Ethics, Compliance, and the PODs Problem

By Matt Wetzel, Advanced Medical Technology Association (AdvaMed), and Jill Wright, Foley & Lardner LLP

On January 9, a U.S. District Court judge sentenced Michigan neurosurgeon Aria Sabit to nearly 20 years in prison on allegations of health care fraud and unlawful distribution of a controlled substance. From 2011 to 2014, spurred by his ownership interest in a physician-owned distributor (POD), Dr. Sabit is alleged to have billed for unnecessary spinal fusion surgeries and products never actually implanted in his patients, thereby defrauding Medicare and private payers. Sabit's POD ownership interest entitled him to a share of company profits in exchange for convincing his hospital to buy the POD's products and using a sufficient number of the POD's devices in his spine surgeries. Sabit, who is alleged to have concealed his POD ownership interest from hospitals and surgery centers, pleaded guilty last year.

Sabit's sentencing caps a year of developments in the area of PODs. Most significantly, on May 10, 2016, the Senate Finance Committee released a long-awaited report expressing serious concerns over PODs.[1] The report strikes a highly skeptical tone about PODs, as does an original 2011 Senate Finance Committee report on PODs[2] and a 2013 Special Fraud Alert on PODs from the U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG).[3] These documents form the primary statements from U.S. government policymakers on PODs, question the legitimacy and legality of certain POD models, and shed significant light on the legal, ethical, and transparency implications of PODs.

According to the Senate Finance Committee's 2016 report, physicians establish PODs in order to derive additional profit from the procedures they perform. The Committee states that PODs:

> [D]erive revenue from selling, or arranging for the sale of, implantable medical devices ordered by their physician-owners for use in procedures the physician-owners perform on their own patients at hospitals or ambulatory surgical centers . . . . [PODs] can have widely varying payment structures, device disbursing methods, owner characteristics, levels of ancillary services provided, and compliance methods. ***However, all PODs are structured to ensure that physician-investors profit from the sale and use of the POD's products that they order for their own patients.***[4]

In other words, the Senate Finance Committee is interested in PODs established to benefit individual physician owners by allowing owners to receive a commission, compensation, distribution, or other payment from the POD in exchange for selling to a hospital a POD product that is used in a procedure performed by the physician-owner or on a patient referred by the physician-owner. In their simplest form, inappropriate POD models permit physician owners to "double dip" into the payment stream—paid to perform the procedure and paid by the POD for the sale to the hospital.

Legal Issues

According to the 2016 report, financial arrangements with PODs raise several legal concerns, including the potential of "violating the Anti-Kickback Statute, the Stark Law, or both."[5] Indeed, the impact of the Anti-Kickback Statute on PODs has been one of the main focuses of policymakers, especially OIG. The Anti-Kickback Statute prohibits knowingly and willfully offering, paying, soliciting, or receiving any remuneration to induce, or in return for, referrals of items or services payable by a federal health care program.[6] The Anti-Kickback Statute can be enforced criminally or administratively against either party to a prohibited kickback. As OIG notes in its Special Fraud Alert, one of the purposes "of the anti-kickback statute is to protect patients from inappropriate medical referrals or recommendations by health care professionals who may be unduly influenced by financial incentives."[7] While OIG also notes that the question of whether a particular POD is permissible under the Anti-Kickback Statute depends on the intent of the parties, the Special Fraud Alert specifically notes that PODs are inherently suspect under the law.[8]

Conflicts of Interest

In addition to the legal issues PODs raise, the Senate Finance Committee emphasizes the conflicts of interest that these arrangements implicate. The report clarifies that POD owners' financial incentive to perform surgeries "may compromise a doctor's medical judgment and place financial incentives at odds with the best interest of the patient."[9] The report includes a joint statement released by the Committee Chairman, Senator

Orrin Hatch (R-UT), and Ranking Member, Senator Ron Wyden (D-OR), in connection with a November 2015 Senate Finance Committee hearing that makes plain the conflict of interest that PODs create:

