UNITED STATES SENATE FINANCE COMMITTEE

“PHYSICIAN-OWNED DISTRIBUTORS:
ARE THEY HARMFUL TO PATIENTS AND PAYERS?”

NOVEMBER 17, 2015

STATEMENT FOR THE RECORD:

THE ADVANCED MEDICAL TECHNOLOGY ASSOCIATION (ADVAMED)

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Introduction

The Advanced Medical Technology Association (AdvaMed) appreciates the opportunity to provide a statement for the record for the Senate Finance Committee’s November 17, 2015 hearing entitled “Physician-Owned Distributors (“PODs”): Are They Harmful to Patients and Payers?” Put simply, we believe the answer to this question is “yes.”

AdvaMed is a trade association that represents nearly 300 members, consisting of the world’s leading innovators and manufacturers of medical devices, diagnostics products, and health information systems. Together, our members manufacture much of the life-enhancing health care technology purchased annually in the United States and globally. Our members are committed to the development of new technologies that allow patients to lead longer, healthier, and more productive lives. The devices AdvaMed members make help patients stay healthier longer and recover more quickly after treatment, thus allowing patients to participate more fully at work and in the community. Our constant innovation leads to the introduction of new technologies that prevent illness, allow earlier detection of diseases, and treat patients as effectively and efficiently as possible.

In addition to advancing patient care and creating innovative technology, AdvaMed is committed to serving as a voice for ethics and integrity in the industry. AdvaMed and its member companies recognize that strong ethical standards are critical to ensuring appropriate collaboration between the medical device industry and health care professionals to produce the world’s most advanced medical technologies, to fostering healthy competition, and to helping ensure that patients receive the highest quality, most appropriate care. AdvaMed developed its Code of Ethics on Interactions with Health Care Professionals in order to distinguish between (i) legitimate interactions that result in bona fide contributions to the advancement of medical
technology and (ii) arrangements that may inappropriately influence medical decision-making, pose conflicts of interest for health care professionals, and negatively impact patient care. AdvaMed and its members’ unwavering commitment to ethical conduct and integrity creates a strong foundation upon which the medical device industry can rest, yielding treatment decisions that remain free from conflicts of interest and untainted by inappropriate monetary incentives that could have a lasting (even fatal) impact on patients.

**Physician-Owned Distributors**

While AdvaMed and its members work to promote ethical conduct, PODs “pose dangers to patient safety,” “produce substantial risk of fraud and abuse,” and are “inherently suspect” under the Anti-Kickback Statute, as noted in the U.S. Department of Health and Human Services Office of Inspector General (“OIG”) 2013 Special Fraud Alert. As shown time and again, PODs enter the supply chain as a means for their physician owners, who are in a position to choose product for their patients and hospitals to which they refer patient and to be paid for both the procedure and for the sale of the product. There is no reason for physicians to order devices through PODs (rather than other manufacturers’ implantable products) other than for the physicians to profit from the choice of POD implantable devices for use with their patients. As a result, PODs may incentivize physicians to perform medically unnecessary procedures or to use medically unnecessary products, thereby driving overutilization and causing inefficiencies and overpayments by Federal health care programs.

PODs are focused on selling product to hospitals at which their owners treat their patients and not creating new, groundbreaking medical technology. In order to maximize profits for the

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physician owners, PODs have little – if any – incentive to expend capital on product innovation and regulatory approvals or to purchase and resell innovative products. Instead, PODs give physicians an incentive to order the implants that will benefit them financially rather than to choose the products that are potentially better for their patients. In sum, unlike manufacturers, PODs do not compete based on the quality of their services and products or on good patient outcomes but based on their owners’ ability to dictate to hospitals which products must be purchased for the physician’s use. PODs pose conflicts and ethical concerns that are incompatible with the Anti-Kickback Statute and the Physician Self-Referral Law (“Stark Law”), and a physician’s independent judgment may be compromised when influenced by inappropriate financial incentives.

The prevalence and impact of PODs has grown. PODs have a presence throughout the United States, and these entities are emerging in more sectors of the industry. The government’s own reports demonstrate the potential impact that PODs may have. For example, the OIG’s 2013 Report on Spinal Devices Supplied by Physician-Owned Distributors indicates that in 2011, PODs supplied the devices used in nearly one in five spinal fusion surgeries billed to Medicare, and the POD device costs were not lower than non-POD device costs. Further, when hospitals started to purchase from PODs, the spinal surgery rate grew three times faster than the rate for hospitals overall. The OIG cites 2012 data, wherein hospitals that purchased from PODs performed over 28% more spinal surgeries than those that did not purchase from PODs.²

AdvaMed also points to the recent enforcement action against Dr. Aria Sabit as another example of the potential patient harm, overutilization, and unnecessary procedures that can result

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from inappropriate PODs. In the Sabit case, as the Committee is aware, the government alleged that payments received from Sabit’s POD drove him to perform medically unnecessary or excessive surgeries.

