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Note, Physician-Owned Distributorships

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NOTES

PHYSICIAN-OWNED DISTRIBUTORSHIPS

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While there is little consensus for how to go about fixing health care in America, one can hardly disagree that the current health care status quo is deeply flawed.[1] Health care spending is out of control—2013 U.S. health care spending reached a staggering $2.9 trillion, representing 17.4% of the Gross Domestic Product.[2] Despite the fact that the U.S. spends more on health care than any other country, both in the aggregate and per capita, it lags behind other countries in the quality of care.[3] Escalating costs threaten affordability of care and access, and are only partially attributed to the rampant fraud,[4] waste,[5] and

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1. *See, e.g.*, UMANG MALHOTRA, SOLVING THE AMERICAN HEALTH CARE CRISIS: SIMPLY COMMON SENSE 124 (2009) ("The Health industry is the fastest growing economy in the U.S., wherein money and profit have become the important and integral factors rather than a patient's health care. The current fragmented health care system in the U.S. is more prone to scandals, greed, and bureaucracy, than the health care systems of other rich countries."); *see also* Michael Lee, Note, *Unilateralism, Defunding, and the Shrapnel of Health Reform*, 29 YALE L. & POL'Y REV. 41, 48 (2011) (describing the nation's health care industry as having an "extraordinarily-flawed status quo").

2. *NHE Fact Sheet*, CTRS. FOR MEDICARE AND MEDICAID SERVS., http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NHE-Fact-Sheet.html (last updated July 28, 2015).

3. *See* KAREN DAVIS ET AL., THE COMMONWEALTH FUND, MIRROR, MIRROR ON THE WALL: HOW THE PERFORMANCE OF THE U.S. HEALTH CARE SYSTEM COMPARES INTERNATIONALLY 7 (2014) ("The United States health care system is the most expensive in the world, but . . . the U.S. underperforms relative to other countries on most dimensions of performance. Among the 11 nations studied in this report—Australia, Canada, France, Germany, the Netherlands, New Zealand, Norway, Sweden, Switzerland, the United Kingdom, and the United States—the U.S. ranks last, as it did in . . . 2010, 2007, 2006, and 2004 . . . .").

4. Though the extent of health care fraud is not known, it is estimated that Medicare and Medicaid programs each lose anywhere from $20 billion to more than $100 billion annually. *See* Press Release, U.S. Senate Comm. on Fin., Hatch, Baucus Lead Finance Committee Members in Bipartisan Effort to Combat Waste, Fraud, and Abuse in Medicare & Medicaid Programs (May 2, 2012), http://www.finance.senate.gov/news-

abuse that pervade the health care system. These statistics illuminate the urgency for reducing costs, improving quality, and eliminating fraud, waste, and abuse. In response to these challenges, a number of innovative business structures have emerged as potential solutions for financing and delivering heath care.

The physician-owned distributor ("POD") is one example of the various business entities that have materialized. In recent years, a hot debate has ensued over whether PODs are legitimate business arrangements that offer solutions, or instead exacerbate industry challenges and implicate improper conduct. This Note will assess both sides of the debate and take the position that the harms created by the existence of PODs dwarf any potential benefits. PODs create conflicts of interest and are susceptible to abuse, working against the goals of health care reform—improving quality, affordability, and accessibility.

Part I of this Note will provide an overview of the health care status quo, the POD business model, and the legal landscape in which PODs operate. Part II will examine the problematic nature of PODs and demonstrate the need for legal clarity. In Part III, I propose that PODs should be deemed unlawful business arrangements and I recommend how to address them in the future. I conclude by reiterating that the conflicts of interest and potential for abuse stemming from PODs are not palatable, and that government action is necessary. Even if legislatures and regulatory agencies choose not to regulate PODs, one thing is for sure: PODs are in the government's crosshairs and additional enforcement actions are just over the horizon.

I. BACKGROUND

A. *The Flawed Status Quo*

Today's health care challenges are not new and can be linked to past policy choices. For decades, the U.S. health care system predominantly used a fee-for-service model, in which physicians and hospitals were compensated for each service performed and had full discretion over treatment decisions, incentivizing overutilization and increased costs.[6] The implantable medical device market also has challenges.

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room/ranking/release/?id=d2527088-4f4c-434f-863f-5e980aaa2637; *see also Financial Crimes Report to the Public: Fiscal Years 2010–2011*, FED. BUREAU OF INVESTIGATION, http://www.fbi.gov/stats-services/publications/financial-crimes-report-2010-2011 (last visited Mar. 5, 2016) ("Estimates of fraudulent billings to health care programs, both public and private, are estimated between 3 and 10 percent of total health care expenditures.").

5. *See* INST. OF MED., BEST CARE AT LOWER COST: THE PATH TO CONTINUOUSLY LEARNING HEALTH CARE IN AMERICA 104 (Mark Smith et al. eds., 2015) (stating total amount of unnecessary health care costs and waste in 2009 was an estimated $750–765 billion, more than a third of total health care expenditures); *see also* PRICEWATERHOUSECOOPERS, THE PRICE OF EXCESS: IDENTIFYING WASTE IN HEALTH CARE SPENDING 1 (2008), http://www.pwc.com/us/en/healthcare/publications/the-price-of-excess.html ("Wasteful spending in the health system has been calculated at up to $1.2 trillion of the $2.2 trillion spent in the United States, more than half of all health spending.").

6. *See generally Farewell to Fee-For-Service?: A "Real World" Strategy for Health Care Payment Reform* (UnitedHealth Ctr. for Health Reform & Modernization, Working Paper No. 8, 2012); *see also* MAURA CALSYN & EMILY OSHIMA LEE, CTR. FOR AM. PROGRESS, ALTERNATIVES

Generally speaking, the market suffers from a lack of transparency, especially around pricing and cost. The orthopedic implant sector is a "highly consolidated market" that controls about ninety-five percent of the worldwide market share for hips and knees.[7] Historically, major device manufacturers have exercised tight control over product pricing, thus benefitting from some of the highest profit margins in the industry.[8] Generally, implant prices have increased an average of eight percent annually, designs have remained the same for decades, and there is minimal differentiation between vendors. Such profit margins, as well as improper payments and conflicts of interest, contribute to the rising cost of health care.[9]

In the traditional supply model for implantable devices, manufacturers sell devices directly to end purchasers.[10] Manufacturers often rely on an intermediary, usually an employee or independent contractor working as a sales representative, to deliver the device to the end purchaser.[11] These individuals frequently advise the physician in the operating room during surgical procedures. Due to the technical nature of implantable devices, this support was included in the cost of the device and seen as a value-added service.[12] Rising health care costs

TO FEE-FOR-SERVICE PAYMENTS IN HEALTH CARE: MOVING FROM VOLUME TO VALUE 2 (2012) (stating that fee-for-service payments drive up costs and potentially lower value because they encourage wasteful use and fail to align financial incentives).

7. Jaimy Lee, *Devicemaker Sales Reps Being Replaced in the OR*, MODERN HEALTHCARE (Aug. 16, 2014), http://www.modernhealthcare.com/article/20140816/MAGAZINE/308169980.

8. *See* JAY K. WHITAKER, HOW CAN HOSPITALS SIGNIFICANTLY REDUCE THE COST OF PURCHASING ORTHOPEDIC MEDICAL DEVICES? 22 (2013).

9. *See, e.g.*, Press Release, U.S. Dep't of Justice, Monitoring and Deferred Prosecution Agreements Terminated with Companies in Hip and Knee Replacement Industry (March 30, 2009), http://www.justice.gov/usao/nj/Press/files/pdffiles/2009/hips0330%20rel.pdf.

10. YASAR A. OZCAN, QUANTITATIVE METHODS IN HEALTH CARE MANAGEMENT: TECHNIQUES AND APPLICATIONS 248 (2d ed. 2009) (stating that high-end implants and medical devices, specialty items of low volume but high price, are good examples of such medical supplies for which suppliers use direct delivery, usually via express services (like FedEx, UPS, or DHL) or have their own local/regional sales representatives make the just-in-time delivery and serve as consultants to physicians); *see also* HOGAN & HARTSON LLP, PHYSICIAN-OWNED INTERMEDIARIES IN THE MEDICAL DEVICE INDUSTRY: THE CASE FOR GOVERNMENT SCRUTINY UNDER THE FEDERAL FRAUD AND ABUSE LAWS 3 (2009), https://www.ropesgray.com/~/media/Files/Mini-Sites/POD/physician-owned-intermediaries-in-med-device-industry.ashx ("Though some end users keep product on consignment due to the difficult task of keeping implantable devices sterile throughout the shipping process and the associated cost of storing unordered product, most sales are direct shipped from the manufacturer to the hospital in response to a specific order from a physician who plans to implant the product into his or her patient.").

11. *See* HOGAN & HARTSON LLP, *supra* note 10.

12. *See* Lee, *supra* note 7, at 3 ("Sales reps long have played a major role in providing technical assistance to surgeons. Sales reps often bring implants to the OR before a procedure or suggest what devices should be used during surgery. A standard orthopedic surgery may have 10 to 15 product trays, each with hundreds of instruments."). These services, combined with other costs can make up nearly forty percent of the device price. *Id. See also* Joseph Truhe, *Should Surgeons be Encouraged to Take an Active Role in the Implantable Device Supply Chain Through Physician-Owned Entities?*, FDLI's FOOD AND DRUG POLICY FORUM (May 23, 2012), http://www.fdli.org/mobile/resources-detail-view/?friendly

and other challenges have put pressure on the traditional supply model. In response, industry stakeholders are looking for alternative models, such as PODs.

B. *POD Business Model*

PODs are a relatively new innovation in the health care industry.[13] A POD is any "physician-owned entit[y] that derive[s] 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 surgery centers . . . ."[14] PODs are usually associated with implantable devices, such as spinal implants, hips, and knees, because these are physician preference items.[15] According to the 2011 Senate Finance Committee Report,

> The typical structure of a POD is that a small group of individuals, who may or may not be physicians, establish a company to manufacture or distribute medical devices for implantation in primarily orthopedic . . . surgeries. The company then seeks investors, primarily physicians who can generate referrals that benefit the company. The physicians are then offered either partnership or ownership interests in the company in return for a cash buy in of anywhere from $10,000 or more, and in return are promised the potential to earn returns at a far higher rate than they would get investing in more traditional investments.[16]

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name=should-surgeons-be-encouraged-to-take-an-active-role-in-the-implantable-medical-device-supply-chain-through-physican-owned-entities- (noting the sales model can add forty percent and more to the hospital device costs, on top of the premium built into the base price of brand-name products from dominant manufacturers).

13. *See* Senate Fin. Comm. Minority Staff, Physician Owned Distributors (PODs): An Overview of Key Issues and Potential Areas for Congressional Oversight 4 (2011) [hereinafter 2011 SENATE FINANCE POD INQUIRY] (acknowledging the appealing nature of PODs to physicians, especially where they could earn "dividend returns of 25 percent or more, guarantees to increase patient load, and no real financial risk beyond the initial investment").

14. U.S. DEP'T OF HEALTH & HUMAN SERV., OFFICE OF INSPECTOR GEN., SPECIAL FRAUD ALERT: PHYSICIAN-OWNED ENTITIES 1 (2013), http://oig.hhs.gov/fraud/docs/alertsandbulletins/2013/POD_Special_Fraud_Alert.pdf [hereinafter 2013 OIG FRAUD ALERT: POEs]. *See also* Mark T. Morrell & Jaya F. White, Comment, *Heightened Regulatory Scrutiny Facing Innovative POD Arrangements*, 7 J. HEALTH & LIFE SCI. L. 44, 47 (2014); John E. Kelly & Anne P. McNamara, *Physician-Owned Medical Device Distributors: A Controversial Business Model*, ABA HEALTH ESOURCE (Oct. 23, 2012), http://www.americanbar.org/content/newsletter/publications/aba_health_esource_home/aba_health_law_esource_1012_kelly.html.

