

By Robert Betz, Ph.D.



# The New Middleman

Physician Owned Distributors (PODs) get front stage

## The issue of physician-owned distributorships hit

the policy front stage in June when U.S. Senator Orrin Hatch (R-Utah), Ranking Member of the Senate Finance Committee, released a Committee Minority analysis titled, *Physician Owned Distributors (PODs): An Overview of Key Issues and Potential Areas for Congressional Oversight*.

PODs have been called the new “middleman” of the healthcare supply chain and, according to the report, allow some participating surgeons to profit from the medical devices they use on their patients. PODs first appeared in California in 2003 as a potential way for surgeons to offset declining reimbursement for their services. Initially, these organizations were primarily focused on orthopedic implants. Over the next two years, PODs spread to 19 other states, but now include additional devices such as cardiac implants.

The Hatch Report questions the legality of such organizations under the antitrust statutes as well as the Medicare and Medicaid Fraud and Abuse law. As surgeons often dictate which devices are to be used, the implications of physicians’ financial interest in a distributor providing the devices has serious implications for policymakers. To the point, the Senate report states that “physician investors in PODs may perform more procedures than are medically necessary” because the surgeons can earn extra income each time they implant a device in a patient. As an example, according to the Senate investigators, surgeries involving spinal re-operation rates at one hospital increased more than 300 percent following the creation of a POD in the hospital’s service area. The implications for Medicare of the establishment of such organizations is substantial. According to a recent *Wall Street Journal* article analysis of Medicare claims data, spinal fusion went from costing Medicare \$343 million in 1997 to costing \$2.24 billion in 2008.

Legal firms are sprouting up to assist surgeons interested in establishing PODs, arguing that they are legal if set up and operated appropriately. The confusion in the medical device marketplace about the legality and ethics of PODs really is breathtaking given some of the implications for the future. Subsequently, the proliferation of these models, along with several variations of each, raise immediate issues for policymakers that will likely lead to regulatory and/or legislative interventions.

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## Letters of concern

In accompanying letters to the Health and Human Services (HHS) Inspector General (IG), Daniel Levinson and to the Centers of Medicare and Medicaid Services (CMS) Administrator, Donald Berwick, U.S. Senators Max Baucus (D-Mont.), Chairman of the Senate Finance Committee, Herb Kohl (D-Wis.), Chairman of the Special Committee on Aging, Bob Corker (R-Tenn.) Ranking Member of the Special Aging Committee, and Chuck Grassley (R-Iowa), Ranking Member of the Judiciary Committee joined Senator Hatch in calling for an investigation into the structure of PODs and their potential adverse impact on the Medicare program

and its beneficiaries. In their letter to the IG, the five U.S. senators urged for an investigation to be opened into PODs stating that “Until there is clarity, inappropriate versions of these entities could continue to proliferate, potentially driving up medical device costs to the Medicare and Medicaid programs and putting patient safety at risk.”

In a similar letter to CMS, the five senators focused their concern on the Physician Payment Sunshine Act and to various provisions of the Affordable Care Act related to Accountable Care Organizations (ACOs). The Sunshine Act concerns payments to physicians by pharmaceutical and medical device companies and the potential negative effects on national healthcare expenditures. It specifically calls for disclosure to the HHS Secretary by manufacturers of such payments and public disclosure by HHS of the information gathered. The Sunshine Act also requires reporting of ownership and investment interests by physicians. In the letter to CMS, the five senators note “The POD model at its basic level is exactly the type of entities envisioned by the Sunshine Act...”. Furthermore they state “This would mean that the distribution model of these physician-owned companies would need to be included as CMS develops (in pending regulations) a final definition of ‘applicable manufacturers’ and ‘applicable group purchasing organizations.’”

Specifically, the five senators are concerned that the recently released proposed regulations governing Accountable Care Organizations (ACOs) inadvertently may have opened a loophole allowing “less reputable” POD models to fall under the Stark and Anti-Kickback law waivers set up for ACOs. They say “The final rule should prohibit ACOs from purchasing products and services from entities that are owned by physicians participating in the ACO.”

What have manufacturers been doing during the rise of PODs? As an example, it appears most of the large orthopedic manufacturers have not been negotiating with these enti-

ties. Therefore the price impact on major brands appears to be minimal. Additionally, some believe there are two financial decision points for PODs based on site of surgery... (1) when the procedures are conducted in a hospital, it doesn't behoove the surgeon to get the price too low for hospital payment, as they gain financially from the profitability of the POD. (2) When the POD serves an ambulatory surgery center (ASC) or other physician-owned facility, they are making their money off the profitability of the ASC. The issue here for policymakers seems to come down to the transparency of the POD books, so as not to favor customers differently, i.e. hospitals vs. ASC and other physician-owned facilities.

So far the establishment of PODs does not seem to be significantly impacting the overall Medicare numbers. Some think this is because the premier institutions in this country (those doing the high-volume high-quality procedures) are already getting a relatively low price for the implantable devices. Moreover, the difference between that sentinel pricing and what the surgeons can command through a POD reportedly does not seem to be significant. This could mean the POD models may find their best growth opportunities in the community or rural hospital arenas.

CMS and the IG better hurry their work along and provide some regulatory guidance in this area. Reports are there is increasing interest in the establishment of physician-owned distributorships out there. The evolution of the POD model is increasing. Also, the national organizations for group purchasing and medical device manufacturers will weigh-in on this issue although the discussion may lead to calls for opening up antitrust and fraud and abuse laws governing healthcare purchasing today. Nevertheless, five senators from the U.S. Senate Finance Committee, CMS, and the HHS IG all now have a laser focus on PODs. To quote Sir Thomas More from Robert Bolts play “A man for All Seasons” – “Not a bad public, that.” **JHC**



*Robert Betz, Ph.D., is president of Robert Betz Associates, Inc. (RBA), a well-established federal health policy consulting firm located in the Washington, D.C. area. Additionally, Dr. Betz is an adjunct professor teaching at The George Washington University where he specializes in political science and health policy. For more information about RBA, visit [www.robertbetz.com](http://www.robertbetz.com).*