> While the vast majority of doctors operate with the highest ethical standards, those with a vested stake in medical device distributorships raise a number of concerning questions about the physician's motivation in prescribing a procedure, as well as the overall cost to the health care system. When physicians have a financial incentive to recommend and perform a surgery, a potential conflict of interest can occur and jeopardize the health of patients.[10]

The Committee also describes the convergence of physicians' heavy influences on (a) hospital purchasing decisions, which "can give PODs spinal surgeons the opportunity to grant themselves a steady stream of income by increasing the use of the products supplied by their POD";[11] (b) the frequency and type of surgeries performed;[12] and (c) patients' decision-making, noting the likelihood that patients will follow their doctors' recommendations.[13] In other words, physicians often not only appear to have a financial incentive that could impact the independence of medical judgment, but a physician may also have the influence to push a POD product in the waiting room, the operating room, and the board room. The result is an anticompetitive position that drives up use, cost, and patient risk.

Overutilization

The report notes that POD models result in overutilization, as physicians may consider performing "additional, more complex, or medically unnecessary surgeries" in order to attain additional remuneration.[14] Indeed, the Committee and the OIG both look at spinal implant data to conclude that PODs result in overutilization and higher costs for federal health care programs.[15]

Patient Safety

The Committee clearly notes that PODs compromise patient safety, stating that "[a]ny unnecessary medical procedure increases the risk that the patient may be harmed."[16] The Committee cites "extremely troubling reports of POD surgeons performing revision surgery to replace previously implanted hardware with the same or nearly equivalent hardware sold by their own PODs."[17]

As noted above, the most well-known instance of a POD physician's impact on patient safety is the Sabit case. The significance of Sabit's sentence (20 years) reflects the patient harm he is alleged to have caused in the course of defrauding private and public payers of millions of dollars. According to the report, Sabit's patients not only had "poor outcomes," but two patients died and 28 patients sued Sabit for malpractice.[18] As a result, the report goes as far as stating that the Committee "fully supports DOJ efforts to prosecute surgeons who put patients at risk for personal financial gain."[19]

Increased Costs

While many PODs have asserted that these business models are intended to lower costs for hospitals, the Committee disagrees, finding that costs are increased due to PODs and their anticompetitive behavior. The Committee report quotes Dr. Scott Lederhaus, President of the Association for Medical Ethics, who states:

> On the basic question of competition, PODs eliminate it. Because implants are physician preference items, once physicians invest in a POD, the hospitals . . . where they perform their procedures either buy from the POD, or the physicians will take their cases elsewhere . . . . Physicians whose income is supplemented by their self-referral earnings from a POD can agree to what would otherwise be unrealistically low insurance reimbursement rates for their physician services. Thus, the physicians who are members of a POD can simply eliminate competition between the POD and non-POD physicians by signing ridiculously low reimbursement healthcare contracts.[20]

Transparency Issues

In addition to conflicts of interest, overutilization, patient safety concerns, and anticompetitive and cost concerns, there is very little transparency around PODs, and PODs generally do not comply with various financial disclosure requirements. This includes failing to comply with obligations found in the Physician Payments Sunshine Act (Sunshine Act).[21] The Committee clarifies that PODs in fact *should* be filing annual reports under the Sunshine Act, noting that the Centers for Medicare and Medicaid Services (CMS) explicitly included PODs as entities required to report under the transparency measure.[22] Even so, according to the report, PODs do not comply with the Sunshine Act and the "gaps" in reporting occlude data on physicians' financial interests, which is precisely what the Sunshine Act was intended to reveal.[23]

Distinguishing Legitimate Manufacturers from PODs

Given all of the legal and ethical concerns that PODs raise, many hospitals have developed policies that prohibit engaging in business relationships with PODs. The Committee report encourages hospitals to construct internal policies and vendor due diligence processes to "enable early identification of POD suppliers."[24]