**Recommendations**

AdvaMed applauds the Committee for its efforts to combat illicit POD arrangements. AdvaMed would also like to take this opportunity to emphasize the following points and recommendations:

A. *Distinguish Illicit PODs from Legitimate Innovator Companies*

In any policy or recommendation put forward, AdvaMed urges the Senate Finance Committee, OIG, the Centers for Medicare and Medicaid Services (“CMS”), and other policymakers to distinguish clearly between (i) illicit PODs that inappropriately incentivize physician owners and (ii) legitimate innovator and start-up medical technology companies that may have some element of physician ownership. PODs tend to sell only to a handful of entities, frequently even just one entity, and a majority of a suspect POD’s revenue is derived from its physician owners, their referrals, and/or the procedures they perform using POD-distributed devices. As noted above, this implicates the Anti-Kickback Statute and the Stark Law.

Conversely, innovator medical device manufacturers, which are subject to FDA regulation and state distributor/wholesaler licensure, may also have an element of physician ownership (*e.g.*, as a result of a founding investment or a contribution of novel, significant, or innovative intellectual property, etc.). An innovator manufacturer’s revenue, however, is not tied to physician owners, their referrals, or the procedures they perform using the manufacturer’s products. Rather, these manufacturers (even with some physician ownership) compete based upon innovation and market and sell (or expect to market and sell) products *widely* rather than
primarily to health care facilities where the physician-owners refer patients or perform procedures. Physician ownership interests in these innovator manufacturers form an insignificant portion of the manufacturer’s shareholders. Accordingly, unlike illicit PODs, innovator manufacturers do not implicate the Anti-Kickback Statute or Stark Law.

The following chart details some of the key distinctions between PODs and innovator medical technology companies:

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<th>PODs</th>
<th>Innovator Medical Technology Companies</th>
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<tr>
<td><strong>Physician Ownership?</strong></td>
<td>Yes – physician owners purchase shares for low cost, derive remuneration from referrals of POD products</td>
<td>There may be incidental physician ownership for legitimate reasons, such as an angel investment or contribution of significant IP. Physician ownership accounts for an insignificant portion of the manufacturer’s shareholders</td>
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<tr>
<td><strong>Remuneration Based on Self-Referrals?</strong></td>
<td>Yes</td>
<td>No</td>
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<tr>
<td><strong>Revenue Source?</strong></td>
<td>Derived from physician owners, their referrals, and/or procedures physician owners perform using POD-distributed devices</td>
<td>Not derived from physician ownership; rather, based on standard sales and marketing practices without regard to whether physician owner is using product or referring patients for surgery using product</td>
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<tr>
<td><strong>Customer Base?</strong></td>
<td>Small number of hospitals or other health care facilities where physician owners have privileges or perform procedures</td>
<td>Wide customer base, selected without regard to whether incidental physician owners have privileges or perform procedures there</td>
</tr>
<tr>
<td><strong>Subject to FDA Regulation / State Regulation?</strong></td>
<td>Unclear</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Report under Sunshine Act?</strong></td>
<td>Unclear</td>
<td>Yes</td>
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Despite these distinctions, innovator medical device startups have been disproportionately impacted by hospital policies issued in response to previous Senate Finance Committee and OIG reports. Many hospitals have implemented broad policies that prohibit doing business with any company with any physician ownership, not just PODs. As a result,
many startups with groundbreaking, innovative products are banned from doing business with a particular health care provider simply because one of the founding investors may be a physician. Accordingly, AdvaMed requests that the Senate Finance Committee, the OIG, and other policymakers clearly distinguish between illicit POD arrangements and innovative startup medical device manufacturers in any future recommendations, reports, or other policy proposals.

B. Mandate POD Compliance with the U.S. Physician Payments Sunshine Act

AdvaMed believes that U.S. Physician Payments Sunshine Act (“Sunshine Act”) data can prove to be a beneficial tool in any recommendations or policy proposals and in demonstrating to government investigators the impact and reach of PODs. The Sunshine Act clearly requires that group purchasing organizations (“GPOs”) must file annual reports of payments and transfers of value made to U.S. physicians and teaching hospitals. CMS has been clear that the term “GPOs” includes PODs. Whether PODs are complying with this obligation is unclear. AdvaMed encourages the Senate Finance Committee to urge the OIG and CMS to conduct a detailed review and audit of the Sunshine Act data to determine whether PODs are reporting as required by the Act and, if so, whether any payments might be a violation of the Anti-Kickback Statute or the Stark Law. While exchanges between the Senate Finance Committee, the OIG, and CMS in 2011 resulted in an OIG review of PODs, AdvaMed believes that the time is now for Congress to issue a stronger directive to the OIG and CMS to take action on the 17 months’ worth of Sunshine Act data available for review.

