February 5, 2016

Via Electronic Delivery

The Honorable Orrin G. Hatch  
Chairman  
Committee on Finance  
United States Senate  
219 Dirksen Senate Office Building  
Washington, D.C. 20510

The Honorable Kevin Brady  
Chairman  
Committee on Ways & Means  
United States House of Representatives  
1102 Longworth House Office Building  
Washington, D.C. 20515

Re: Potential Revisions to the Physician Self-Referral Law (“Stark Law”)

Dear Chairman Hatch and Chairman Brady:

The Advanced Medical Technology Association (“AdvaMed”) thanks you for the opportunity to submit written comments to the Senate Finance Committee and the House Ways and Means Committee with respect to potential approaches for improving the Stark Law. AdvaMed is the largest medical technology association in the world. It represents approximately 300 member companies that develop medical devices, diagnostic tools, and health information systems. Its members vary in size from cutting-edge startups to the largest manufacturers in the industry. The innovative products they develop and sell account for much of the life-enhancing healthcare technology purchased annually in the United States and globally.

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I. BACKGROUND

The process for modifying and enhancing the Stark Law requires careful crafting and consideration. AdvaMed recognizes that there may be multiple challenges facing providers and other participants in the health care delivery system in trying to comply with the Stark Law. This includes, as you note in your request, distinguishing between technical violations of Stark and more serious, problematic violations — i.e. those conflicts of interest that jeopardize a physician’s independent decision-making and patient treatment, the type of conflicts that ultimately gave rise to the original Stark Law. In fact, Congressman Pete Stark, who first introduced the law, is frequently quoted as having stated:

[W]hat is needed is what lawyers call a bright line rule to give providers and physicians unequivocal guidance as to the types of arrangements that are permissible and the types that are prohibited. If the law is clear and the penalties are severe, we can rely on self-enforcement in the great majority of cases.

One area that AdvaMed believes should be addressed more clearly in the Stark Law is the parameters of physician-owned distributors (“PODs”). PODs — as described in our recommendations below — pose the type of serious, problematic violation of Stark that the law was originally intended to combat. PODs “pose dangers to patient safety,” “produce substantial risk of fraud and abuse,” and are “inherent suspect,” as noted in a 2013 U.S. Department of Health and Human Services Office of Inspector General Special Fraud Alert (“OIG Special Fraud Alert”). PODs are created primarily to allow treating physicians to enter the medical device supply chain in order for the physician owners to profit from selling product to hospitals at which the POD’s physician owners treat their patients. Once the hospital agrees to purchase product from or through the POD, the physicians are able to order the device models that will benefit them financially, thereby potentially compromising what is best for their patients instead of exercising independent judgment.

PODs pose conflicts of interest and ethical concerns that are incompatible not only with the anti-kickback statute, but also with the Stark Law, and a physician is placed in a conflict situation when he/she has personal financial incentives that are dependent on the treatment options he/she elects. The prevalence and impact of PODs has grown significantly. PODs have a presence throughout the United States, and these entities are emerging in more sectors of the healthcare industry. The federal government’s own reports demonstrate the potential impact that PODs may have.

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3 AdvaMed points to the recent enforcement action against Dr. Aria Sabit as but one example of the potential patient harm, overutilization, and unnecessary procedures that can result from inappropriate PODs. In the Sabit case, the government alleged that payments received from Sabit’s POD drove him to perform medically unnecessary or excessive surgeries.

II. CURRENT APPLICATION OF THE STARK LAW

Under the Stark Law, a physician cannot make referrals for “designated health services” ("DHS") to entities with which he or she (or an immediate family member) has a direct or indirect financial relationship. The Centers for Medicare & Medicaid Services ("CMS") has previously indicated that DHS includes inpatient and outpatient hospital services that involve surgical implants. By agreeing to purchase implantable devices from or through the POD for physician owners to use in procedures they perform on their own patients at the hospital, the hospital is creating the opportunity for the physicians to earn a profit. This three-way arrangement creates potential illegal remuneration to the physician owners under the Federal Anti-Kickback Statute and constitutes a prohibited compensation arrangement under the Stark Law. In fact, CMS has previously expressed skepticism as to the validity of a POD three-way arrangement under Stark. In its 2008 proposed rulemaking under Stark, CMS noted that “an unbroken chain of financial relationships . . . connect the physician owner of a [physician-owned company] to a DHS entity [i.e. the hospital] to which the physician makes referrals,” and that the result is a so-called “indirect compensation” arrangement that would “run afoul of the physician self-referral statute.”

Because of the existence of the financial relationship between the hospital and the POD’s physician owners, those physicians are prohibited from referring patients to the hospital unless an exception to the Stark Law exists. POD supporters invoke the regulatory language of the “indirect compensation” exception to suggest that these arrangements are permitted under Stark; however, this exception to the Stark Law clearly does not exempt a POD arrangement from liability. Under the regulations, so-called “indirect compensation” received by the physician must:

- Reflect the fair market value for services and items provided and not determined in a way that accounts for the volume or value of referrals or other business generated by the physician for the DHS entity;
- Be set out in writing, signed by the parties, and specifying the services covered; and
- Not violate the anti-kickback statute.