But, importantly, the Committee also makes clear that such policies should not stymie innovation or limit the ability of physicians to invent and develop new technologies. According to the report, physician ownership in a company is not, by itself, impermissible and in the case of legitimate, start-up innovator companies, is allowable.[25] Many small, start-up manufacturers may exchange equity for physician intellectual property or for bona fide consulting or research and development efforts, among other reasons. These are not the type of companies that hospital POD policies should encompass. In fact, the Committee is emphatic that "hospitals must be able to recognize that certain physician ownership in legitimate innovator companies is allow-

able, and to differentiate legitimate physician-owned businesses from problematic POD arrangements."[26]

> These companies are manufacturers who may have a relatively small portion of physician ownership (examples include physician ownership as a result of an initial capital investment, or development of new or innovative intellectual property) which generally diminishes as the company's products gain market acceptance. Unlike PODs, these companies widely market and sell their products to healthcare facilities where their physician owners do not practice, and in addition, physician owners' revenue is not tied to their referrals or usage of the company's devices.[27]

In other words, physician ownership alone is not the hallmark of an illicit POD, and a hospital due diligence program goes too far to the extent that it prohibits doing business with any company with an element of physician ownership.

After examining the legal issues, conflicts of interest, over-utilization, patient safety, and transparency concerns and highlighting the need for reasonable hospital policies that differentiate between troublesome PODs and legitimate manufacturers, the Senate Finance Committee's report concludes with a series of five findings and nine related recommendations, which are excerpted below:[28]

FINDINGS	RELATED RECOMMENDATIONS
Finding 1: Lack of Transparency Federal law does not currently require disclosure of physician ownership directly to hospitals or patients. Hospitals and patients furthermore face many challenges identifying if physicians have a financial relationship with PODs. Overall, PODs operate in a very opaque environment and some PODs have taken steps to conceal their financial relationships.	***Recommendation 1:*** Federal law should require physicians to disclose any ownership that they or their family members have in non-publicly traded device companies to the hospitals where they practice, and should also require disclosure to patients. Patients should also be notified and instructed of the implications and risks associated with physician ownership in device companies specifically including the risks of unnecessary procedures and patient harm. ***Recommendation 2:*** CMS should require hospitals and ambulatory surgical centers to examine the Open Payments data collected under the Sunshine Act, and document that they have taken such data into account when making device purchasing decisions. ***Recommendation 3:*** CMS and OIG should examine whether current compliance guidance about PODs is sufficient, or if it should be supplemented in response to changes in the industry. In particular, consideration should be given to amending the OIG compliance guidance for hospitals to recommend that hospitals adopt policies that would restrict dealing with PODs to circumstances that avoid any of the suspect characteristics identified in the OIG Special Fraud Alert (SFA).
Finding 2: PODs Result in 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.	***Recommendation 1:*** The Government Accountability Office (GAO) should examine the costs and benefits of CMS requiring hospitals that choose to purchase from PODs to perform enhanced quality assurance and utilization review activities for surgeries using POD-supplied products.
Finding 3: POD Illegal Behavior The business structure and payments associated with certain PODs have been found to be illegal. Overt or implied threats made by physicians to move their practice unless a hospital accepts their POD would likely violate fraud and abuse laws.	***Recommendation 1:*** Law enforcement should continue and expand their efforts to charge and prosecute those doctors, PODs, and hospitals that violate the law.