Further, AdvaMed supports clarifying that the Sunshine Act requires all PODs to submit data regarding payments and transfers of value to physicians, including ownership information, regardless of the number of entities with which the POD does business. This does not create an

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implied acknowledgement that PODs are legally appropriate. Rather, clarifying the Sunshine Act’s applicability simply makes explicit that PODs must file annual reports under the Sunshine Act. Whether the payments disclosed on these reports reflect illicit activity is a separate question. According to the OIG, a lack of transparency raises concerns about the OIG’s ability to ensure that providers do not violate the Anti-Kickback Statute and the Stark Law as well as protecting patient safety and quality of care. Indeed, Senator Grassley (R-IA), author of the Sunshine Act, on numerous occasions has quoted Justice Louis D. Brandeis’s line – “Sunshine is the best disinfectant” – in describing the purpose of the Sunshine Act. Transparency of POD relationships with physicians would enable providers and patients to identify more clearly unlawful PODs and conflicts of interest of their treating physicians.

C. Reaffirm and Strengthen the Government’s Policy that PODs are Inherently Incompatible with the Anti-Kickback Statute and the Stark Law

Disclosure of physician ownership interests in PODs and payments made to POD physicians certainly sheds much-needed sunlight on these arrangements. But, transparency alone is not enough to combat inappropriate POD arrangements. Indeed, it may not be possible to assure full POD transparency as shown by the recent OIG report regarding the difficulties in identifying PODs and their physician owners. Using transparency alone as a means of combatting inappropriate POD arrangements also assumes all PODs will report regardless of their business model or practices. Furthermore, disclosure – even under the Sunshine Act – does

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4 The OIG has even stated, “We do not believe that disclosure to a patient of the physician’s financial interest in a POD is sufficient to address these concerns” – i.e. corruption of medical judgment, overutilization, increased costs to the Federal health care programs and beneficiaries, and unfair competition. U.S. Department of Health and Human Services, Office of Inspector General, Special Fraud Alert: Physician Owned Entities (Mar. 26, 2013), available at http://www.oig.hhs.gov/fraud/docs/alertsandbulletins/2013/POD_Special_Fraud_Alert.pdf.

not negate the fact that payments made to a POD’s physician owners in exchange for performing procedures using a POD’s products implicate the Anti-Kickback Statute and the Stark Law, risking fraud and abuse violations and harm to patients. Keeping in mind that the primary reason for the physician owner to choose a POD product over a product supplied to the hospital by a competing manufacturer is that the physician will profit from use of the POD product, using transparency as a lone “ethical” standard for PODs is deeply insufficient to achieve the goals of protecting patients or Federal health care program integrity.

Using transparency as a lone standard may in fact have a reverse consequence. Presumably, a physician’s disclosure about a financial interest in a POD and the POD’s involvement in a particular product could even serve to assure the patient that the physician’s financial interest is immaterial to his/her patient care decisions – i.e. to perform a specific procedure or to choose a specific implant. Patients may not be sufficiently skeptical of their physicians or informed about the risks of conflicts to make meaningful use of such information. Indeed, social science suggests that disclosure of financial conflicts-of-interest may even have the perverse effect of lending credibility to the message of the discloser rather than breeding skepticism.  

Moreover, consumer choice in the implant market operates differently than other markets. Surgeons tend to use the implants that they prefer and a patient’s only choice, if he or

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6 See, e.g., Jason Dana and George Lowenstein, A Social Science Perspective on Gifts to Physicians from Industry, 290 JAMA 252, 254 (July 9, 2003). The authors write:

[T]he general misconceptions about conflict of interest weigh in against the effectiveness of disclosure as an antidote to bias. Disclosure can only be effective if those informed can rationally update their beliefs—discount the advice they receive from physicians who disclose conflicts of interest—in light of the disclosure. However, most patients would have little idea about, for example, how much to discount their physician’s recommendation to participate in a clinical trial if they were informed that their physician would benefit financially from their participation.
she prefers a different product, typically would be to change physicians. Unlike, for example, a
disclosure by an ophthalmologist that the patient may buy eyeglasses from him or take the
prescription elsewhere, physicians do not present their patients with a choice of implants. Even
if they did, patients are not in a position to evaluate whether one is better than another.