15. 2013 OIG FRAUD ALERT: POEs, *supra* note 14, at 2 ("We are particularly concerned about the presence of such financial incentives in the implantable medical device context because such devices typically are 'physician preference items,' meaning that both the choice of brand and the type of device may be made or strongly influenced by the physician, rather than being controlled by the hospital or ASC where the procedure is performed."). It is important to note that hospitals will often purchase these items at the direction of the physician, which means these items often bypass many of the checks and balances of a hospital's typical purchasing process.

16. 2011 SENATE FINANCE POD INQUIRY, *supra* note 13, at 4.

According to members of Congress, PODs emerged in response to physicians' seeking alternative sources of revenue to recoup from "reductions in reimbursements, increased demands on their time, hospital cost initiatives and growth in patient procedures and volumes . . . ."[17] The "lure of financial incentives and lack of regulatory oversight" contributed to their proliferation, achieving a national presence by 2012.[18] A physician-owner essentially wears two hats: as a medical provider, he advises the facility where services are to be rendered and which device he wants to use; as a distributor, he supplies the requested devices to the purchasing institution. It is common for PODs to sell and distribute devices to the facilities where their physician-owners perform surgeries because the physician-owners receive a portion of the profits generated by the sale of the very devices they requested.[19] The physicians' lofty influence and control over what devices to use on their patients makes them ideal POD investors.

The POD model is different from the traditional implant device supply model in several ways. In contrast to a direct sale, PODs act as distinct middlemen to the transaction. There are a few common POD models, but the focus of this Note is on the "physician distributor" model where "the POD acts as a product distributor that buys devices from manufacturers, and then resells them to the hospitals where the physician-investors refer their patients for procedures."[20] While all PODs perform some intermediary role, not every POD acts as a true distributor. In its pure form, a distributor takes physical possession of the product, assumes liability, and is accountable to regulatory agencies for reporting any adverse events related to the device. Given the risks associated with implantable devices, such as damage and sterility, it does not make practical sense for a manufacturer to sell to a middleman and give up control over its products when it could sell directly to the end purchaser. In reality, "a recent trend has seen the growth of [PODs] that make no pretense of being a product distributor, but instead simply receive commissions from manufacturers for arranging implant purchases by the hospitals where the [POD] physician owners

17. *Id.* at 3.

18. *Id.* (reporting that more than twenty states had multiple PODs); *see also* Joseph V. Geraci & Kelly Schulz, *Door Begins to Close on Physician-Owned Distributorships and the "Company Model"*, *in* 2015 HEALTH LAW & COMPLIANCE UPDATE §3.02[B] (John Steiner ed., 2015) ("As noted by the U.S. Senate, 'the use of PODs may have been enabled by the absence of policy statements, guidance or visible enforcement proceedings that demonstrate, with sufficient clarity and emphasis, the extent of the government's concern with the ways that PODs differ from physician joint ventures to provide legitimate health care services and the risks of abuse posed by some PODs.'").

19. *See* 2011 SENATE FINANCE POD INQUIRY, *supra* note 13, at 3.

20. Kelly & McNamara, *supra* note 14, at 1; *see also* 2011 SENATE FINANCE POD INQUIRY, *supra* note 13, at 3 (describing the two other common models: the "physician manufacturer" model, where the POD claims to be a manufacturer and distributes devices produced by an outsourced manufacturer using the PODs designs, and "physician group purchasing organization," where the POD acts as a Group Purchasing Organization).

perform surgery."[21] Unlike the traditional model, where sales representatives perform a number of support functions, it is unclear what contributions PODs make to the device's supply chain.

C. *The Value of PODs: Arguments Advanced by Proponents and Critics*

Proponents assert that PODs are an effective way to lower health care costs, both directly and indirectly. PODs claim to purchase and resell medical devices at lower prices than both the device manufacturer and non-POD distributors.[22] These direct cost savings, which are purportedly passed along to hospitals, are realized by removing unnecessary costs, leveraging economies of scale, and sharing inventory risks. By purchasing directly from the manufacturer, PODs eliminate the need for sales commissions and promotional costs associated with marketing and advertising, thus lowering the device cost.[23] Proponents assert that PODs are in a better position to negotiate volume discounts.[24] Additionally, by taking possession and storing devices, PODs are able to negotiate lower prices from manufacturers because they assume the financial burdens that come with holding inventory.[25] According to POD advocates, these savings can be substantial. For example, a California-based POD claimed to have saved a hospital over thirty-four percent on implantable devices over a two-year period, totaling more than one million dollars.[26]

POD proponents also claim they can indirectly lower prices by increasing market competition that has traditionally been lacking. One physician-owner explained, "The opportunity to insert efficiency and market forces into medical device delivery was the stimulus for [their] physician owned medical device distribution model."[27] Historically, the

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21. *See* HOGAN & HARTSON LLP, PHYSICIAN-OWNED INTERMEDIARIES IN THE MEDICAL DEVICE INDUSTRY: FRAUD AND ABUSE COMPLIANCE RISKS FOR PHYSICIANS, HOSPITALS AND MANUFACTURERS 4 (2010), http://www.jisrf.org/pdfs/hogan-and-hartson.pdf.

22. 2011 SENATE FINANCE POD INQUIRY, *supra* note 13, at 5.

23. Geraci & Schulz, *supra* note 18, at § 3.07[D](1) (citing Joe Carlson, *Spotlight on PODs: HHS Fraud Alert Hits Doc-Owned Device Distributors*, MODERN HEALTHCARE (Mar. 30, 2013), http://www.modernhealthcare.com/article/20130330/MAGAZINE/303309985); *see also* Truhe, *supra* note 12 (stating that commissions and fees in the traditional orthopedic sales model can increase device costs as much as forty percent).

24. Mary Ann Porucznik, *Physician-Owned Distributorships: A Problem or a Solution?*, AAOS (Feb. 2012), http://www.aaos.org/aaosnow/2012/feb/advocacy/advocacy1/ ("The current model is based on one-at-a-time purchases, while implants have reached commodity status . . . .").

25. *Id.*

26. *See generally* JOHN STEINMANN ET AL., SURGEON OWNERSHIP IN MEDICAL DEVICE DISTRIBUTION: ECONOMIC ANALYSIS OF AN EXISTING MODEL (2009) [hereinafter STEINMANN STUDY] (results presented as an exhibit at the 2009 AAOS meeting); *but see* KATHLEEN MCDERMOTT & JACOB J. HARPER, MORGAN LEWIS & BOCKIUS LLP, ANTI-FRAUD CONCERNS FOR PHYSICIAN-OWNED DISTRIBUTORS FOR MEDICAL DEVICE PRODUCTS: WHAT'S NEW IS OLD. WE WON'T BE FOOLED AGAIN 16 (2013) (suggesting that data used in the STEINMANN STUDY is biased and therefore suspect).

27. Letter from Angela Carlson, President, Alliance Surgical Distributors, LLC, to Donald S. Clark, Sec., Fed. Trade Comm'n (March 10, 2014) (stating, in a public comment in response to Announcement of Public Workshop, "Examining Health Care Competition," Project No. P13-1207, that manufacturers have maintained high prices by

implant device industry was dominated by a handful of manufacturers. Despite the recent commoditization of implant devices and availability of some generic products, there has been no significant reduction in price.[28] By increasing competition, advocates believe PODs will increase transparency and exert downward pricing pressures on device manufacturers. While the effect of PODs on the market is debated, reports do lend credibility to the contention that PODs add competition to the marketplace.[29]

In contrast, POD critics claim these business arrangements are problematic because they give rise to conflicts of interest, overutilization, increased costs, lower quality care, unfair competition, and possible violations of federal laws.[30] PODs create conflicts of interest because the physician has a financial incentive to recommend devices sold by the POD and a competing obligation to make medical decisions in the best interests of the patient. These financial incentives may improperly influence medical decisions, corrupt medical judgment, and compromise the quality of care. When compensation is directly related to the volume, overutilization (including the performance of medically unnecessary, excessive, or overly invasive procedures) is a natural consequence.[31] For example, a study that examined spinal fusion treatments found that the utilization rate of a certain spinal procedure and its associated medical device increased more than 300 percent in

requiring "doctors' groups and hospitals to sign nondisclosure agreements about prices, which means institutions do not know what their competitors are paying").

28. Elisabeth Rosenthal, *In Need of a New Hip, But Priced Out of the U.S.*, N.Y. TIMES (Aug. 3, 2013), http://www.nytimes.com/2013/08/04/health/for-medical-tourists-simple-math.html?_r=0 ("The basic design of artificial joints has not changed for decades. But increased volume—about one million knee and hip replacements are performed in the United States annually—and competition have not lowered prices, as would typically happen with products like clothes or cars.").

29. *See* Letter from Angela Carlson to Donald S. Clark, *supra* note 27, at 3 (referencing two market reports, one directly attributing to sales decline to the increasing market share of PODs, and the other suggesting that PODs will continue to threaten device manufacturers as they compete for market share). The language cited in the second report is of particular interest because it may provide some insight to the motivations behind AdvaMed's September 2006 letter to the OIG requesting additional guidance on PODs.

30. *See* 2013 OIG FRAUD ALERT: POEs, *supra* note 14, at 2.

31. *See* Proposed Changes to Disclosure of Physician Ownership in Hospitals and Physician Self-Referral Rules, 73 Fed. Reg. 23528, 23694 (April 30, 2008) (codified at 42 C.F.R. pt. 411, 412, 413, 422, 489) ("We have recently become aware of an increase in physician investment in implant and other medical device manufacturing, distribution, and purchasing companies. . . . When physicians profit from the referrals they make to hospitals through physician-owned implant and medical device companies, we are concerned about possible program or patient abuse."); *see also* U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-12-355, REPORT TO CONGRESSIONAL REQUESTERS: IMPLEMENTATION OF FINANCIAL INCENTIVE PROGRAMS UNDER FEDERAL FRAUD AND ABUSE LAWS 1–2 (2012) ("[C]urrent provider payment systems used by traditional Medicare create conflicting incentives and contribute to the growth in spending by rewarding volume of services regardless of quality and cost, leading to duplication and overutilization of services that is wasteful and potentially harmful. . . . [P]aying physicians for an intervention that may only be justified by a slim clinical rationale adds a strong financial incentive to deliver more services.").

the first year after the POD began operating in the area.[32] Inferior device quality is another explanation for increased utilization rates, as it increases the likelihood of device failure and additional surgeries.

Contrary to advocates, POD critics assert that these business arrangements are anti-competitive and give PODs an unfair market advantage because they have considerable control over both supply and demand of devices. According to critics, "Markets and competition are frustrated and undermined when PODs control the setting of price. This is because the incentive to compete for business and demonstrate value through better patient outcomes is taken away."[33] Hospitals may feel pressured to procure devices from physician-owners who use their facilities because they do not want to risk losing that revenue source.[34] Where business is awarded solely on price, PODs have an advantage because their price is already stripped of value-added services. To summarize the anti-competitive critique of PODs, critics caution that "the competitive unfairness is likely to lead to all the evils traditionally associated with monopolies: higher costs, poorer product quality, and less innovation."[35]

Critics claim that PODs may actually increase costs or lower the quality of available devices because PODs offer no independent value and instead "merely perpetuate inefficiencies in the traditional supply chain model."[36] This argument is premised on the notion that most PODs are shell entities, with no real infrastructure or capital investment, which provide minimal (if any) support services to justify profits and lack incentives to negotiate lower pricing.[37] This concern has also been raised by the Center for Medicaid Services ("CMS"). It stated that PODs "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."[38]

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32. *See* QUALITY IMPLANT COALITION, PHYSICIAN-OWNED IMPLANT COMPANIES: EVIDENCE OF PRODUCT QUALITY DEFICIENCY AND/OR OVERUTILIZATION AT ONE HOSPITAL 1 (2009); *see also* 2011 SENATE FINANCE POD INQUIRY, *supra* note 13, at 5.

33. Walter Eisner, *Winners and Losers of PODs: The Great Debate—Part II*, ORTHOPEDICS THIS WEEK (June 12, 2012), https://ryortho.com/2012/06/winners-and-losers-of-pods-the-great-debate-part-ii/.