FINDINGS	RELATED RECOMMENDATIONS
Finding 4: Hospital Policies Many large hospitals and hospital systems have adopted policies to govern their relationships with PODs. However, many small hospitals do not have a POD-specific policy governing their interactions with PODs, and as a result PODs are migrating from large hospitals to small hospitals.	***Recommendation 1:*** All hospitals should establish their own hospital-specific policies to manage their relationship with PODs consistent with the OIG SFA and any further guidance to be promulgated by OIG under Finding1/Recommendation 3. Hospitals should draft comprehensive policies to address PODs and should rigorously enforce them. 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 until they have developed and implemented a POD-specific policy.
Finding 5: PODs' Changing Payment Structures PODs have shifted to alternative payment structures in an attempt to circumvent the Anti-Kickback Statute and the Sunshine Act. Some PODs are declaring physicians to be employees rather than investors and having companies make payments to physicians under the name of a family member or friend.	***Recommendation 1:*** CMS should undertake increased enforcement actions to ensure compliance with Sunshine Act reporting requirements. CMS and Congress should examine the benefit of increased penalties for intentional violations of the Sunshine Act. OIG and law enforcement should investigate potential violations of the Stark Law and the Anti-Kickback Statute. ***Recommendation 2:*** OIG should study the impact of the SFA and recent litigation on PODs and update its 2013 report and SFA as needed. In particular, OIG should consider whether the list of suspect POD characteristics in the SFA should be revised or expanded to account for developments since its issuance. ***Recommendation 3:*** CMS should provide additional Sunshine Act guidance or rulemaking to make clear that the exception from reporting requirements for employment applies only to manufacturers (not Group Purchasing Organizations), and only to bona fide employment, including standards that would preclude sham "employment" relationships from qualifying.

Interview

Matt Wetzel also conducted an interview with Jill Wright, Special Counsel at Foley & Lardner LLP, about the legal, ethical, and compliance issues associated with PODs as identified in the recent U.S. Senate Finance Committee report on this critical health care fraud and abuse topic.

MW: Jill, you have committed much of your career to the issue of PODs. Please share with us your background and how your interest in PODs developed.

JW: I started my career with the federal government in 2007, and for nearly a decade, I worked for HHS. I began my time at HHS with the HHS Departmental Appeals Board as an advisor to administrative law judges who hear, among other things, appeals of OIG exclusions and civil monetary penalties. In 2010, I moved to HHS OIG, where I served as senior counsel for six and a half years. At OIG, I worked on OIG exclusion and civil monetary penalty matters, as well as False Claims Act matters, including those arising under the Anti-Kickback Statute. In 2015, while still working for OIG, I was asked to go on a detail to the Senate Finance Committee to work with the oversight staff on health care issues. At the Finance Committee, I had the opportunity to work on PODs issues, including the Committee's 2015 hearing and 2016 report.

MW: In your expert opinion, what are the most critical legal or ethical aspects of PODs, as highlighted in the Senate Finance Committee's 2016 report or the 2013 OIG Special Fraud Alert?

JW: I see three key, interrelated issues. First and most significant is the potential for patient harm and the quality of care issues that PODs can raise. The case that best exemplifies why the government is concerned about PODs is that of the neurosurgeon Aria Sabit. A recent DOJ press release noted that

Sabit admitted the financial incentives that he received from a POD caused him to use more spinal implants in surgeries than were medically necessary to generate sales revenue for the POD, which resulted in serious injury to his patients. Sabit also admitted that, in a few instances, the money he made from using the POD's devices motivated him to refer patients for unnecessary spine surgeries or for more complex procedures. The patients' stories have been covered by the media, and they are harrowing. Kevin Reynolds, the son of a patient who lost her life after receiving a complicated spinal fusion surgery performed by Sabit, shared his family's experience with Senate Finance Committee at its 2015 PODs hearing.

In 2015, Sabit pleaded guilty to conspiracy and health care fraud, but the federal judge presiding over his case refused to accept the plea deal, under which Sabit would have faced a maximum of 11 years in prison. At that point, not all of Sabit's victims had been notified of the opportunity to be heard before a sentencing determination was made, and some of the victim impact statements had not been filed with the court until the day Sabit would have been sentenced. On January 9, 2017, over a year after the initial plea deal was rejected, Sabit was sentenced to nearly 20 years in prison.

