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Senate Finance Report Puts another Nail in the POD Coffin

On May 10, 2016, the Senate Finance Committee Majority Staff released a long-awaited report entitled "Physician Owned Distributorships: An Update on Key Issues and Areas of Congressional Concern" (Report). The Report follows the hearing that the Committee held on Physician Owned Distributors of implantable medical devices ("PODs") on November 17, 2015. Although the Committee has been critical of PODs in the past, this Report relies on new data demonstrating that PODs lead to overutilization and increased costs, contains the strongest language yet against PODs, and puts forth specific recommendations for actions by regulators and law enforcement that, if adopted, would go a long way towards putting an end to the POD business model.

Among the Report's important findings and recommendations:

- *Conflict of Interest*: "PODs present an inherent conflict of interest that can put the physician's medical judgment at odds with the patient's best interests."
- *Harm to Patients*: "PODs compromise patient safety as patients receive high-risk treatment beyond what is medically warranted."
- *Overutilization*: "POD doctors see more patients, perform more surgeries, and perform more complex surgeries . . . [which] come at a cost, not only by increasing costs for the entire health care system, but also by harming patients who receive unnecessary treatment."
- *Illegality*: "The business structure and payments associated with certain PODs have been found to be illegal," and physician threats to move their procedures unless hospitals purchase from their POD "would likely violate fraud and abuse laws."
- *Risks to Hospitals*: "[T]he fact that a POD has taken some steps to try to mitigate the risks associated with its business model does not mean that those risks no longer exist. Hospitals face serious risks when they do business with PODs, and the only way to completely eliminate those risks is to not conduct business with any POD or POD-like entity. . . ."
- *Enhanced Hospital Regulation*:
  - Government Accountability Office ("GAO") should evaluate the costs/benefits of requiring hospitals that purchase from PODs to perform enhanced utilization review, and
  - CMS should consider withholding reimbursement from hospitals that have not adopted POD-specific policies and do not document that they consider the Sunshine Act database in making procurement decisions involving medical devices.

The Report begins by stating the Committee staff's concern that physician ownership of and self-referral to PODs result in:

- anti-kickback statute (AKS) and Stark law violations
- physician conflict of interest
- evidence of overutilization and higher health care costs
- danger to patients
- continued medical industry confusion over legality
- lack of transparency of physician ownership, including failure of PODs to meet their legal obligations to report under the Sunshine Act

After summarizing key federal action on PODs – taken by Congress (2011 report, 2015 hearing), Office of Inspector General ("OIG") and CMS (2013 OIG Special Fraud Alert ("SFA") and report on prevalence of use, CMS regulation implementing the Sunshine Act), and the Department of Justice (two criminal and two False Claims Act lawsuits) over the last several years – the Report presents its analysis of several new pieces of evidence.

- *Overutilization*. Relying on a comprehensive data set compiled by CBS News and many other sources, Committee staff reached the "troubling" conclusion that, compared to non-POD surgeons, POD surgeons performed more procedures, including complex procedures, resulting in increased health care costs and harm to patients who receive unnecessary treatment. Specifically, the Report concluded that, compared to non-POD surgeons, POD surgeons:
  - saw 24% more patients
  - performed fusion surgery on nearly twice as many patients
  - performed surgery at a rate 44% higher
  - performed nearly twice as many fusion surgeries

- *Other marketplace changes since the SFA*. The Report also concluded that despite legislative, regulatory and enforcement actions, PODs had continued to proliferate, were having a distorting effect on the cost of health care services, and perhaps because of the growth in hospital procurement policies prohibiting purchasing from PODs, were changing their payment models in an apparent effort to obscure physician involvement.
  - Number of states where PODs operate up from 20 to 43
  - Distortion of prices for related health care services (e.g., testimony that POD profits allow doctors to take unreasonably low managed care rates for physician services)
  - PODs acting to obscure ownership by hiring physicians as employees
  - Increasing numbers of larger hospitals adopting no-POD policies, with resulting migration of PODs to smaller hospitals

The Report concludes with several important findings and recommendations:

- *Finding 1: Lack of Transparency*. PODs operate in an opaque environment and have taken steps to conceal their financial relationships.
  - Disclosure to hospitals and patients. Federal law should require physicians to disclose ownership to hospitals and patients, and patient notices should include the implications and risks associated with PODs, specifically including the risks of unnecessary surgery and patient harm.
  - Require hospitals to use Sunshine database in purchasing. CMS should require hospitals and ASCs to review the Open Payments database and document that they take it into account in making device purchasing decisions.
  - Consider hospital policies avoiding any POD suspect characteristics. CMS and OIG should examine whether further guidance is necessary, including specifically amending OIG's hospital compliance guidance to recommend that hospitals adopt policies that would restrict dealing with PODs "to circumstances that avoid any of the suspect characteristics identified" in the SFA.

- *Finding 2: Overutilization*. "When hospitals purchase products from PODs, the number of surgeries goes up, suggesting that some of the surgeries performed are medically unnecessary or overly complex."
  - Consider enhanced utilization review requirements for POD hospitals. GAO should examine the costs and benefits of CMS's requiring hospitals that choose to purchase from PODs to perform enhanced utilization review.

- *Finding 3: Illegal Behavior*. "The business structure and payments associated with certain PODs have been found to be illegal," and physician threats to move their procedures unless hospitals purchase from their POD "would likely violate fraud and abuse laws."
  - More AKS/Stark enforcement against PODs. Law enforcement should continue to expand efforts to charge and prosecute doctors, PODs and hospitals that violate the law.

- *Finding 4: Hospital Policies*. The adoption by large hospitals and hospital systems of specific POD policies is causing migration of PODs to smaller hospitals.
  - Require SFA-consistent POD policies for all hospitals. All hospitals should adopt specific POD policies consistent with the SFA, and rigorously enforce them.
  - Withhold reimbursement for non-compliant hospitals. CMS should establish a date whereby all hospitals must implement POD policies, and non-compliant hospitals should not be reimbursed for surgeries involving POD-supplied devices.

- *Finding 5: PODs' Changing Payment Structures*. PODs are acting to "circumvent" the AKS and the Sunshine Act.
  - More Sunshine, Stark and AKS enforcement. CMS should undertake increased enforcement of Sunshine Act requirements, CMS and Congress should consider increased penalties for violation, and OIG and law enforcement should investigate potential violations of the Stark Law and the AKS.
  - Expand list of POD suspect characteristics. OIG should study the impact of the SFA and recent DOJ enforcement and update its prior guidance on PODs as needed, in particular considering "whether the list of suspect POD characteristics in the SFA should be revised or expanded".
  - Plug Sunshine employment reporting loophole. CMS should provide additional Sunshine Act guidance to make clear that the exception to reporting requirements for employment applies only to manufacturers (not to GPOs, which is what most PODs are), including standards that would prevent sham employment from qualifying.

Although the Committee heard testimony at last Fall's hearing from both sides of the POD debate, including from the American Association of Surgeon Distributors, the Report is bereft of *any* positive statements, findings or recommendations about PODs. In fact, page one of the Report includes a footnote summarizing its attitude towards the concept of "ethical" PODs: "[T]he fact that a POD has taken some steps to try to mitigate the risks associated with its business model does not mean that the PODs are operating in a legal or ethical manner." In sum, the Report contains nothing but bad news for PODs, and ought to be the most serious reminder yet of the legal risks that physicians and hospitals take when they choose to deal with them.