34. HOGAN & HARTSON LLP, "DISTRIBUTORS" OF SPINAL IMPLANTS: THE IMPROPRIETY OF PHYSICIANS AS COMMISSIONED SALES REPRESENTATIVES 15 (2009), https://www.ropesgray.com/~/media/Files/Mini-Sites/POD/physician-owned-distributors-of-spinal-implants.ashx ("Hospitals must acquire the implants their referring physicians require or the physicians will perform their procedures at other hospitals that do.").

35. *Id.*

36. Kelly & McNamara, *supra* note 14, at 3.

37. *Id.*; *see also* HOGAN & HARTSON LLP, *supra* note 34, at 15 ("There is an obvious flaw in any claim that PODs can deliver the same quality implant services at lower cost. In a real competition based on price, it is ludicrous to suggest that the manufacturer itself, selling directly, could not offer a lower price than a middleman distributor with its extra costs.").

38. Proposed Collection of Information Regarding Financial Relationships Between Hospitals and Physicians, 73 Fed. Reg. 23528, 23694 (Apr. 30, 2008) (codified at 42 C.F.R. pt. 411, 412, 413, 422, 489).

Finally, critics emphasize that PODs operate outside of federal anti-fraud and abuse laws and are therefore unlawful.[39] This concern has been echoed by elected officials and governmental agencies. For example, in 2006, the Office of Inspector General ("OIG") stated that, "Given the strong potential for improper inducements between and among the physician investors, the entities, device vendors, and device purchasers, we believe these ventures should be closely scrutinized under the fraud and abuse laws."[40] A few years later, a member of the OIG's Office of Legal Affairs testified as follows:

> The financial relationships between device manufacturers and physicians merit scrutiny under anti-fraud statutes because the relationships raise the types of risks that those statutes are designed to address. . . . When a physician's self-interest compromises independent judgment, the patient faces the risk that the physician is making decisions that are not in the patient's best interest. . . . When a device manufacturer pays a physician to influence the physician's use or recommendation of its products, rather than to advance a legitimate medical interest, the additional costs are passed on to the patients, Federal health care programs, and private insurers.[41]

In 2013, the OIG issued a Special Fraud Alert stating, "[PODs] produce substantial fraud and abuse risk, and pose dangers to patient safety. . . . PODs are inherently suspect under the anti-kickback statute."[42] Despite these statements, no governmental agency has officially taken the position that PODs are unlawful. The material in the following section will establish the parameters of the law as it applies to PODs.

D. *Legal and Regulatory Framework Applicable to PODs*

The legal and regulatory landscape of the health care sector is complex—there are numerous laws and regulations, many have been interpreted to have broad applicability, and they apply to a diverse array of actors.[43] This complexity resulted from the increasing intricacy of health care business arrangements, which gave rise to increased oppor-

39. *See infra* Part I.D, providing an overview of the legal and regulatory framework applicable to PODs.

40. Letter from Vicki L. Robinson, Office of Inspector Gen., to Stephen J. Ubl, President and CEO of AdvaMed (Oct. 6, 2006).

41. *Examining the Relationship Between the Medical Device Industry and Physicians: Hearing on S. 110-22 Before the S. Special Comm. on Aging*, 110th Cong. 9 (2008) (statement of Gregory E. Demske, Asst. Insp. Gen., Legal Affairs, OIG) [hereinafter *Examining the Relationship*].

42. 2013 OIG FRAUD ALERT: POEs, *supra* note 14, at 1, 3 (noting the OIG was "particularly concerned when PODs, or their physician-owners" exhibited any of the listed suspect characteristics).

43. Janet Nolan et al., *Foundations of Health Law: HIPAA, Anti-Kickback, Stark, False Claims, Tax and Related Laws*, *in* THE 23RD ANNUAL NATIONAL INSTITUTE ON HEALTH CARE FRAUD A-1, A-2 (2013) ("The analysis of health care regulation through anti-fraud, self-referral and other laws is the study of the regulation of relationships among health care consumers, support service providers/vendors, providers, payers, and regulators. These relationships are complex, with a single participant often playing more than one role.").

tunities for improper influence and fraud.[44] This section will provide an overview of four significant *federal* health care laws relevant to the legal analysis for PODs: the Federal Anti-Kickback Statute ("AKS"), the Ethics in Patient Referrals Act ("Stark Act"), the False Claims Act ("FCA"), and the Physician Payment Sunshine Act ("Sunshine Act").[45]

1. Anti-Kickback Statute

Of the relevant statutes, the AKS is most directly applicable to PODs. It was enacted in 1972 to protect patients and federal health care programs from fraud and abuse and has served as the primary vehicle for combating health care kickbacks. The AKS is a criminal statute making it a felony to exchange anything of value, cash or otherwise, for referrals, arrangements to furnish items or services, or for purchasing or recommending any good, facility, or service for which payment may be made under a federal health care program.[46] It targets the ability of providers to make referral decisions based on their own economic interests rather than on the best interests of the patient or third-party payer, which leads to unnecessary health care services, selection of higher cost providers, and selection of providers for reasons unrelated to quality.[47] There are two sides to any kickback transaction: those offering or paying and those soliciting or receiving. The AKS applies equally to both sides of the transaction, regardless of whose conduct was more egregious.[48] Courts have interpreted the statute broadly, and several federal appellate courts have adopted the "one purpose" test to guide their legal analysis. Under this test, if even one purpose (as opposed to a sole or primary purpose) of a business arrangement is to induce referrals for services or purchases of items reimbursed under a federal program, the AKS is violated.[49]

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44. *See* James G. Sheehan & Jesse A. Goldner, *Beyond the Anti-Kickback Statute: New Entities, New Theories in Healthcare Fraud Prosecutions*, 40 J. HEALTH L. 167, 174 (2007) (explaining anti-kickback law "can be complex because the techniques used by payors and recipients vary by industry, and there are more extensive and complicated money flows among the parties and related entities").

45. Additional federal statutes may be implicated by PODs. *See generally* 18 U.S.C. § 1035 (1996) (false statement relating to health care matters) and 18 U.S.C. § 1510 (2010) (obstruction of criminal investigation of health care fraud offenses); *see also* 15 U.S.C. § 1 (2013) (anti-trust violations) and 21 U.S.C. § 331 (2013) (introducing adulterated or misbranded devices into interstate commerce).

46. *See* 42 U.S.C. § 1320(a)-7b (2012).

47. *See* Sheehan & Goldner, *supra* note 44, at 169 (citing W. Bradley Tully, *Federal Anti-Kickback Law*, 1500 Health L. & Bus. Ser. (BNA) § 1500.01(B)).

48. *See* 42 U.S.C. § 1320a-7b(b) (2012). Persons found guilty of violating the AKS may be subject to a fine of up to $25,000, imprisonment of up to five years, and exclusion from participation in federal health care programs for up to one year. *See also infra* Part III for court-interpreted meanings of "remuneration."

49. *See* United States v. Greber, 760 F.2d 68, 70 (3d Cir. 1995), discussed *infra* Part III. The Fifth, Ninth, and Tenth Circuits have also adopted the "one purpose" test. *See* United States v. Bay State Ambulance & Hosp. Rental Serv. Inc., 874 F.2d 20 (1st Cir. 1989); United States v. Davis, 132 F.3d 1092 (5th Cir. 1998); United States v. Kats, 871 F.2d 105 (9th Cir. 1989); United States v. McClatchey, 217 F.3d 823 (10th Cir. 2000).

As part of healthcare reform and the Obama Administration's strategy to combat fraud and abuse, the Patient Protection and Affordable Care Act of 2010 ("PPACA") modified the AKS in two important ways. First, it amended the intent requirement of the AKS, requiring only that the government prove a more general intent to "commit a crime" or engage in unlawful activity in order to establish a violation of the statute.[50] Second, it expanded the scope of the FCA, clarifying that anti-kickback violations may be used to establish a false claims violation. Due to concerns that the Act could swallow legitimate business arrangements due to its expansive reach, the OIG codified a number of safe harbor provisions detailing how business practices can be structured so they are shielded from criminal and civil enforcement. One such provision states that "[f]ull safe harbor protection is secured only when an arrangement completely complies with all safe harbor elements."[51] However, even if an entity fully complies with the safe harbor provisions, conduct can lose that protection if its purpose was to induce in an unlawful manner. When this Note was drafted, no safe harbor provision expressly applied to PODs and such arrangements were unprotected under the AKS.

2. Ethics in Patient Referrals Act

The Ethics in Patient Referrals Act, commonly known as the Stark Act, is a civil statute enacted to "address perceived overutilization of services by physicians who stood to profit by referring patients to facilities or entities in which they had a financial interest."[52] It is a strict liability statute that prohibits certain physician referrals.[53] If a physician (or his immediate family member) has a "financial relationship" with an entity, that physician may not make a referral to that entity for the provision of any designated health services ("DHS") that may be paid for by Medicare or Medicaid. Additionally, the Act makes it unlawful for an entity to present a claim to any federal health care program or bill to any individual or entity for DHS pursuant to a prohibited referral. A "financial relationship" under the Act includes an "ownership or investment interest"[54] in the entity or a compensation agree-

50. *See* Nolan et al., *supra* note 43, at A-2 (stating that the PPACA eliminated "the potential applicability of the holding in the *Hanlester* case, which held that proof of a specific intent to violate the [Anti-Kickback] statute, was a necessary requirement for a successful kickback prosecution.").

51. ROBERT G. HOMCHICK, AM. HEALTH LAWYERS ASSOC., FEDERAL ANTI-KICKBACK STATUTE PRIMER (2012), https://www.healthlawyers.org/Events/Programs/Materials/Documents/FC12/101_homchick_williams.pdf. Compliance with the elements of the safe harbor provisions are given the presumption of compliance.

52. Council for Urological Interests v. Sebelius, 668 F.3d 704, 704 (D.C. Cir. 2011); *see generally* Steven D. Wales, *The Stark Law: Boon or Boondoggle? An Analysis of the Prohibition on Physician Self-Referrals*, 27 L. & PSYCHOL. REV. 1 (2003).

53. The term "referral" in the Stark Act is broadly defined to include any request or order by a physician for DHS or a physician certifying the need for the provision of DHS. 42 U.S.C.A. § 1395nn (West 2010).

54. "Ownership or investment interest" includes "equity, debt, or other means," as well as "an interest in an entity that holds an ownership or investment interest in any entity providing the [DHS]." 42 U.S.C.A. § 1395nn(a)(2)(B) (West 2010).

ment between the physician and the entity. Violators of the Stark Act may be subject to civil monetary penalties up to $15,000 per prohibited referral, denied payment or refunds for amounts billed in violation of the statute, or excluded from federal health programs.[55] Sanctions apply to both the referring physician and the entity billing DHS. A violation of the Stark Act can also create potential liability under the FCA. Because this rule is harsh, many exceptions have been added, two of which may affect PODs: the indirect compensation exception and the compensation agreement exception.[56] Whether the Stark Act applies to PODs is debated, but the existence of a financial relationship between a physician-owner and hospital customer in PODs suggests it likely applies, especially because physicians make referrals for designated health services.[57]

3. False Claims Act

The FCA is a generally applicable law that is commonly used in the health care context to combat fraud against the U.S. government.[58] Generally, an individual who knowingly submits a fraudulent claim to the government may be liable under the statute.[59] A violation of the AKS or Stark Act can establish the basis for prosecution under the FCA.[60] Because neither the AKS nor the Stark Act have a private cause of action, applicability of the FCA to POD activity is significant because it opens the door for qui tam relator suits. This allows whistleblowers to initiate suits on behalf of the federal government in which they are entitled to share up to thirty percent of all damages recovered by the government.[61] The FCA may apply to PODs where PODs create financial incentives that result in procedures that are found not medically necessary or that improperly increase Medicare costs. The FCA provides for treble damages and a civil penalty between $5,500 and $10,000 per violation.[62]

4. Physician Payment Sunshine Act

The Physician Payment Sunshine Act, commonly known as the Sunshine Act, was enacted as part of the PPACA legislation with the purpose of increasing financial transparency between industry members and providers.[63] In 2011, CMS promulgated a final rule that

55. *See* 42 U.S.C.A. § 1395nn(g) (West 2010).

56. *See* 42 U.S.C.A. § 1395nn(e)(5) (West 2010) for compensation agreement exception.