Second, having focused much of my professional career on protecting federal health care programs and beneficiaries, I find the Senate Finance Committee and OIG conclusions regarding overutilization to be particularly noteworthy. According to the Senate Finance Committee report, POD doctors appear to be over-utilizing spinal implant products. A 2013 OIG report found that when hospitals began purchasing from a POD, their rates of spinal surgery grew approximately three times faster than the rate for hospitals overall. In that same report, OIG found that hospitals that purchased POD products performed over 28% more spinal surgeries than those that did not purchase from a POD. Such overutilization results in higher costs for the entire health care system, and particularly for Medicare. Sabit's scheme cost taxpayers and insurance companies $11 million for fraudulent services.

But, more important than the financial costs associated with overutilization are the costs to patients' health and well-being, particularly when considering complicated surgeries like spinal fusion. Going back to the Sabit case, patients went to him seeking pain relief. They were willing to undergo a difficult surgery and rehabilitation to relieve their pain. Instead, many patients found themselves in more pain and in some cases with less mobility.

Finally, to understand PODs' commercial operations and for patients and the public to understand physicians' financial arrangements, greater transparency is a must. As the Senate Finance Committee has reported, there is a dearth of publicly available information on PODs, including which physicians are owners, who benefits from ownership, the terms of ownership, and more. In the 2016 report, the Committee recommends that CMS and OIG examine whether current Sunshine Act guidance on the topic is sufficient and calls on hospitals and providers to examine Sunshine data in the course of conducting vendor due diligence. Without greater clarity in the information reported and without stronger measures to require all PODs to report under the Sunshine Act, the lack of information available to patients and the public obstructs efforts to eliminate POD-related risks.

MW: We've seen a great deal about PODs over the last decade. The Senate Finance Committee in particular has issued the clearest and most critical statements about PODs in several years. What changes have we seen over the last few years? Has the growth of PODs slowed at all?

JW: The growth of PODs has continued. The Senate Finance Committee and OIG noted that it is impossible to know exactly how many PODs are out there because of the lack of transparency, but we know that PODs are growing in prevalence geographically (the Finance Committee report states that PODs are operating in 43 states and the District of Columbia). PODs appear to be moving away from large hospital chains and toward smaller, rural hospitals. Although the majority of known PODs are in the spinal surgery field, PODs are also reportedly moving to other areas. Even more unsettling are accounts that PODs are changing their payment models to further obscure financial relationships with owners—for example, classifying surgeons as employees instead of owners, requesting payments to be made to family members instead of owners directly, or outsourcing payments to third parties who make payments to surgeons. In my new role at Foley & Lardner, I've seen how challenging it can be for hospitals to identify physician financial interests if the physician or POD is seeking to obscure it. But some reasonable hospital policies should be able to flag the vast majority of these types of transactions for individualized consideration.

MW: Why do you think the Senate Finance Committee and OIG have taken such a great interest in PODs?

JW: In addition to protecting the public fisc, policymakers have been moved by the dreadful experiences of patients at the hands of some unscrupulous POD physicians. When Kevin Reynolds, the son of one of Sabit's patients, testified at the Finance Committee hearing, it made a strong impression on the senators and everyone else in the room. Mr. Reynolds, testified that Sabit did not disclose his financial stake in the POD—or the fact that he would profit from using the POD's products in the surgery—to Mr. Reynolds or his mother. Instead, Mr. Reynolds testified, Sabit told them that he would perform a level 1 spinal fusion and then, without obtaining consent for a more complex surgery, Sabit performed a level 4 surgery.