It is also worth noting:

- Hospitals conduct product evaluation with physician technology committees
  whose members are not conflicted by an ownership interest in the potential
  supplier. If such individuals were conflicted due to POD ownership, product
  evaluation would provide little assurance with regard to product quality – even if
  the ownership were disclosed.

- Even with POD ownership interests disclosed to a hospital or to patients, a
  distributor’s taking title to product adds no protection against the conflicts of
  interest created by PODs. In fact, this model may raise additional risks with
  regard to compliance with FDA requirements and state laws.

Transparency alone as a safeguard, in other words, is an illusion and provides no
additional protection to hospitals from the anti-competitive effects of PODs nor does it protect
patients because hospitals have little ability to assess the extent to which the financial interest in
the POD influenced the physician owners’ judgment regarding the patient’s treatment or choice
of implant.

Accordingly, AdvaMed strongly urges that the Senate Finance Committee and the OIG
continue to build on the hallmarks of illicit POD arrangements outlined in the OIG’s 2013
Special Fraud Alert (e.g., size of the investment varies based on the volume or value of devices
used by the physicians; physician-owners pay different prices for ownership interests; ownership
is conditioned on referrals to specific health care facilities; etc.) to restate and reaffirm that these types of entities violate the Anti-Kickback Statute and the Stark Law. As noted throughout this statement, inappropriate POD arrangements can permit physician owners to refer patients for procedures using POD-distributed devices or to perform procedures themselves using POD-distributed devices. In either case, the physician benefits from receiving a commission or portion of the POD’s revenue stream based on his/her own referral or use of a product. In the case where the physician owner performs the procedure himself or herself, the physician would also receive payment from a third-party payer for performing the procedure. These scenarios show that a POD’s specific physician ownership status and ability to self-refer are clearly incompatible with the Anti-Kickback Statute and with the Stark Law.

D. Enhance the OIG’s Compliance Program Guidance

Hospitals’ broad policies that prohibit doing business with any company with any element of physician ownership unintentionally limit their ability to purchase goods from legitimate innovator medical technology companies. AdvaMed recommends that the OIG update its Compliance Program Guidance (“CPG”) for hospitals and other health care entities to account for physician-owned companies:

- First, revised CPG should clearly state that inappropriate POD arrangements pose a substantial risk to patient safety and create overutilization, implicate the Anti-Kickback Statute, and the Stark Law, and create a risk of causing health care providers to run afoul of these fraud and abuse laws. CPG should indicate that an effective compliance program includes policies that prohibit business with POD arrangements that meet the criteria of suspect PODs outlined in the OIG’s 2013 Special Fraud Alert.
Additionally, CPG documents should also make clear that an effective compliance program cannot be overly broad. Providers cannot simply prohibit doing business with any physician-owned company. Rather, providers should include exceptions in their policies for doing business with physician-owned companies that distinguish between (i) inappropriate PODs – with which facilities should not do business – and (ii) legitimate innovator companies that may have some appropriate physician ownership but that do not meet the hallmarks of a POD, as outlined in the OIG’s 2013 Special Fraud Alert – with which health care facilities can do business.

Finally, the OIG should update its CPG to require health care facilities’ diligence of vendors and suppliers to include a review of compliance with all applicable FDA and state regulations.

E. Consider a Longer Term Solution to Reexamine the Stark Law

AdvaMed acknowledges that there may be room to draw distinctions between minor or technical violations of the Stark Law (for example, missing signatures on documentation) and violations that pose a clear self-referral conflict of interest (for example, PODs) that the Stark Law was originally intended to prohibit. This longer-term approach is deliberate and time-consuming and requires significant contemplation of the issues and a carefully crafted solution. The time is now, however, for the government to generate more immediate recommendations to prohibit POD arrangements.

Conclusion

In closing, we would like to reiterate our appreciation to Chairman Hatch, Senator Wyden, and the Senate Finance Committee for their work on this issue, and to also emphasize
AdvaMed’s support for policymakers’ efforts to combat illicit PODs. We believe that clear statements regarding the impact of PODs on patients and payers, a strong acknowledgement of the incompatibility of PODs with the Anti-Kickback Statute and Stark Law, and leveraging the Sunshine Act and OIG Compliance Program Guidance are all initiatives to be considered in addressing PODs. Any such initiatives, however, must clearly distinguish between inappropriate POD arrangements and innovator medical technology companies. We appreciate the Committee’s continued leadership on this issue.