57. *See* MCDERMOTT & HARPER, *supra* note 26, at 13 (stating inpatient and outpatient hospital services include items falling under DHS). *See* 42 U.S.C.A. § 1395nn(h)(6) (West 2010) for a list of DHS services.

58. *See* Jennifer A. Staman, *Health Care Fraud and Abuse Laws Affecting Medicare and Medicaid: An Overview, in* REDUCING MEDICARE FRAUD, WASTE AND ABUSE 1 (Anthony L. Johnson ed., 2011).

59. *See* 31 U.S.C. § 3729 (2012).

60. *Id.*

61. 31 U.S.C. § 3730 (2012).

62. 31 U.S.C. § 3729(a).

63. *See generally* 42 U.S.C. § 1320a-7h (2010).

required applicable group purchasing organizations ("GPOs") to report certain information regarding ownership or investment interests held by physicians or their immediate family members in such entities.[64] The term "applicable group purchasing organization" means "a group purchasing organization (as defined by the Secretary) that purchases, arranges for, or negotiates the purchase of a covered drug, device, biological, or medical supply which is operating in the United States, or in a territory, possession, or commonwealth of the United States."[65] CMS explained the rule was intended to include entities that purchase goods and devices for resale and for distribution to groups of individuals or other entities, which therefore includes PODs. As PODs purchase goods and devices for resale, they fall within the scope of the rule and therefore must comply with the reporting obligations. Reported data is stored in *Open Payments*, which is managed by CMS and which is publically available. This data may assist in qui tam actions, allow hospitals to check up on any physicians with whom they share a financial relationship, and highlight physicians whose ownership interest might exceed safe harbors or Stark Act exceptions. Failure to timely, accurately, or completely report required information can result in fines as high as $150,000 per applicable GPO, per each annual submission.[66]

II. WHY IT MATTERS: MINIMAL GUIDANCE, RISK, AND LEGAL UNCERTAINTY

Since the emergence of PODs, advocates and critics have intensely debated their lawfulness. While it is clear that PODs pose a number of risks, existing guidance fails to adequately inform physicians, hospitals, and device manufacturers on how to properly structure and operate these business entities. Because of the complex and broad nature of health care fraud provisions and the significant sanctions that attach to violations, "it is crucial that the health care community understand how the government intends to apply them. The abstract contours of fraud and abuse principles must be translated into practical requirements to which health care providers can adhere—and against which their compliance can be measured."[67] Guidance may be communicated through regulation, issuance of informal guidance, and enforcement actions.[68]

A. *Minimal POD Guidance*

Overall, governmental guidance on PODs has been minimal. Despite increasing concern, the government has yet to issue a firm

64. *See* Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests, 78 Fed. Reg. 9458 (Feb. 8, 2013) (codified at 42 C.F.R. pt. 402, 403).

65. 42 U.S.C.A. § 1320a-7h(e)(1) (West 2010).

66. 42 U.S.C.A. § 1320a-7h(b)(1)(B).

67. Joan H. Krause, *Regulating, Guiding, and Enforcing Health Care Fraud*, 60 N.Y.U. ANN. SURV. AM. L. 241, 247 (2005).

68. *Id.* (noting that health care fraud enforcement increasingly has taken the latter two forms due to the cumbersome nature of the regulatory process).

statement on the lawfulness of PODs or to clarify where PODs fall within the legal framework. Despite requests from members of the Senate Finance Committee to modify existing regulations to clarify their relationship to PODs,[69] very few administrative changes have been made to identify where PODs fall within the anti-fraud framework. While the Sunshine Act was modified to reference and include PODs within GPO reporting requirements, CMS declined Congressional requests to prohibit Affordable Care Organizations from purchasing from PODs in proposed rule-making amending provisions of PPACA.[70] CMS also declined to modify language in the Stark Act to include PODs within the definition of an "entity."[71]

Health and Human Services ("HHS") has issued some informal guidance to explain its concerns with PODs. A prime example is the *Special Fraud Alert: Physician Owned Entities* issued by the OIG in March 2013. While the alert stated the agency's concern that PODs could violate anti-fraud provisions, it fell short of clarifying what POD conduct is lawful and how to properly structure a POD to ensure it falls within the boundaries of the law. In an effort to justify the slim guidance, the OIG explained that:

> The legality of any individual physician-owned entity under the Federal Anti-Kickback Statute is highly dependent on each entity's particular characteristics, including the details of its legal structure; its operational safeguards; and, importantly, the actual conduct of its investors, management entities, suppliers, and customers during the implementation phase and ongoing operations. For these reasons, OIG's ability to issue guidance about the application of the statute to these business structures is limited.[72]

By referencing the 1989 OIG *Special Fraud Alert: Joint Venture Agreements*,[73] which outlines questionable features of joint venture arrangements, one can argue that POD conduct may be scrutinized under the rubric that applies to joint ventures and referrals. Like most other terms used in the health care fraud context, the definition of a joint

69. *See* Letter from Orrin G. Hatch et al., Senate Fin. Comm., to Donald Berwick, Admin., Ctrs. for Medicare & Medicaid Svcs. (June 9, 2011), http://www.finance.senate.gov/newsroom/ranking/download/?id=1e6e609a-20ae-46cf-b85e-ea567a7ecc8c.

70. *See* Medicare and State Health Care Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, 79 Fed. Reg. 59717 (Oct. 3, 2014) (codified at 42 C.F.R. pt. 1001, 1003).

71. Changes to Disclosure of Physician Ownership in Hospitals and Physician Self-Referral Rules, 73 Fed. Reg. 48434, 48727 (Aug. 19, 2008) (codified at 42 C.F.R. pt. 411). In the August 2008 Final Rule, CMS specifically stated, "we are not adopting the position that physician-owned implant or other medical device companies necessarily 'perform the [designated health services],' and are therefore an 'entity' on that basis." *Id.* Because of CMS's mixed message on PODs, there is still debate about whether the Stark Law is applicable to PODs. *See also* Morrell & White, *supra* note 14, at 63–64.

72. Letter from Daniel Levinson, Inspector Gen., Office of Inspector Gen., to Members of the Senate Fin. Comm. (Sept. 13, 2011), http://op.bna.com/hl.nsf/id/droy-8lqlwn/$File/OIG%20Response%20to%20Hatch%20POD%20letter.pdf.

73. Special Fraud Alert: Joint Venture Arrangements (Aug. 1989), *reprinted at* 59 Fed. Reg. 65,372, 65,374 (Dec. 19, 1994), https://oig.hhs.gov/fraud/docs/alertsandbulletins/121994.html.

venture is broad, potentially pulling PODs within its scope.[74] While not guidance per se, the OIG issued its first report on PODs in 2013, in which it noted various concerns related to their problematic nature.[75]

In late 2014, federal prosecutors filed their first enforcement action against a POD.[76] The government charged Reliance Medical Systems LLC, two distributors (Apex Medical Technologies, Inc. and Kronos Spinal Technologies LLC), and several physician-owners with FCA violations based on the legal theory that investment returns from these PODs were intended to induce purchasing decisions and unlawful kickbacks.[77] The government also intervened in a civil qui tam FCA suit against Dr. Aria Sabit, one of the same named-defendants in the Reliance criminal suit.[78]

These enforcement actions are quite significant because they are the first against a POD and therefore have implications for the future. Despite the fact that nearly two years have passed since the OIG issued its fraud alert, PODs remain on the government's radar.[79] By launch-

74. *See* J. STUART SHOWALTER, SOUTHWICK'S THE LAW OF HEALTHCARE ADMINISTRATION 119 (3d ed. 1999) ("In healthcare, the term 'joint venture' has been used more broadly to refer to a variety of legal relationships between institutional providers of care and physicians who have in many cases formed a corporation or a group practice.").

75. *See* DANIEL R. LEVINSON, U.S. DEP'T OF HEALTH AND HUMAN SERV., OFFICE OF INSPECTOR GEN., SPINAL DEVICES SUPPLIED BY PHYSICIAN-OWNED DISTRIBUTORS: OVERVIEW OF PREVALENCE AND USE 3 (2013), http://oig.hhs.gov/oei/reports/oei-01-11-00660.asp ("PODs are a substantial presence in the spinal device market. Our findings raise questions about PODs' claim that their devices cost less than those of other suppliers. Surgeons performed more spinal surgeries at hospitals that purchased from PODs, and those hospitals experienced increased rates of growth in the number of spinal surgeries performed in comparison to the rate for hospitals that did not purchase from PODs. Taken together, these factors may increase the cost of spinal surgery to Medicare over time. Finally, hospitals' policies varied in whether they required physicians to disclose ownership interests in PODs to either the hospital or their patients. Thus the ability of hospitals and patients to identify potential conflicts of interest among these providers is reduced.").

76. *See generally* United States v. Reliance Med. Sys., LLC, No. CV 14-06979, 2014 WL 5761113 (C.D. Cal. Nov. 5, 2014); *see also* Thomas Bulleit & Peter Holman, *Ominous Outlook for Physician-Owned Distributors*, LAW360 (Sept. 22, 2014), http://www.law360.com/articles/577485/ominous-outlook-for-physician-owned-distributors.

77. *Reliance Med. Sys.*, 2014 WL 5761113, at *2. *See also The Department of Justice Targets Physician-Owner Distributors in Recent False Claims Act Lawsuit*, HEALTH L. ATT'Y BLOG (Nov. 25, 2014, 6:05 PM), http://www.healthlawattorneyblog.com/stark-and-anti-kickback/ (listing allegations in the complaint: payments to physician investors were based on profits generated by the physician investor, the number of surgeries dramatically increased after the physician invested in the POD, the POD would not allow physicians to become investors unless hospitals where they performed surgeries agreed to purchase the PODs implants, that many physicians did not make any initial capital contributions for their investment interests, and physician-investors lied to hospitals about their ownership in the POD).

78. *See Reliance Med. Sys.*, 2014 WL 5761113, at *1; Complaint, United States *ex rel.* Savitch v. Sabit, No. 2:13-cv-03363 (C.D. Cal. Sept. 8, 2014) (alleging that Sabit received kickbacks and performed unnecessary spinal fusion procedures with Reliance products after acquiring an interest in its POD). Criminal charges were filed and physician was arrested on November 24, 2014 for health care fraud. James Swann & Eric Topor, *Outlook 2015: Uptick Expected in Stark, Anti-Kickback FCA Cases, Self-Disclosures*, 19 Health Care Fraud Rep. (BNA) No. 30, at 7 (Jan. 7, 2015).

79. *See generally* Swann & Topor, *supra* note 78; *see also* Bulleit & Holman, *supra* note 76, at 3 ("That the government also chose to file a separate lawsuit . . . demonstrates that

ing its first full-scale offensive against a POD, the government made a bold statement: IT IS NOT MESSING AROUND. As the government has extensively used the FCA as well as the AKS to prosecute health care fraud, these actions suggest this is its "go to" weapon of choice.[80] Additionally, the government's intervention in the qui tam suit suggests future support for relators, which may prove significant given the increased availability of data reported under the Sunshine Act and the lower threshold required for independent sources.[81] The facts and circumstances surrounding the Reliance cases show clearly egregious conduct.[82] Therefore, this case sheds no light on how much leeway parties have, what conduct will be tolerated, what defenses or exceptions are appropriate, and what level of safeguards, if any, will persuade the government to withhold prosecution under its enforcement discretion. Because these two related cases are the first in a chain of many, it seems premature to put wagers on whether the government will regulate through litigation[83] or adopt a position in the POD debate and issue subsequent guidance. While it is obvious that individual owners are prime targets for prosecution, it is not yet clear how tough prosecutors will be on hospitals that enter into business relationships with PODs. Specifically, what level of due diligence is sufficient to protect the hospital's interests? To what extent must hospitals probe to root out concealed disclosures of financial interests with PODs?

B. *Risks and Legal Uncertainty*

Proper risk management is particularly important in a highly regulated sector where the consequences have detrimental financial, reputational, safety, and legal effects. Given the legal uncertainty surrounding PODs, there are at least three courses of action stakeholders can take—they can engage with PODs based on the conclusion that they are per-

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its enforcement interests extend to the ordinary business structure of PODs, and are not limited to the special circumstances of any one physician.").