Mr. Reynolds testified that he believed "Sabit had a clear financial incentive to use more screws and rods in my mother's back surgery" and that the "financial incentive played a role in [Sabit's] decision to perform more complex surgery on her that was not medically necessary." His testimony was extremely compelling. It illustrates why conflicts of interest are dangerous in medicine, which is why we have laws like the Anti-Kickback Statute. It also gives a face to the patients and families that were affected by Sabit's actions. In his plea deal, Sabit admitted that his financial incentives "caused him to compromise his

medical judgment" and to "over instrument" his patients to generate more sales revenue for his POD. Patients' stories can be powerful motivators, especially when they show that performing medically unnecessary surgeries or over-instrumenting in surgeries is not merely a financial crime. The results were devastating for many of Sabit's patients.

MW: Is the Sabit sentencing sufficient to send a message to POD owners about the risks PODs pose?

JW: For some owners of improper PODs, but not all. Most POD owners likely do not perceive their arrangements as raising the same extreme risk profile—patient harm, clear overutilization, false billing, etc.—as raised by Sabit. Accordingly, POD owners may not view their actions and Sabit's extreme actions as raising the same ethical, legal, and compliance-related concerns, and therefore the sentencing may not deter other POD owners.

Sabit is clearly an outlier in the medical profession, but his behavior shows the extreme scenario of what can happen when surgeons have a financial incentive to perform more procedures or use more devices. This does not mean that all PODs are necessarily unethical or illegal. A carefully structured entity with physician ownership may survive OIG scrutiny, particularly where safeguards are included to address concerns outlined in the Senate Finance Committee report and the Special Fraud Alert. As OIG stated in the Special Fraud Alert, "the lawfulness of any particular POD under the Anti-Kickback Statute depends on the intent of the parties." The POD's characteristics can shed light on the parties' intent, and in the Special Fraud Alert, OIG listed many characteristics that would weigh in favor of finding an intent to induce referrals. But, OIG and the Senate Finance Committee have concluded that PODs are inherently suspect under the Anti-Kickback Statute, and I think that suggests that most PODs should anticipate intense scrutiny from OIG. Besides the OIG's interpretation, the Department of Justice has shown its commitment to fighting health care fraud and protecting patients from physicians who compromise their medical judgment to enrich themselves.

MW: Recognizing that financial incentives can be huge, it still seems that the risks associated with PODs would outweigh the potential benefits. Why are physicians willing to invest in PODs?

JW: Many do not believe that financial interests would influence their own medical judgment or the medical judgment of good physicians. One of the witnesses at the Finance Committee hearing testified to that effect. The thinking is, good physicians will not make decisions based solely on personal gain. That's true for most physicians, but many of our fraud and abuse laws were passed because inappropriate financial incentives have been found to cloud medical judgment.

For some physicians, PODs' financial incentives seem too good to pass up. In Dr. Sabit's case, the owners of the device manufacturer, Reliance, set up several PODs through which to sell their products to hospitals. The Department of Justice has alleged that Reliance's owners were recorded telling a potential POD investor that Reliance pays its physician-investors enough in the first month or two to "put their kids through college." The owners also allegedly told the potential investor that Reliance was formed to "get around" the Anti-Kickback Statute, a statement that hopefully would spark further inquiry by any potential investor.

MW: Thank you very much, Jill, for your clear thinking on the topic of PODs. Two closing questions: are there any aspects of POD business models that you would highlight for other lawyers representing hospitals, physician groups, and other providers? What policy changes or steps would assist lawmakers and others who seek to combat the ethical and legal issues that PODs raise?

JW: I would point to two concepts. First, it's important to recognize the Finance Committee report's call for hospitals and other providers to distinguish between legitimate manufacturers and inappropriate POD arrangements. Hospitals are in a tough position, and many have opted to forgo purchasing products with any physician ownership. While this may seem like a safe approach, it could also end up depriving patients of cutting-edge technologies. Hospital policies should draw careful lines between PODs that display the suspect characteristics that OIG outlines in its 2013 Special Fraud Alert and legitimate medical technology manufacturers. An overly broad policy, for example, would prohibit business with legitimate manufacturers, which can lead to losing access to innovative medical technology that start-ups produce.

