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MedPAC Takes Anti-POD Stance in Report to Congress, Echoing an Increasingly Uniform Consensus

On June 15, 2017, the Medicare Payment Advisory Commission (MedPAC), a non-partisan group that advises Congress on Medicare policy, released its annual Report to the Congress on Medicare and the Health Care Delivery System (the "Report"). Of particular importance to some hospitals and physicians, the Report includes MedPAC's first-ever discussion of physician-owned distributorships of implantable medical devices (PODs), and specifically calls for actions to "reduce the number" of PODs. Echoing the findings of prior governmental investigations, the Report also notes that PODs can lead and have led to increased costs and inappropriate care.

MedPAC's commentary follows on the heels of a 2016 report critical of PODs from the majority staff of the Senate Finance Committee (SFC), which, as we discussed in a recent article in Compliance Today, concluded among other things that PODs are "harmful to patients and payers." The Report builds on an ever-increasing consensus of policymakers, regulators, law enforcement, consumer groups, health care providers, and other stakeholders—including the SFC, the Office of Inspector General of the U.S. Department of Health and Human Services (OIG), the Centers for Medicare & Medicaid Services (CMS), the U.S. Department of Justice (DOJ), the Association for Medical Ethics, and the Advanced Medical Technology Association (AdvaMed)—that the conflict of interest inherent in the POD business model should be eliminated.

MedPAC's Report includes a discussion of issues that critics have sounded regarding PODs, including that they may lead to increased volume of surgery, increased intensity of procedures, inappropriate care, and higher device costs. It also provides considerations for potential policy changes:

1. **Improve Open Payments Reporting and Monitoring**. MedPAC observed that few PODs report through the Sunshine Act Open Payments reporting system—it indicated that it was able to identify a total of only 22 PODs in 2015 reporting data. In part, that low volume may be due to the fact that under the current regulatory interpretation of the Sunshine law, PODs that do not manufacture the implants ordered by their physician-owners are deemed exempt from reporting if they sell to only one hospital (and thus do not meet the regulatory definition of "Group Purchasing Organization" required to disclose payments to physicians). MedPAC also suggested that the low number may be due in part to PODs having changed how they compensate physicians "to circumvent reporting requirements." Additionally, MedPAC indicated that the low volume of disclosures could be partially due to the fact that current Open Payments data are not transparent regarding the type of reporting entity, making it difficult to identify PODs definitively. Based on its findings, MedPAC suggested policy changes that would do the following:

    - *Require all PODs to report under the Open Payments program.*
    - *Require each disclosing entity to indicate whether it is a POD, and what type of products it makes or distributes.*
    - *Require CMS to coordinate with OIG and to remind PODs or suspected PODs of their reporting obligations, and to impose penalties for non-compliance.*

2. **Reduce Prevalence of PODs**. MedPAC's Report went further than merely suggesting increased transparency, commenting that actions also should be taken "to reduce the number of PODs." It suggested that such measures could include revisions to physician self-referral regulations, presumably a reference to changes that could be made to the regulations implementing the Stark Law (or the Anti-Kickback Statute). Another measure to reduce the number of PODs could be to require that hospitals adopt policies that curtail purchases from PODs. This consideration is not included in the Report, but is one that was suggested by MedPAC staff to the commissioners in April, and echoes similar recommendations made in 2016 in the SFC report.

The MedPAC commentary adds the voice of Congress's chief advisor on Medicare payment issues to a decade-long trend ringing increasingly loud alarm bells about PODs:

- **2008**: CMS expresses concern that PODs may "serve little purpose other than providing physicians the opportunity to earn economic benefits in exchange for nothing more than ordering medical devices or other products that the physician-investors use on their own patients."

- **2011**: SFC (then) minority staff releases its first report questioning the propriety of PODs, observing "[t]he very nature of PODs seem to create financial incentives for physician investors to use those devices that give them the greatest financial return and that, in the process, patient treatment decisions may be based on personal financial gain."

- **2013**: OIG issues its Special Fraud Alert (SFA) enumerating elements exhibited by PODs that make them "inherently suspect" under the Anti-Kickback Statute, including features common in the POD business model, such as:

  i. the POD offers investment interests primarily or exclusively to physicians who are expected to order or recommend implants sold by the POD;

  ii. the POD primarily or exclusively serves its physician-owners' patient base;

  iii. physician-owners shift to the POD's products on a primary or exclusive basis after joining a POD;

  iv. physician-owners condition their referrals to hospitals by coercion (such as threats that they will go elsewhere unless the hospital buys implants sold by the POD); and

  v. physician-owners are few enough in number that the volume or value of a physician's own referrals correlates closely to investment return.

- **2013**: OIG also publishes the results of its research into actual hospital purchases from PODs, concluding that PODs result in increased utilization of implantable devices compared to procedures performed with implants not acquired by PODs, and yield no cost savings (and in some cases increase costs).

- **2014**: DOJ files a civil case against Reliance Medical Systems LLC (Reliance), two of Reliance's affiliated PODs, and some of their investors for violations of the Anti-Kickback Statute and the False Claims Act. The Complaint is based on the legal theory that physician-owner return on investment in Reliance PODs constitutes a kickback to induce the physicians to order Reliance implants for their own patient procedures, resulting in the submission of false claims to Medicare.

- **2016**: SFC majority staff releases its second report on PODs, relying on evidence collected from its investigations, and stating in stronger terms that the committee is "highly concerned about the damage that PODs have done, and are continuing to do, to patient safety and federal healthcare programs."

- **2017**: A physician involved in the Reliance case is sentenced to 19 years, seven months in prison for $2.8 million in criminal healthcare fraud. The physician admitted to persuading a hospital where he performed procedures to buy the implants that he ordered for those procedures from a Reliance POD, Apex Medical Technologies, in which he had ownership stake. Additionally, the physician conceded that economic benefits of the POD motived him to perform medically unnecessary surgeries.

Despite its forceful denunciation of the POD business model, it is unlikely that the Report will lead to any immediate actions by Congress or Medicare regulators. Congress's attention to health care currently is focused on the "repeal and replace" of Obamacare (which we discuss here), and CMS is similarly involved with considering whether and how to move forward with several Obama Administration initiatives, such as value-based health care (which we discuss here). However, it is significant that another independent inquiry, this one by Congress's chief non-partisan advisor on Medicare policy, has concluded that physician self-referral to PODs ought to be curtailed. The Report will add another arrow to the quiver of False Claims Act *qui tam* relators and law enforcement as they challenge POD relationships. Moreover, in the aftermath of the OIG's 2013 SFA and subsequent report, many hospitals adopted policies forbidding or severely restricting dealing with PODs that exhibit any of the SFA's suspect characteristics. Together with the SFC's 2016 report, MedPAC's commentary will make it that much harder for hospitals and physicians to initiate or maintain relationships with PODs.