back on its findings and recommendations for further OIG and congressional action to address related patient and program risks. The letter sets a deadline of August 12, 2011 for an initial report. Given the

7. Letter from Vicki Robinson to Stephen J. Ubl, Oct. 6, 2006.

8. Deyo, Mirza, Martin, Kreuter, Goodman, and Jarvik, "Trends, Major Medical Complications, and Charges Associated with Surgery for Lumbar Spinal Stenosis in Older Adults," JAMA, 2010 Apr. 7; 303(13):1259–65, available at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2885954/ (last visited June 14, 2011).

complexity of the audit and the thorny legal issues inherent with PODs, it remains to be seen whether OIG will meet this requested report date.

Attached to the letter are questions addressing background information on PODs and legal issues affecting hospitals, manufacturers, and physician investors. Some of the background questions, such as those pertaining to statistics on the proliferation and geographic location of PODs, the percentage of implanting physicians who are POD investors, and POD inventory and expenses, would appear to require an extensive study or survey of the POD market, PODs' business operations, and orthopedic surgeons (investors and noninvestors).

With respect to CMS, the Report determined that existing ACO regulations provide an inadvertent loophole for questionable POD models that CMS should address. In addition, it recommended that CMS examine Sunshine Act rules to ensure that physician ownership and investment interests in PODs are addressed in the final reporting requirements. Accordingly, the joint letter to CMS requested that the agency address potential Sunshine Act and ACO loopholes regarding PODs by July 15, 2011. In lieu of a written response, CMS may provide an update on its rulemaking efforts in an in-person staff briefing.

The Sunshine Act requires pharmaceutical and medical device manufacturers to report all payments or other transfer of value, including consulting fees, honoraria, gifts, entertainment, food, travel, education, research, royalties, charitable contributions, ownership or investment interest, speaker fees, and grants.[9] It also requires manufacturers and group purchasing organizations (GPOs) to disclose information about physician ownership or investment interests. This information will be made public on the Internet by September 2013. The joint letter suggested that CMS should specifically address PODs in the definitions of "applicable manufacturers" and "applicable GPOs" to ensure consistent treatment of POD business models that present similar policy and legal risks, including physician-owned manufacturers, GPOs, and distributors.

ACOs, a centerpiece of provider reform efforts under the ACA, are groups of healthcare providers and suppliers organized to coordinate patient care under Medicare. On March 31, 2011, CMS issued its proposed rules on ACOs.[10] The joint letter recommended that CMS make it clear in final rulemaking that waivers of Stark and Anti-Kickback laws extended to ACOs do not extend to PODs. In addition, it stated that the final rule should prohibit ACOs from purchasing products or services from entities owned by physicians participating in the ACO. The joint letter to CMS proposed that "ownership" should be deemed to exist if the physician receives any remuneration from the entity supplying the product or service.

Compliance and Congressional Oversight Implications

As regulatory and enforcement interest in PODs intensifies, industry stakeholders such as physicians and hospitals may be well advised to evaluate potential fraud and abuse and conflict of interest issues associated with POD arrangements. Further, regulatory developments related to the Sunshine Law and ACO rules should also be monitored, in light of the recommendations made in the Hatch Report and the joint letters to OIG and CMS.

9. 42 U.S.C. § 1320a-7h, available at http://www.ssa.gov/OP_Home/ssact/title11/1128G.htm (last visited June 14, 2011).

10. 76 Fed. Reg. 19,528 (Apr. 7, 2011), available at http://edocket.access.gpo.gov/2011/pdf/2011-7880.pdf (last visited June 14, 2011).

Given the level of concern that Hatch has expressed about PODs, congressional oversight of PODs is likely to continue. With Senate Finance Committee Chairman Max Baucus and Special Committee on Aging Chairman Kohl on board, oversight hearings may also be called. As part of ongoing congressional oversight, it is possible that representatives from PODs or other related entities could be asked to testify or provide the committees with information about the POD business model.

Morgan Lewis will continue to monitor the Senate and OIG inquiries into PODs and will provide updates on further significant developments as they arise. If you have any questions or would like more information on any of the issues discussed in this LawFlash, please contact the authors, **Howard J. Young** (202.739.5461; hyoung@morganlewis.com) and **Arianne N. Callender** (202.739.5280; acallender@morganlewis.com).

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