Second, public and patient awareness about the issue is critical. Public and patient access to information about their physicians' financial arrangements with PODs can only benefit the delivery of quality health care by allowing people to ask questions and to take an active, informed role in their own care.

About the Authors

Matt Wetzel is Vice President & Assistant General Counsel of the Advanced Medical Technology Association (AdvaMed), the world's largest trade association of medical device manufacturers. At AdvaMed, Mr. Wetzel leads several global working groups and advocates on behalf of the medical device industry with respect to many key legal issues related to health care fraud and abuse, anti-bribery/anti-corruption measures, physician-industry transparency, and distribution licensure, among others. Prior to joining AdvaMed, Mr. Wetzel served as Senior Counsel, Global Compliance and Ethics at Boston Scientific, where he oversaw several critical elements of the company's global compliance and privacy programs and advised on a variety of legal issues. Previously, Mr. Wetzel practiced law at Reed Smith LLP and Latham & Watkins LLP. Mr. Wetzel is a trained executive and career coach, a member of the AHLA Diversity & Inclusion Council, a Fellow of the Leadership Council on Legal Diversity, and a member of the Board of

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Jill Wright is special counsel and a business lawyer with Foley & Lardner LLP, and a member of the firm's health care practice in the Washington, DC office. Jill joined Foley in September 2016, from the U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG) and the U.S. Senate Committee on Finance. At the OIG, Jill handled cases involving fraud and abuse and compliance issues, including the federal anti-kickback statute and physician self-referral (Stark) law; the civil monetary penalties law; false claims and overpayments; government investigations; and exclusions from federal health care programs. Prior to her time at the OIG, Jill worked at HHS's Departmental Appeals Board, where she advised administrative law judges regarding appeals from federal enforcement determinations related to Medicare and Medicaid compliance and other federal health law enforcement. As senior oversight counsel at the U.S. Senate Committee on Finance on detail from the OIG, Jill helped lead the committee's recent efforts to reform the Stark law and to improve the Medicare audit and appeals processes with the proposed legislation The Audit & Appeal Fairness, Integrity, and Reforms in Medicare Act of 2015.

Endnotes

1 Staff of S. Finance Committee, 114th Cong., *Physician Owned Distributorships: An Update on Key Issues and Areas of Congressional Concern* (Comm. Print 2016) (hereinafter Senate Finance Committee Report).

2 Staff of S. Finance Committee, 111th Cong., *Physician Owned Distributorships: An Overview of Key Issues and Potential Areas for Congressional Concern* (Comm. Print 2011).

3 Department of Health and Human Services Office of Inspector General, Special Fraud Alert: Physician-Owned Entities, 78 Fed. Reg. 19271 (March 29, 2013) (hereinafter OIG Special Fraud Alert).

4 Senate Finance Committee Report, *supra* note 1, at 1 (quoting OIG Special Fraud Alert, *supra* note 3, at 19271) (emphasis added).

5 Senate Finance Committee Report, *supra* note 1, at 2

6 See 42 U.S.C. § 1320a-7b.

7 OIG Special Fraud Alert, *supra* note 3, at 19272.

8 *See id.*

9 Senate Finance Committee Report, *supra* note 1, at 2.

10 *Id.* at 6.

11 *Id.* at 1 (emphasis added). The Committee notes that especially with respect to spinal surgeries, "hospitals typically purchase the devices recommended by their surgeons." *Id.*

