

Physician-Owned Distributors and Agency Guidance: Still Waiting

Agencies' recent responses to Senate call for action on physician-owned distributors offer few details on policies. Stakeholders must await CMS rulemaking and OIG study for possible answers.

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Turning the spotlight on physician-owned distributor (POD) arrangements, in June¹ the Senate Finance Committee Minority Staff issued a report (Hatch Report)² criticizing physician-owned distributor (POD) arrangements. The report was accompanied by bipartisan letters from five Senators representing the Committees on Finance, Aging, and the Judiciary (the Committees) directing the U.S. Department of Health and Human Services Office of Inspector General (OIG) and the Centers for Medicare and Medicaid Services (CMS) to study and address the proliferation of PODs.³ In response, OIG representatives met with Senate staff on July 19, 2011, and outlined the scope of a national study on spine implant PODs in a September 13, 2011 letter to the Committees. On August 10, 2011, CMS responded separately in a letter that provided an update on its Physician Payments Sunshine Act (Sunshine Act) and Accountable Care Organization (ACO) rulemakings without committing to a specific policy position on these provisions' applicability to PODs. These agency letters were recently made publicly available by the Committees.

The Senators' June correspondence to CMS Administrator Donald Berwick and the OIG was a call to action. The Committees highlighted the potential for conflicts, patient safety concerns, and increased healthcare costs associated with PODs. In light of these concerns, the Senators recommended that CMS require PODs to disclose financial interests of physician investors under the Sunshine Act regulations, prohibit ACOs from purchasing from PODs owned by physicians participating in the ACO, and exclude PODs from any Stark Law or Anti-Kickback Statute waivers for ACOs. CMS and OIG have responded to the Committees' concerns over PODs in a somewhat cautious, deliberative manner.

1. See the June 30, 2011 LawFlash, "Physician-Owned Distributors in the Crosshairs: Senate Committees Call on OIG and CMS to Take Action," available at http://www.morganlewis.com/pubs/FDA_LF_SenateCommitteesCallOnOIGandCMS_30june11.pdf.

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. 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-UT), 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).

In the August 10, 2011 letter, Administrator Berwick informed the Senators that the CMS review of comments on proposed rules is ongoing. Administrator Berwick did not, however, articulate a position on the Senators' recommended approach to regulation of PODs under ACO and Sunshine Law authorities. Thus, the Senate and healthcare industry stakeholders will have to wait until CMS issues the final rules or related policy guidance to learn what stance the agency will take, if any, on how to regulate PODs under these new healthcare provisions.

In their letter to HHS Inspector General Daniel Levinson, the Senators scrutinized OIG's prior guidance and enforcement efforts, and requested a national study of POD structures and activities, specifying 21 areas of inquiry for OIG to review. In his September 13, 2011 response, Inspector General Levinson provided the scope for the POD study and addressed the Senators' statements regarding OIG guidance and enforcement activities.

Inspector General Levinson outlined plans for OIG's nationwide study to determine the extent to which PODs supply spinal implants to hospitals. OIG's study will not involve other non-spine orthopedic PODs. The study will review a representative group of hospitals that bill Medicare for spinal surgery. For these hospitals, OIG will evaluate services PODs offer to hospitals, the extent to which the business model has proliferated, and whether PODs offer any cost savings to hospitals related to the acquisition of spinal implants. OIG will also analyze Medicare claims data to determine whether PODs are associated with a high use of spinal implants. According to the Fiscal Year 2012 OIG Work Plan, issued on October 5, 2011, this OIG study, to be conducted by its Office of Evaluations and Inspections, has an expected issue date of sometime before October 2012.

While Inspector General Levinson would not commit to issuance of additional guidance on the Anti-Kickback Statute's applicability to PODs, he reiterated key factors that the agency considers when evaluating POD business arrangements:

- The opportunity for a referring physician to earn a profit
- The terms under which the physician may invest in the POD entity
- 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
- The amount of revenue generated for the entity by the physician-investors

These factors also appear in OIG's prior Anti-Kickback Statute guidance, which the Senators found was "not adequate to protect against the risk of POD abuse." In its letter, OIG took the position that since business models vary and Anti-Kickback Statute analysis depends on the facts and circumstances of a particular financial arrangement, the agency's ability to issue general guidance on the application of the statute to POD structures is limited.

Without committing to issue further guidance, Inspector General Levinson emphasized OIG's ongoing monitoring of POD entities and its commitment to take enforcement actions when appropriate. The Senators' letter had expressed disappointment with the "absence of any visible enforcement proceedings" related to PODs. In his agency's defense, Inspector General Levinson highlighted a \$7.3 million settlement and Corporate Integrity Agreement OIG entered into in July 2010 that did not involve a POD. It instead involved a physician-owned lithotripsy entity that did business with hospitals and, the government alleged, violated the anti-kickback laws by soliciting and receiving remuneration from

various hospitals in exchange for the referral of Medicare beneficiaries controlled by the entity's physician-owners.

With the spotlight on OIG's perceived lack of visible enforcement actions related to PODs, it is possible that OIG will target PODs in similar actions in the future. Further, the results of the OIG's study could dictate the focus of additional OIG monitoring and enforcement efforts. But for now, healthcare industry stakeholders will need to stay tuned to learn how CMS, OIG, or the Senate will address POD-related concerns raised by the June 2011 Hatch Report. Given the current budget environment, Congress and the Obama administration's efforts to reduce costs through fraud and abuse prevention measures, and the Senate Committees' articulated concern for potential overutilization associated with PODs, these entities and their customers may face heightened scrutiny.

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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