80. *See* Press Release, U.S. Dep't of Justice, Office of Pub. Affairs, Justice Department Recovers Nearly $6 Billion from False Claims Act Cases in Fiscal Year 2014 (Nov. 20, 2014), http://www.justice.gov/opa/pr/justice-department-recovers-nearly-6-billion-false-claims-act-cases-fiscal-year-2014 (noting the U.S. Department of Justice obtained a record $5.69 billion in settlements and judgments from civil cases involving fraud and false claims against the government in the fiscal year).

81. PPACA's expansion of FCA removes the jurisdictional impediment for public disclosure. *See* 31 U.S.C. § 3730(e)(4) (2012) (noting that the expansion gives the government complete discretion as to whether previously barred whistleblower actions may proceed despite the "public disclosure" rule, narrows the public disclosure bar, and expands the "original source" exception).

82. John Carreyrou, *Surgeons Eyed over Deals with Medical-Device Makers*, WALL ST. J. (July, 25, 2013, 11:01 PM), http://www.wsj.com/articles/SB10001424127887324263404578615971483271856 (stating Sabit had a twenty percent ownership interest in Reliance, received profit distributions averaging around $12,000 but reaching upwards to $50,000 per month, and had been sued by twenty-eight former patients alleging negligent acts, ranging from misplacing implants in their spines to performing surgeries that were unnecessary).

83. *See* Krause, *supra* note 67, at 272 (noting the growing trend in American law of the phenomenon of "regulation by litigation").

missible when properly structured, they can avoid engaging in business transactions with PODs (either because they think they are illegitimate or because it is better to err on the side of caution), or they can "wait and see" what happens in the POD debate. The course of action embraced depends on how the actor analyzes the risks posed by PODs.

PODs pose some levels of risk to those with whom they interact, whether it is hospitals, patients, or investors. Hospitals, as the end purchasers of POD devices, seem to have the most at risk. PODs may undermine hospital management's ability to objectively control procurement; effectively manage tort liability; adequately train, monitor, and oversee compliance of the medical staff; and establish robust financial conflicts of interest disclosure policies. Given the heightened concerns surrounding PODs, especially as potential enforcement targets, a hospital should be prepared to defend its choice to engage with a POD in the event of fraud charges.[84] If a hospital fails to exercise reasonable care or due diligence when engaging with a POD, they may be subject to prosecution, penalties, and may even be excluded from federal health care programs. Additionally, the hospital may be at risk of being a named party in a qui tam relator suit. Furthermore, PODs could expose hospitals to increased liability in the form of medical malpractice tort suits or class actions as a result of adverse patient outcomes. PODs expose patients to risks along safety, quality, and costs dimensions. So long as PODs exist in the health care sector, financial incentives stemming from conflicts of interest could corrupt medical judgment. With the legality of PODs in limbo, is anyone looking out for the interests of patients? Given these concerns, are their interests sufficiently protected under tort law? Physician investors also face risks. Should physicians invest? Divest? Should they proactively disclose ownership interests to patients? The story of Omega, a California-based POD, illustrates investor risks.[85] In response to publicity from a newspaper article that argued PODs "ran afoul of federal kickback statutes and potentially clouded a physician's ability to choose the best implant for his or her patient," Omega's supplier provided notification it would cease selling products to PODs.[86] Despite the Omega CEO's and physician's assertion that they complied with the legal guidance for how to properly structure a POD, Omega had no choice but to close its doors and now stands to lose a significant capital investment in the form of device inventory.[87]

84. *See* McDermott & Harper, *supra* note 26, at 5 ("Doing business with PODs . . . is a *rebuttable* presumption of an illegal kickback to maintain or obtain physician procedures in the hospital that will always require explanation, express oversight and objective justification by hospital management and Board of Director members.").

85. Walter Eisner, *The Risks of PODS*, Orthopedics This Week (May 9, 2011), https://ryortho.com/2011/05/the-risks-of-pods/.

86. *Id.*

87. *Id.*

C. *Industry Response*

In general, industry actors have viewed PODs with some degree of caution due to the legal uncertainties. Several industry associations have adopted the position that PODs are illegitimate business arrangements that undermine ethical principles and impede necessary reform. The Association for Medical Ethics believes that "participating in PODs is both unethical and illegal, and likely to ensnare physicians and hospitals in future enforcement activities and lawsuits."[88] The American Medical Association ("AMA") takes the position that physicians should make all treatment decisions "based solely upon medical considerations and patient needs and reasonable expectations of the effectiveness of the . . . device or other treatment for the particular patient."[89] The AMA also believes physicians may not accept *any* kind of payment from a device manufacturer and should not be influenced in the prescribing of devices by *any* financial interest regardless of the type of entity.[90] Membership to the AMA is open to all physicians; however to become a member, one must certify that he or she has "no ownership in, or receive any payments for, physician owned distributorships . . . ."[91] In contrast, the American Association of Surgeon Distributorships ("AASD") believes PODs can be lawfully structured and add value to the health care sector. AASD is an accrediting body for "ethical PODS" ("ePODs").[92] It views PODs as "both an alternative distribution model and the only form of real competition to help lower prices" in the market place.[93] To promote ethical and lawful structuring of PODs, AASD developed a set of strict standards they believe protect patients and hospitals, assure proven cost savings (often exceeding thirty percent), guar-

88. *Physician Owned Distributorships*, ASSOC. FOR MED. ETHICS, http://www.ethicaldoctor.org/medical-ethics/physician-owned-distributorship/ (last visited Jan. 22, 2015). A review of the Association for Medical Ethics' website suggests they are staunch opponents of PODs regardless of any legitimate value PODs may present, which is implied by their inaccurate and erroneous recitation of statements issued by the OIG and independent studies. For example, the association stated:

> Public pronouncements by the Chief of the OIG make it clear that indictments of physicians and their associated facilities will be occurring among those participating in PODs. . . . The OIG submitted a comprehensive opinion about PODs in August 2011 which tightens loopholes and declares the POD model as illegal.

Id. I have seen no such statement issued by the OIG.

89. Code of Medical Ethics opinion 8.06 (AM. MED. ASSOC. 2002), http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion806.page.

90. *Id.* ("Physicians may not accept any kind of payment or compensation from a drug company or device manufacturer for prescribing its products. Furthermore, physicians should not be influenced in the prescribing of drugs, devices, or appliances by a direct or indirect financial interest in a firm or other supplier, regardless of whether the firm is a manufacturer, distributor, wholesaler, or repackager of the products involved.").

91. *Join the Association for Medical Ethics*, ASSOC. FOR MED. ETHICS, http://www.ethicaldoctor.org/join-ame/ (last visited Nov. 20, 2015) (implying it also sees PODs as an unacceptable business model).

92. *See generally* AM. ASSOC. OF SURGEON DISTRIBS., http://aasdonline.org (last visited Nov. 20, 2015).

93. *See id.*

antee full transparency, and help ensure competition.[94] For example, it requires PODs to maintain a business structure that complies with the Anti-Kickback Act, the Stark Act, and the Physician Payment Sunshine Act. This standard operates on the assumption that PODs can in fact be structured in a manner consistent with anti-fraud and abuse laws—this assumption lies at the core of the POD debate. Additionally, AASD limits its annual device price increases to three percent above the consumer price index, requires physician disclosure, monitors utilization data, and prohibits PODs from requiring, pressuring, or otherwise leveraging the physician-owners' use of POD devices.[95]

In response to government concerns and potential risks, many hospitals and hospital systems have taken the safe route and limited their business transactions with PODs.[96] Some hospitals prohibit business transactions with PODs. Others have a general prohibition but allow a list of exceptions. These exceptions may include professional services or devices where there is a medical necessity. Some hospitals permit business transactions with PODs but limit the ownership percentage of any affiliated physician. Others have robust conflict of interest policies and require disclosure of ownership interest. For example, Hospital Corporation of America, the world's largest private operator of health care facilities in the world, enacted a policy that discourages its affiliates from conducting business with physician-owned vendors and has a separate policy to ensure its affiliates do not enter into problematic relationships.[97] While these approaches are not by any means universal, they suggest hospitals are wary of PODs and find the risks may outweigh any benefits.

III. THE LAWFULNESS OF PODS AND RECOMMENDATIONS FOR THE FUTURE

A. *Conflicts of Interest*

Conflicts of interest have long existed in the health care industry, so the goal is not to unconditionally eliminate them. Instead, such conflicts should only be tolerated when their value substantially outweighs the burdens they impose. The POD cost-benefit analysis reveals that the risks and associated costs dwarf their potential value.

What purpose do PODs serve? While advocates suggest PODs have the potential to generate considerable cost savings and increase competition, it is more compelling to find that *one purpose* served by PODs is to create an additional revenue stream for physicians. One critic believes

94. *See id.*

95. *See id.*

96. As hospitals and hospital networks have adopted similar strategies regarding PODs, this section will highlight key approaches. For additional detail, see *Hospital Policies*, ROPES & GRAY LLP, http://www.ropesgray.com/Physician-Owned-Distributors/Hospital-Policies-Prohibiting-PODs.aspx (last visited Mar. 26, 2016) (providing a list of all listed hospitals and hospital systems that took adopted policies prohibiting or severely restricting purchases from PODs).

97. *See* HCA ETHICS & COMPLIANCE, PHYSICIAN-OWNED VENDOR RELATIONS (2012), http://ec.hcahealthcare.com/cpm/ll027.doc.

PODs serve no other purpose, finding physicians add zero value to the transaction: "Simple economics teaches that adding a new 'mouth to feed' to the supply chain will add cost, and since the commission payment is a percentage of sale price, the POD has no incentive to negotiate a lower sale price."[98] The unilateral nature of this source of conflict of interest is also problematic—the decision of a physician to invest in a POD is a one-sided choice, often motivated by financial considerations.[99] Something beyond self-serving motivations is needed to justify the presence of these conflicts of interest. Because PODs are not the only way to enhance competition and lower device prices, it is hard to argue these arrangements are necessary.

What can be done to minimize the effects of these conflicts? Data suggests that physicians are motivated by financial incentives that have the potential to taint a physician's independent judgment and lead to adverse patient outcomes.[100] While mechanisms such as mandated disclosure and peer review to ensure independent judgment may mitigate these effects, they add additional costs and introduce additional problems.

To what extent do conflicts presented by PODs undermine larger policy objectives? Opponents strongly believe that the structure of PODs is itself flawed and that PODs cannot be organized in a manner that is consistent with fraud and abuse law or with industry best practices.[101] The Obama Administration has deemed curbing healthcare fraud a top priority and has taken proactive measures to combat health care fraud, waste, and abuse. Because PODs create the opportunity for physicians to profit from their own treatment recommendations, they allow for remuneration in exchange for the exercise of medical judgment, and therefore implicate the anti-kickback statute. These conflicts of interest are clearly in tension with anti-fraud policy objectives. Moreover, evidence suggests financial incentives lead to overutilization that may adversely affect the health of patients.

POD conflicts of interest raise ethical concerns. Referral for profit appears unethical, inconsistent with a physician's fiduciary duty.[102] A

98. HOGAN & HARTSON LLP, *supra* note 34, at 2 ("[W]e do not believe physician ownership of PODs reflects a legitimate investment . . . [and] PODs are likely to result in either increased cost or lower quality.").

99. *See* 2011 SENATE FINANCE POD INQUIRY, *supra* note 13 and accompanying text.

100. *Examining the Relationship, supra* note 41, at 7 ("[I]n an environment where physicians routinely receive substantial compensation from medical device companies . . . evidence suggests that there is a significant risk that such payments will improperly influence medical decisionmaking. Researchers reporting in medical journals, such as the *Journal of the American Medical Association* and the *New England Journal of Medicine*, have found that such financial industry-physician relationships are pervasive and that the impulse to reciprocate for even small gifts has a powerful influence on behavior.").

101. MCDERMOTT & HARPER, *supra* note 26, at 17 (stating the Achilles heel of PODs is the physician-ownership"). *See also* Geraci & Schulz, *supra* note 18, at § 3.02[E](2) (according to Medical device manufacturers, in the "'real world' no POD could be structured with enough safeguards to overcome its inherent inducement attributes").