12 *Id.* Indeed, the OIG's 2013 Special Fraud Alert identifies as one of eight suspect characteristics of problematic PODs the concept of physician-owners conditioning their referrals to hospitals or ASCs on their purchase of the POD's devices through coercion or promises, for example, by stating or implying they will perform surgeries or refer patients elsewhere if a hospital or an ASC does not purchase devices from the POD, by promising or implying they will move surgeries to the hospital or ASC if it purchases devices from the POD, or by requiring a hospital or an ASC to enter into an exclusive purchase arrangement with the POD. Special Fraud Alert, *supra* note 2, at 19272.
The other suspect characteristics of PODs according to OIG are:
- The size of the investment offered to each physician varies with the expected or actual volume or value of devices used by the physician.
- Distributions are not made in proportion to ownership interest, or physician-owners pay different prices for their ownership interests, because of the expected or actual volume or value of devices used by the physicians.
- Physician-owners are required, pressured, or actively encouraged to refer, recommend, or arrange for the purchase of the devices sold by the POD or, conversely, are threatened with, or experience, negative repercussions (e.g., decreased distributions, required divestiture) for failing to use the POD's devices for their patients.
- The POD retains the right to repurchase a physician-owner's interest for the physician's failure or inability (through relocation, retirement, or otherwise) to refer, recommend, or arrange for the purchase of the POD's devices.
- The POD is a shell entity that does not conduct appropriate product evaluations, maintain or manage sufficient inventory in its own facility, or employ or otherwise contract with personnel necessary for operations.
- The POD does not maintain continuous oversight of all distribution functions.
- When a hospital or an ASC requires physicians to disclose conflicts of interest, the POD's physician-owners either fail to inform the hospital or ASC of, or actively conceal through misrepresentations, their ownership interest in the POD. *Id.* at 19272-73.

13 *See* Senate Finance Committee Report, *supra* note 1, at 1.

14 *See id.* at 2-3.

15 *See id.* at 3. Senate Finance Committee staff, in assembling the report, analyzed data related to spinal fusion surgeries from 2011-2012. The Committee found that (a) POD surgeons saw 24% more patients than non-POD surgeons; (b) POD surgeons performed spinal fusion surgery on nearly twice as many patients (91% more) as non-POD surgeons); and (c) POD surgeons performed nearly twice as many fusion surgeries (94%) as non-POD surgeons. *See id.* at 2, 14-15.

16 *Id.*

17 *Id.*

18 *Id.* at 10. Indeed, Kevin Reynolds, the son of Lillian Kaulbach, one of Sabit's patients who died as a result of treatment, has been a vocal advocate for patients' rights and transparency in response to his family's encounter with a POD physician. Mr. Reynolds was a witness at the Senate Finance Committee's November 2015 hearing on PODs, and his testimony is discussed below.

19 *Id.* at 13. The Committee cites to a statement from Assistant Attorney General Leslie Caldwell, who stated in response to Sabit's guilty plea: Doctors who sell their medical judgment and ethics for personal profit endanger the lives and safety of vulnerable patients who count on their advice to make life-altering decisions. The Criminal Division of the Department of Justice will continue to prioritize the prosecution of doctors whose criminal behavior puts patients at risk. *Id.* (citing a U.S. government press release dated May 22, 2015).

20 *Id.* at 17.

21 *See id.* at 3; *see also* 42 U.S.C. § 1320a-7h(a).

22 *See* Senate Finance Committee Report, *supra* note 1, at 5, 10 (referencing Centers for Medicare & Medicaid Services, Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests, 78 Fed. Reg. 9458, 9493 (Feb. 8, 2013)) (Preamble to the final rule explains that Group Purchasing Organizations required to report physician ownership under the Sunshine Act "would include, for example, physician owned distributors (PODs) of covered drugs, devices, biologicals, and medical supplies." CMS recognized that not all POD models would be captured by its definition, but noted its intent "to capture as many PODs as possible . . . .").

23 *See* Senate Finance Committee Report, *supra* note 1, at 10. The Committee points to PODs' modifying their business models "in order to hide their financial relationships with surgeons," including classifying surgeons as employees (not owners) and paying owners' family and friends instead of the physician owners themselves. *See id.* at 17-18.

24 *Id.* at 22.

25 *See id.* at 20.

26 *Id.*

27 *Id.*

28 Senate Finance Committee Report, *supra* note 1, at 24-25.