102. *See, e.g.*, Barry R. Furrow, *Patient Safety and the Fiduciary Hospital: Sharpening Judicial Remedies*, 1 DREXEL L. REV. 439, 446 (2009) ("A fiduciary obligation in medicine means that the physician focuses exclusively on the patient's health, the patient assumes

fiduciary relationship is one in which one person is under a duty to act for the benefit of another on matters within the scope of the relationship.[103] In describing the nature of this duty, Justice Benjamin Cardozo famously stated:

> Many forms of conduct permissible in a workaday world for those acting at arm's length, are forbidden to those bound by fiduciary ties. A trustee is held to something stricter than the morals of the market place. Not honesty alone, but the punctilio of an honor the most sensitive, is then the standard of behavior.[104]

The notion that a fiduciary duty exists between the physician and the patient is "a dominant metaphor in medical ethics and law today and is presumed by much of the legal and ethical analysis of physicians' conflicts of interest."[105] At a minimum, these duties include the duty to act with skill, knowledge, and competence, to obtain the patient's informed consent, to not abandon one's patients, to protect confidential information, and to disclose financial interests in clinical research.[106] Unfortunately, the law regarding physician disclosure is inconsistent across the country—it remains unclear what physicians are legally obligated to disclose, and studies show that financial conflicts are often not disclosed.[107] Moreover, even though many courts recognize the obvious force that fiduciary principles have in doctor-patient relationships and are generally hostile to financial conflicts of interest, most courts have declined to allow suits for damages arising from a breach of fiduciary duty related to financial incentives.[108] While there seems to be some misalignment between legal theory and practice, there are legal precedents that support the imposition of this duty to disclose financial conflicts of interest to the patient.[109]

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the doctor's single-minded devotion to him, and the doctor-patient relationship is expected to be free of conflict.").

103. *Fiduciary Relationship*, BLACK'S LAW DICTIONARY (10th ed. 2014). Fiduciary relationships usually arise in one of four situations: (1) when one person places trust in the faithful integrity of another, who as a result gains superiority or influence over the first, (2) when one person assumes control and responsibility over another, (3) when one person has a duty to act for or give advice to another on matters falling within the scope of the relationship, or (4) when there is a specific relationship that has traditionally been recognized as involving fiduciary duties. *Id.*

104. Meinhard v. Salmon, 164 N.E. 545, 546 (N.Y. 1928).

105. Marc A. Rodwin, *Strains in the Fiduciary Metaphor: Divided Physician Loyalties and Obligations in a Changing Health Care System*, 21 AM. J.L. & MED. 241, 242 (1995) (citing MARC A. RODWIN, MEDICINE, MONEY, AND MORALS: PHYSICIANS' CONFLICTS OF INTERESTS (1993)). *But see* Gunter v. Huddle, 724 So. 2d 544, 546 (Ala. Civ. App. 1998) ("Alabama caselaw [sic] holds that a physician-patient relationship is *not* a fiduciary relationship as a matter of law.").

106. Rodwin, *supra* note 105, at 247?48.

107. Historically, the duty to disclose has been part of state tort law.

108. *See* Mark A. Hall, *Law, Medicine, and Trust*, 55 STAN. L. REV. 463, 504 (2003).

109. *See* Moore v. Regents of the Univ. of Cal., 793 P.2d 479, 485 (Cal. 1990), *cert. denied* 499 U.S. 936 (1991) ("[A] physician who is seeking a patient's consent for a medical procedure must, in order to satisfy his fiduciary duty and to obtain the patient's informed consent, disclose personal interests unrelated to the patient's health, whether research or economic, that may affect his medical judgment.").

B. *PODs Are Inconsistent with Anti-Fraud Principles*

1. Legislative Intent of Anti-Fraud Laws and Regulations

The over-arching purpose of the anti-fraud regulatory scheme is to prevent inappropriate financial considerations from influencing the amount, type, cost, or selection of a provider of medical care received by federal health care beneficiaries.[110] The purpose of the anti-kickback statute is to remove any financial element or incentive from a physician's medical advice or medical intervention for a patient. As such, advice or intervention should be objective, independent, and reliable.[111] In the context of the AKS, June Gibbs Brown, former Inspector General of HHS, stated, "[the law] is the guarantor of objective medical advice for federal health care program beneficiaries and helps ensure that providers refer patients based on the patients' best medical interests and not because the providers stand to profit from the referral."[112] Over the past several decades, in response to industry changes and the emergence of new challenges, the anti-fraud framework has been refined to "strengthen the capability of the Government to detect, prosecute, and punish fraudulent activities under medicare and medicaid programs . . . ."[113] AKS's "broad reach and 'one purpose' legal standard for assessing the legal rationale of arrangements is likely violated in virtually every arrangement."[114] Businesses are formed for the purpose of making a profit. Rational people invest time, money, and resources with the intent to see a return on their investment. While some physicians may be altruistic, they are generally rational actors. While other motivations may exist for their investment in PODs, physicians generally do so for the purpose of making money. It is hard to argue with this simple logic, and nearly impossible to refute when source after source suggests physicians invest in PODs as a means to generate additional revenue.[115] Regulating physician financial conflicts of interest and assuring strong enforcement and regulatory policies to avoid kickbacks or tainted self-referrals is not advanced by giving physicians the opportunity to make extra income from the sale of products they decide will be used in the performance of their own procedures.[116]

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110. *See* Thomas N. Bulleit, Jr. & Joan H. Krause, *Kickbacks, Courtesies or Cost-Effectiveness?: Application of the Medicare Antikickback Law to the Marketing and Promotional Practices of Drug and Medical Device Manufacturers*, 54 FOOD & DRUG L.J. 279, 282 (1999).

111. *See* MCDERMOTT & HARPER, *supra* note 26, at 8.

112. Press Release, Office of Inspector Gen., Inspector General Announces Eight New Anti-kickback Statute Safe Harbors (Nov. 18, 1999), https://oig.hhs.gov/fraud/docs/safeharborregulations/safenr.htm.

113. H.R. REP. NO. 95-393, pt. 2, at 53 (1977), as *reprinted in* 1979 U.S.C.C.A.N. 3039, 3040.

114. MCDERMOTT & HARPER, *supra* note 26, at 3.

115. *See, e.g.*, WHITAKER, *supra* note 8, at 28 ("Based on Medicare payment methods to hospitals and based on Medicare reimbursement formulas, annual escalations in orthopedic implant prices eroded both hospital profitability and exert a negative influence on surgeon reimbursement.") (citing STEINMANN STUDY, *supra* note 26). *See also* 2011 SENATE FINANCE POD INQUIRY, *supra* note 13, at 3.

116. *See* MCDERMOTT & HARPER, *supra* note 26, at 2.

2. Statutory Interpretation and the Application of Case Law Principles to PODs

According to the OIG, the lawfulness of any POD arrangement is dependent on the facts of each case and the conduct of its actors.[117] While case law should not be analyzed in a vacuum, they are instructive and shed light on the legality of PODs. This section will highlight several anti-fraud principles derived from case law and demonstrate how they directly apply to PODs. The principles espoused come from three federal courts of appeal cases and are presented in chronological order.

United States v. Bay State Ambulance & Hospital Rental Services, Inc.,[118] a 1989 Medicare fraud case, provides three useful legal principles regarding the federal AKS and its applicability to PODs. First, the court held that *any* amount of inducement renders a transaction improper, regardless of whether there was a valid reason for the payment.[119] Stated differently, because "[t]he gravamen of Medicare Fraud is inducement,"[120] so long as there is some factual support for an inducement, the burden will be met. The second principle relevant to PODs is that an "opportunity to earn money may well be an inducement to that person to channel potential Medicare payments towards a particular recipient."[121] The court's position that the mere "opportunity" for a sale creates a potential inducement in violation of the AKS lends support to the view that PODs are not lawful—wherever there is a financial incentive, there is an underlying conflict of interest. PODs are structured so that "opportunity" is always present. Physicians with an ownership interest in the distributorship stand to benefit every time they recommend products from that distributor. According to the third applicable principle, "That a particular payment was a remuneration (which implies that a service was rendered), rather than a kickback, does not foreclose the possibility that a violation nevertheless could exist."[122] Even remuneration for services of an insignificant nature could be, and should be, unlawful. This principle applies with even more force where remuneration is substantial, as the disparity in value creates considerable room for an inducement. If a POD serves only as the middleman in a financial transaction but adds nothing of value to the process, it is acting as nothing more than a shell entity. In situations where it provides only minor support services, such as checking for damage or sterility concerns, a kickback violation would still be possible because the value to those services is insignificant as compared to the remuneration or kickback.

Next, *Hanlester Network v. Shalala*[123] is instructive to this POD analysis because it explains the congressional intent behind earlier anti-kickback amendments, summarizes those changes, and clarifies the

117. 2013 OIG FRAUD ALERT: POEs, *supra* note 14, at 3.
118. 874 F.2d 20, 22 (1st Cir. 1989).
119. *Id.* at 30.
120. *Id.* at 29.
121. *Id.*
122. *See* United States v. Greber, 760 F.2d 68, 71 (3d Cir. 1995).
123. 51 F.3d 1390 (9th Cir. 1995).

definition of "remuneration." In 1977, based on congressional concerns stemming from increased fraud and abuse in federally funded programs, the text of the anti-kickback language was amended to prohibit "(1) the solicitation or receipt of '*any* remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind,' in return for referrals, and (2) the offer or payment of such remuneration to 'induce' referrals."[124] The court explained, "Congress introduced the broad term 'remuneration' in the 1977 amendment of the statute to clarify the types of financial arrangements and conduct to be classified as illegal under Medicare and Medicaid."[125] The "*any remuneration*" language "was intended to broaden the reach of the law which previously referred only to kickbacks, bribes, and rebates."[126] Congress also changed violation of the kickback statute to a felony "to strengthen the government's ability to prosecute and punish fraud in the system."[127] Additionally, the 1987 amendments consolidated Medicare and state kickback laws into the Social Security Act and added a provision delegating authority to the Secretary of HHS to exclude any individuals or entities from participating in Medicare or Medicaid if they violated Section 1228B(b) of the Act.[128]

In 1985, the court in *United States v. Greber*[129] addressed whether a payment made to a physician for professional services in connection with laboratory tests could constitute medical fraud. The government argued such a payment relationship could be fraudulent by referencing Congress' intent to combat financial incentives for ordering particular services patients did not need.[130] As both the text and the purpose of the statute supported the government's view, the court held that "if one purpose of the payment was to induce further referrals, the medicare statute has been violated."[131] As a result, "*any* remuneration" included kickbacks and bribes, thus expanding the definition of remuneration to cover situations where no professional services were rendered.[132] *Greber* bolstered support for this conclusion by citing *United States v. Hancock*,[133] which incorporated the term "kickback" as used in an earlier statute rather than remuneration, for the principle that,

> The potential for increased costs to the Medicare-Medicaid system and misapplication of federal funds is plain, where payments for the [non-value added services] are added to the legitimate costs of

124. *Id.* at 1396 (citing Medicare-Medicaid Anti-Fraud and Abuse Amendments, Pub. L. No. 95-142, 91 Stat. 1175, 1182 (1977)) (emphasis added).

125. *Hanlester*, 51 F.3d at 1398 (citing H.R. REP. NO. 95-393, pt. 2, 95th Cong., 1st Sess., *as reprinted in* 1977 U.S.C.C.A.N 3039, 3056).

126. *Id.* (emphasis added).

127. *Id.* at 1396.

128. *Id.* (citing Medicare & Medicaid Patient Program Protection Act of 1987, Pub. L. No. 100-93, 101 Stat. 680, 681–82, 689 (1987)).

129. 760 F.2d 68 (3d Cir. 1995).

130. *Id.* at 71.

131. *Id.* at 69.

132. *See id.* at 71 (emphasis added).

133. 604 F.2d 999 (7th Cir. 1979).

> the transaction. . . . [T]hese are among the evils Congress sought to prevent by enacting the kickback statutes.[134]

By adding "remuneration" to the language of the statute in the 1977 amendment, Congress made it evident that, "even if the transaction was not considered to be a 'kickback' for which no service had been rendered, payment nevertheless violated the Act."[135] Thus, the *Greber* court adopted an expansive interpretation of the AKS, in line with the congressional intent, and concluded that if the payments were intended to induce the physician to use certain services, the statute was violated, even if payments were also intended to compensate for professional services.[136]

C. *The Relationship Between PODs and Physician Self-Referrals—A Useful Analogy*

The evolution of the Stark Act, which regulates physician self-referrals,[137] provides a useful analogy for the lawfulness of PODs and how they can be addressed in the future. There are striking similarities between PODs and physician self-referrals as business structures.[138] Like self-referrals, PODs create opportunities for physician-owners to profit from their own referrals. Instead of making a referral for services to a facility where the physician has an ownership interest, a physician-owner makes a referral for the purchase of a device sold by a company in which he or she has an ownership interest. Both arrangements give rise to a conflict of interest as a result of the referring physician's ability to derive a financial benefit from self-referrals. Additionally, proponents of physician self-referrals advanced similar arguments as POD advocates—they increase competition (thus lowering costs), improve access (making new or otherwise cost-prohibited technology available and bringing existing medical technology to underserved areas), and spread risk.[139] Critics of physician self-referrals advanced arguments that mirror those of PODs—they create conflicts of interest, lower quality, result in overutilization, and are anti-competitive.[140] CMS has further noted that the Stark Act was specifically enacted to:

> address over-utilization, anti-competitive behavior, and other abuses of health care services that occur when physicians have financial relationships with certain ancillary services entities to which they refer Medicare or Medicaid patients . . . . Overutiliza-

134. *Greber*, 760 F.2d at 72 (citing *Hancock*, 604 F.2d at 1001).

135. *Id.*

136. *Id.* at 71.

137. *See supra* Part I.D.2.

138. *See generally* Jean M. Mitchell & Elton Scott, *Evidence on Complex Structures of Physician Joint Ventures*, 9 YALE J. ON REG. 489 (1992).

139. *See generally* Theodore N. McDowell, *Physician Self Referral Arrangements: Legitimate Business or Unethical "Entrepreneurship"*, 15 AM. J. LAW MED. 61, 65, 70–73 (1989).

140. *See, e.g.*, *id.* at 65; MCDERMOTT & HARPER, *supra* note 26, at 2 (describing the likeness between PODs and self-referral arrangements as "déjà vu all over again for fraud, waste, and abuse business practices negatively affecting publicly funded health care programs.").

> tion [sic] increases program costs because Medicare (or Medicaid) pays for more items or services than are medically necessary.[141]

These are the same negative effects referenced by the OIG in its 2013 fraud alert.[142]

The evolution of PODs parallels that of the Stark Act governing physician self-referrals. Similar to the emergence of PODs as an innovative solution to current challenges, self-referral advocates explained such arrangements were "necessary adjustments to the reimbursement and practice style changes that occurred in the health care sector . . . ."[143] Due to their lucrative nature and lack of regulatory guidance, physician ownership in health care facilities proliferated. Concerns over the lawfulness and ethical nature of physician self-referrals precipitated a number of studies, the results of which indicated that physician investments tended to increase both the frequency of referrals to clinics and the cost of services provided by the clinics.[144] Studies also found that physician owners "often established more complex ownership arrangements than nonphysician [sic] owners, and that at least part of the reason for the complexity [was] to circumvent laws and regulations that restrict physician ownership."[145] Once the problematic nature of self-referrals caught the attention of regulators and legislators, the government mandated studies to assess the effect physician self-referrals had on decision-making, patient outcomes, and costs (to health care generally and to Medicare specifically). The 1989 OIG study concluded that Medicare-provider physicians who invested in certain ancillary medical facilities were more likely to refer patients to self-owned facilities than physicians who did not have such interests.[146] Physician investment in medical facilities to which they refer patients resulted in physicians steering patients to specific facilities irrespective of lower quality of care or higher costs, supporting the proposition that many physicians respond to financial incentives.[147] As with PODs, OIG guidance for physician self-referrals initially suggested that physician ownership in health care entities was not a per se violation of anti-kickback

141. 69 Fed. Reg. 16124 (Mar. 26, 2004).

142. *See generally* 2013 OIG FRAUD ALERT: POEs, *supra* note 14.

143. Mitchell & Scott, *supra* note 138, at 493 (citing Robert H. Rosenfeld, *Market Forces Set off Skyrocketing Interest in Hospital-Doctor Ventures*, 14 MODERN HEALTHCARE 70 (1984)).

144. Mitchell & Scott, *supra* note 138, at 490.

145. *Id.* at 491.

146. *See generally* OFFICE OF INSPECTOR GEN., DEP'T OF HEALTH & HUMAN SERV., FINANCIAL ARRANGEMENTS BETWEEN PHYSICIANS AND HEALTH CARE BUSINESSES: REPORT TO CONGRESS (1989), https://oig.hhs.gov/oei/reports/oai-12-88-01410.pdf [hereinafter 1989 REPORT TO CONGRESS].

147. *See Physician Ownership and Referral Arrangements and H.R. 345, "The Comprehensive Physician Ownership and Referral Act of 1993": Hearing on H.R. 345 Before the H. Comm. on Ways and Means*, 103rd Cong. 163?71 (1993) (statement of Larry Morey, Deputy Inspector Gen. for Investigations, Office of Inspector Gen.).

laws.[148] However, once studies revealed the level of influence facility ownership had on decision-making and the costs to Medicare, the government enacted the first phase of the Stark Act. The purpose of this analogy is not to argue that PODs fall within the scope of the Stark Act, but that the commonalities between the PODs and self-referrals suggest PODs pose similar substantial risks, warrant similar controls, and therefore should at least be regulated.

D. *Moving Forward: Proposed Changes to the Legal Framework*

Part II of this Note demonstrated that PODs are precarious business entities that operate in a complicated arena. Given their problematic nature, what should be done in the future to properly manage the risks posed by PODs? There seem to be three general options for what should be done: (1) do nothing; (2) declare PODs unlawful entities and categorically prohibit them; or (3) regulate PODs.

First, policymakers could choose not to act with regard to PODs and hope they will not play a significant role in the future of health care. One possible rationale for government inaction is that PODs are short-lived and thus their potential for future harm is minimal. PODs will exist only as long as they remain profitable. However, the risk-averse response to PODs has arguably undercut the demand for their services. It can be reasonably inferred that the number of purchasers willing to buy medical devices from PODs has declined, as evidenced by the general hospital response to PODs. Where there is no demand, there is no profit. There also seems to be a decrease in supply levels to PODs, which may be attributed to device manufacturers' lack of willingness to sell to them (because they are seen as competitors) or an increase in regulatory hurdles. If the supply of devices dries up, PODs would have to purchase from generic contract manufacturers or become manufacturers themselves (which is unlikely given the capital investment). Either way, PODs would then fall within the ambit of the Food and Drug Administration, subjecting them to substantial regulatory oversight, as well as safety and quality standards. Regrettably, it is unrealistic that PODs will go away so long as they purport to offer cost savings, are able to secure supply, and can find buyers for their products. A second rationale for inaction with regards to PODs is that they do not have a sufficient share of the market to warrant action. In other words, the cost of regulation exceeds the harms mitigated. Finally, policymakers may believe the existing legal and regulatory framework is sufficient to regulate the conduct of PODs and that no specific action is necessary. Any egregious POD conduct that violates the law will be detected and prosecuted using mechanisms already in place.

Second, the government could take a hardline stance on PODs and declare them unlawful. Before any outright prohibition, the government would likely need to grant an amnesty period to give physician-

148. *See* 1989 REPORT TO CONGRESS, *supra* note 146, at 5 ("The current view of Federal authorities is that physician ownership does not, *in and of itself*, violate the anti-kickback laws.").

owners an opportunity to divest their ownership interests. Drawing a bright line on their legality is cheaper to administer and easier to enforce because PODs arguably pose a regulatory and enforcement nightmare. It is difficult to identify those with a financial stake in a POD.[149] They often have complex and indirect ownership structures. The various forms of remuneration, such as investment options, quasi-ownership, and creative compensation interests, further obscure ownership in PODs. Where business relationships require conflict of interest and financial interest disclosures, people may lie. Additionally, the practice of medicine itself presents challenges to regulation and enforcement, particularly where causation is hard to establish. Every day, physicians make medical judgments based on circumstances unique to each patient, the availability of resources, and technology levels, all in the face of scientific unknowns. Physicians are the experts—to what extent should one question whether a procedure is necessary, whether a procedure was excessive, or whether a physician's financial investment corrupted his independent medical judgment? It is extremely difficult to determine cause and effect where a number of factors, as well as judgment, may affect an outcome. Rendering PODs illegal would also lessen administrative burdens by eliminating the need to conduct a case-by-case analysis.

While a complete ban on PODs is more efficient than enacting regulation, it is not without negative consequences. Banning PODs could undermine cost goals by eliminating one class of competition and enable big device manufacturers to assume greater control over the market. If physicians are required to divest all financial interests in PODs, it is likely that due process lawsuits would follow. Many could find an outright prohibition inflexible and excessively harsh, especially where additional studies lack conclusive results. A final argument in support of a blanket prohibition on PODs is that exceptions undermine the law's effectiveness.[150] Once exceptions are carved out, it becomes more difficult to enforce the law. In the event the government has serious concerns regarding PODs but is not yet ready to enact a ban, the government could issue a moratorium on PODs for a set period of time, giving itself additional time to conduct further research.

The third option is to regulate PODs. This option strikes a balance between the two extremes. Regulating takes into account the concerns posed by PODs, proactively protects public interests, and could provide a narrow space for low-risk entities to be structured and operated within

149. *See, e.g.*, Memorandum from Suzanne Murrin, Deputy Inspector Gen. for Evaluation & Inspections, to Andrew M. Slavitt, Acting Adm'r for Ctrs. for Medicare & Medicaid Servs. 2 (Aug. 13, 2015), http://oig.hhs.gov/oei/reports/oei-01-14-00270.pdf ("Available information about [physician] ownership interests is limited and raises concerns about lack of transparency"). In its report, the OIG researched the ownership of twelve PODs from which hospitals in its 2013 study reported purchasing spinal devices. *See* LEVINSON, *supra* note 75. Of the twelve PODs, only two identified their physician-owners by name. The OIG was able to identify the physician owners of another three by reviewing State business registration websites. *Id.*

150. *See generally* Brent K. Hollenbeck & Brahmajee K. Nallamothu, *Financial Incentives and the Art of Payment Reform*, 306 JAMA 2028 (2011).

the boundaries of the law. If the solution to the POD debate is that they should be regulated, the question morphs into *how*. There are several ways PODs could be regulated, which include accreditation, the issuance of informal guidance, and changes to the legislative and rulemaking framework.

The first way to regulate PODs is through an accreditation process establishing a set of standards, establishing an accrediting body, and delegating responsibility for administering, monitoring, and ensuring compliance with the established standards. The standards created by the AASD to ensure ethical and lawful conduct could serve as a model for how to structure a similar regulatory scheme.[151] The existence of the AASD suggests that at least some PODs are committed to "protect[ing] patients, promot[ing] healthcare savings, and develop[ing], endors[ing], and enforc[ing] standards for the advancement of ethical and legal surgeon-owned distributorships."[152] While the government could model the AASD framework, I believe more robust oversight, monitoring, and enforcement is warranted. Utilization reports, audits, and capping cost increases to three percent of the consumer price index are the primary monitoring mechanisms and may not be enough to detect unethical or unlawful conduct. For example, the AASD utilization review allows for a fifteen percent range from the baseline before triggering review. If a physician was already using a certain medical device before acquiring an ownership interest in a POD that distributes the same product, the baseline could be skewed. Also, if utilization rates are based on procedure types and the frequency of device use, a fifteen percent range may not adequately protect patients where infrequent high-dollar devices may have influenced the physician's judgment. Finally, it is troubling that the most negative consequence for non-compliance with the AASD standards is the revocation of one's membership. If improper conduct is identified, it should be investigated more fully and reported to the appropriate government agency.

A second option, published by the Food and Drug Law Institute, is for HHS to issue interpretive guidance on PODs using the Special Fraud Alert framework, with the goal to "distinguish between ideal and problematic structural and operational features [of PODs], and, in particular, emphasize the importance in maintaining their independence from all manufacturers and their distributors."[153] This option would provide the device industry what they so desperately need—timely and clear(er) guidance. Because "actual behavior is the key determinant of regulat[ed] compliance and . . . enforcement action against improper behavior will remain the OIG's chief tool in combatting abusive conduct," guidance that differentiates fraudulent from the legitimate business relationships would eliminate some of the legal uncertainty.[154]

151. *See supra* Part II.C for the discussion on the American Association of Surgeon Distributors, an accrediting entity for ePODs.

152. *About AASD*, AM. ASSOC. OF SURGEON DISTRIBS., http://aasdonline.org/about-aasd/ (last visited Nov. 20, 2015).

153. Truhe, *supra* note 12, at 7.

154. *Id.*

While this sounds like a respectable solution, it also has limitations. As noted by the Supreme Court, "Interpretive rules do not require notice and comment, although . . . they also do not have the force and effect of law and are not accorded that weight in the adjudicatory process."[155] While this option may be helpful to those with financial interests in PODs, it has limited legal value and does not change the existing regulatory framework.

A third option is to modify the existing legal and regulatory framework through legislation and rulemaking. After legislation has been enacted into law, regulators can choose to regulate broadly and create exceptions to the rule or they can issue a more narrowly tailored rule. Regardless of the means selected to promulgate regulations governing PODs, both ultimately reach the same end. When deciding between these two options, a critical consideration is whether one is less confusing for those who will have to comply with its requirements. While rulemaking is the primary manner by which administrative agencies regulate, rulemaking in the health care fraud context has drawbacks. Generally, rulemaking takes time and lacks efficiency.[156] Another important consideration is that "[r]ulemaking is particularly ill-suited to an industry in constant flux. The health care market is a dynamic one, with providers adjusting to changing market conditions by continually developing new business arrangements (and often new forms of fraud)."[157] In contrast, anti-fraud regulation is reactive and is promulgated in response to improper practices.[158] The POD dilemma highlights this very issue and demonstrates how innovative business structures naturally arise where there are legal or regulatory gaps.

In light of the current political reality, it is more pragmatic and less destabilizing to modify the existing framework rather than abandon it and start over. As such, I recommend that PODs should be generally prohibited and that legislation should be enacted to make two key changes: (1) create a POD-specific statute which prohibits physician ownership in device distributorships where there is a financial conflict of interest, and (2) amend the Sunshine Act with a requirement for physicians themselves, as opposed to GPOs and other covered entities, to report all ownership interests.

A POD-specific statute should be enacted establishing a general prohibition on PODs (similar to the Stark Act for physician self-referrals). Unless there is an amnesty period, existing physician ownership in PODs should be grandfathered and capped at a small percentage (not to exceed five percent). While exceptions should generally be avoided, a few are warranted in this case. First, there should be an exception that permits physicians who were substantially involved in the

155. Krause, *supra* note 67, at 261.

156. *See id.* at 249–52, 276 (stating that few topics illustrate the pitfalls of the regulatory process as much as the Stark Law, where interim final regulations were not announced until more than eight years after the enactment of the expanded Stark II prohibitions).

157. *Id.* at 249.

158. *See id.* at 249–50.

design and development of a device to have a role in its distribution. While the same argument can be made that a fundamental conflict of interest exists, those concerns are outweighed by the expertise, knowledge, and value added as a result of developing physicians' involvement. In these circumstances, there needs to be evidence of the physician's role in the design and development, such as having the patent for the device in his or her name. There should be an exception for the "passive [physician] investor" who does not use any of the products sold by the POD in which he or she has an ownership interest.[159] This could include situations where the physician has an active license but is not active or does not use any devices sold by the POD in his medical practice. In these circumstances, the risk is low because it is a pure investment where there is no conflict of interest. A potential weakness arises when one asks why the physician does not just purchase stock in a publicly traded company. A third exception could include POD sales to end-users based on referral from physicians who have no financial stake in the transaction. In this scenario, the risk is lower because the "referring physician is exercising independent medical judgment, unclouded by financial incentives, with respect to a particular medical device."[160] A final exception might be permissible where there is medical necessity and an independent review has been documented when a recommending physician has a financial conflict. While this could serve as an adequate check and balance, it also adds additional problems, such as increased liability and difficulty conducting audits.

As an alternative to enacting a POD-specific statute, the legislature could make several smaller changes. First, it could amend the AKS to better address the complexity of business relationships that did not exist when the statute was first enacted, specifically addressing concerns that it is overbroad and deters potentially beneficial conduct.[161] Second, it could add a provision to the existing list of AKS safe harbor regulations, explicitly detailing what payment practices and arrangements would be legitimate for physicians investing in medical device distributorships. Third, it could modify the Stark Act to explicitly reference PODs as "entities" that provide DHS. This would make it crystal clear that the legislature intended for PODs to fall within the scope of the physician-self referral statute and end all debate on the issue. Finally, the legislature could restrict PODs from participating in Accountable Care Organizations in federal programs, effectively removing any POD's ability to sell to institutions that participate in federal health care programs.

159. *See* Ben Sutherly, *Physicians' Investments in Medical-device Companies Face Scrutiny*, COLUMBUS DISPATCH (Aug. 3, 2015, 5:53 AM), http://www.dispatch.com/content/stories/local/2015/08/03/physicians-investments-scrutinized.html.

160. Morrell & White, *supra* note 14, at 58.

161. *See* Sheehan & Goldner, *supra* note 44, at 168 (suggesting that the Anti-Kickback Statute "was not designed and has not been adapted to deal with either the benefits or the risks of many current healthcare relationships").

The second proposed change calls for an amendment to the Sunshine Act. The physician should bear the burden of disclosing and reporting conflicts of interest arising from POD ownership. Both the OIG and CMS have acknowledged that disclosure of financial conflicts of interest alone does not provide adequate protection.[162] While there is an administrative cost for those obligated to report under the statute and for those who administer the reporting process and database, reporting under the Sunshine Act promotes greater transparency of potential financial interests that may influence treatment decisions and increase health care prices. The amendment should include a statutory mandate for physicians to disclose and report *all* ownership interests in PODs where the physician recommends the use of devices sold by that POD. Disclosure should take the form of posting notice in their offices, providing patients with a written copy, and incorporating an acknowledgment in the patient consent form prior to treatment. Physician ownership interests should be reported and certified annually and be publicly available in the *Open Payments* system managed by CMS. Access to this information supports informed consent, promotes joint decision-making in treatment decisions, and improves quality of care. The rationale for this additional report stems from a general lack of disclosure, inconsistent requirements across the country, and the fact that courts have been hesitant to require financial disclosure of interests in the health care sector. As previously mentioned, it is difficult to identify indirect ownership interests due to the complexity of actors and layers of ownership that may be set up to circumvent the laws and avoid liability. Requiring that physicians report and certify these ownership interests puts the onus squarely on each physician. Consequences for failing to report, misrepresenting data, or knowingly certifying inaccurate information to the government should include civil fines, criminal penalties, exclusion from federal programs, and possible suspension or forfeiture of one's medical license. A possible counter-argument is that such a disclosure might be perceived as a breach of trust and may taint the relationship, resulting in more harm than actually posed by the financial conflict. Where a patient does not have alternative providers due to a lack of physicians, limited insurance coverage, or cost constraints, this disclosure may actually limit access to treatment. While this is a relevant concern, it is outweighed by quality and safety concerns. Moreover, because the medical profession is not subject to any constraints on conflicts of interest, disclosure of physician financial conflicts just makes sense.

E. *Recommended Enforcement Mechanisms*

Once the regulatory framework is modified and in place, enforcement is needed to deter unlawful conduct. There are a number of federal enforcement mechanisms available to ensure compliance with the

162. *See* 2013 OIG FRAUD ALERT: POEs, *supra* note 14, at 2 ("We do not believe that disclosure to a patient of the physician's financial interest in a POD is sufficient to address these concerns.").

law. As previously discussed, these include the AKS, the Stark Act, the FCA, and the Sunshine Act. Each serves a different purpose when it comes to enforcement in the health care anti-fraud context and can be used to police both individuals and business entities.[163] The preferred method of enforcement is a hybrid approach that relies on both the AKS and the FCA. This combination provides the most flexibility because the government can rely on either the AKS or the Stark Act as grounds for an FCA action. This ensures that, depending on the facts of the case, there is more than one enforcement approach. Additionally, the government has seen the most success battling fraud using the FCA. Allowing private citizens to file civil qui tam suits essentially provides the government with a free source of fraud-hunters. The individuals have to do the initial work to uncover the fraud, which then allows the government to pick and choose which cases it has an interest in enforcing. Moreover, this is a useful way to conserve judicial resources. Using the FCA as an enforcement tool can yield substantial judgments, especially where a number of records have been presented, treble damages apply, or the unlawful conduct included an evasion scheme. Finally, using the FCA does offer flexibility for how to structure the suit in civil cases due to its broad joinder and venue provisions, lower burdens of proof, and greater scope of discovery.

The AKS has the most developed case law, has proven effective in combatting fraud, includes safe harbors to cover legitimate business arrangements, and can serve as the basis for an FCA claim, thereby allowing qui tam suits to augment the government's fraud initiatives. But there are drawbacks, which show it should not be the sole enforcement method of choice. First, as the AKS is a criminal intent-based statute, the government must prove, beyond a reasonable doubt, the defendant engaged in unlawful conduct with the requisite mens rea. Where the facts of the case do not lend themselves to proving intent under the AKS, it makes no sense to pursue an enforcement action. Second, it is possible that because it casts such a wide net, the AKS may reduce innovation and the development of potential solutions to issues plaguing health care. Where the conduct teeters on the boundary, there may be policy reasons not to pursue the case. Third, due to more than twenty safe harbor provisions, a defendant may succeed in shielding his or her conduct from prosecution, which could result in case dismissal.

Neither the Stark Act nor the Sunshine Act are ideal enforcement mechanisms for policing PODs. Unless the law is modified or guidance issued to clarify how the Stark Act applies, using it to enforce compliance raises questions about both scope and applicability, such as whether exceptions for compensation agreements and investments apply to PODs. While the Stark Act has the advantage of being a strict liability statute, its unclear application to PODs weakens its value as an

163. *See supra* Part I.D, providing the legal and regulatory framework applicable to PODs. Again, this Note focuses on only a few of the enforcement mechanisms, but there are a number of other ways compliance with the laws can be enforced.

effective enforcement mechanism. Likewise, using the Sunshine Act as an enforcement tool is not desirable because the system has kinks, humans will make reporting mistakes, and it makes no sense to go after potentially harmless conduct (i.e., failure to submit a report) when there are criminals looking to circumvent the laws and drain money from the federal health care system. Additionally, while civil fines may deter bad conduct, the legislative intent of the statute was not to police improper behavior, but to promote transparency.

IV. CONCLUSION

U.S. health care is in a state of crisis. We must find ways to lower costs, reduce fraud, waste, and abuse, and improve the quality of patient care. Business relationships that inject serious conflicts of interest and create opportunities for fraud do not pursue resolution of these problems, but instead move us further away from the goals of health care reform. PODs, labeled as "inherently suspect" by the OIG,[164] fall into this problematic category and should be generally prohibited and strictly enforced. As with any business investment, physicians invest in medical device distributorships for the purpose of making a profit. This financial stake, coupled with the physicians' duty to make treatment decisions in the best interests of their patients, creates a conflict of interest that may improperly influence medical decisions, result in unnecessary procedures, adversely affect patient outcomes, and may enable fraud, waste, and abuse. Physicians should focus on the needs of their patients and take steps to avoid both real and perceived conflicts of interest, not create them. These ethical principles are rooted in the Hippocratic Oath. Even if the government does not issue further guidance on the legality of PODs, changes are necessary to ensure that patients and the public are adequately protected. PODs should be required to shoulder the burdens they have created and reap the consequences that they have sown.

164. 2013 OIG FRAUD ALERT: POEs, *supra* note 14, at 3.