First, Stark regulations define “fair market value” to mean the value “in arm's length transaction,” consistent with “general market value.” General market value means the price an asset would bring or compensation for services that would be determined as the result of bona fide bargaining between well-informed buyers and sellers who are not otherwise in a position to generate business for the other party. Because POD owners are in a position to implicitly or explicitly

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5 See 66 Fed. Reg. 856, 934 (Jan. 4, 2001) (stating, “If a physician performs the surgery in a hospital, and the hospital bills for the implant, the service would be a designated hospital service, regardless of whether the implant is a prosthetic or prosthetic device. In these cases, any financial relationship between the physician and the hospital would have to fit in an exception or the physician could not perform the surgery, much less the implant, since all hospital services are DHS.”).

6 The OIG guidance has repeatedly made clear that the “opportunity for a referring physician to earn a profit, including through an investment in an entity for which he or she generates business could constitute illegal remuneration under the anti-kickback statute.” OIG Special Fraud Alert at p. 2. In an October 6, 2006 letter, the OIG expressed concerns about POD arrangements with physician investors and hospital purchasers, noting that “the strong potential for improper inducements between and among the physician investors, the entities [PODs], device vendors and device purchasers [hospitals].” Letter from Vicki L. Robinson, Chief, Industry Guidance Branch, U.S. Department of Health and Human Services Office of Inspector General (Oct. 6, 2006). available at http://www.oig.hhs.gov/fraud/docs/alertsandbulletins/GuidanceMedicalDevice%20%282%29.pdf (emphasis added).

7 73 Fed. Reg. 23528, 23695 (April 30, 2008). Here, the physician-owner of the POD refers a patient to the hospital [DHS entity] to perform a procedure [DHS] using the POD product. The POD is paid by the hospital for the product, and the physician is paid a return on investment by the POD.

8 42 C.F.R. § 411.357(p).

9 42 C.F.R. § 411.351 (emphasis added).

10 Id.
condition their patient referrals to hospitals on the purchase of a POD’s devices for use in procedures with those patients, the hospital’s agreement to purchase devices from a POD is hardly an arm’s length fair market value transaction with which non-POD sellers can compete, either at the outset or with regard to each purchase transaction. Moreover, because POD owners control both the supply and demand for a product, the profits earned by the physician-owners also fail to meet the arm’s length, fair market value requirement.

Second, under the POD arrangement with the hospital, the remuneration paid by the hospital to the POD is determined in a manner that takes into account the volume or value of referrals or other business generated for the DHS entity. Each medical device purchased by a hospital from a POD, or as a result of a purchasing arrangement with a POD, is tied to a physician-owner’s patient referral to the hospital and, by definition, the remuneration paid by the hospital to the POD takes into account the volume or value of business generated for the DHS entity.

POD supporters point to the regulatory definition of “unit-based compensation” to suggest that indirect compensation arrangements do not take into account the volume or value of referrals, provided that (a) the compensation reflects the fair market value of the services or items actually provided, and (b) during the term of the arrangement, the compensation does not vary in any manner that takes into account referrals of DHS. In other words, if the per unit price does not vary during the term of the arrangement, POD supporters believe that a physician owner may profit from referrals under the exception. By taking this position, POD supporters attempt to evade any meaningful restriction on physicians’ entering the medical device supply chain for the sole purpose of profiting from their hospital referrals. Because POD profits are generated directly or indirectly by physician owners’ patient referrals and POD device sales to hospital customers, the profits also account for the volume or value of referrals and business generated between the hospital and the physician-owners. Whether or not the per unit price varies over the course of a single year does not address the fact that PODs are formed for the purpose of creating an opportunity for their physician-owners to profit from referrals to a hospital. This remuneration is ongoing and not unit-based, and as a result, the per click exception does not protect the POD-hospital arrangement.

Finally, as noted in the OIG Special Fraud Alert, the POD arrangement with the hospital and physician owners likely represents a violation of the Anti-Kickback Statute and accordingly, the terms of the exception cannot be met.

Despite this plain language reading of the Stark Law statute and regulations and despite CMS’s statements regarding the inappropriateness of distributor-like physician-owned companies, CMS has elected not to finalize specific regulations on this issue. PODs continue to proliferate, and definitive clarity under Stark is a necessity.

III. RECOMMENDATIONS

Given the inherent conflicts of interest posed by PODs, AdvaMed recommends that the Stark Law should be modified to clarify that POD arrangements are not shielded by the indirect

11 Moreover, OIG studies have shown that POD device prices may be higher than competitive non-POD device prices. See generally OIG Spinal Device Report.

12 See 42 C.F.R. § 411.354(d)(2).

13 See OIG Special Fraud Alert at p. 4; see also 42 U.S.C. § 1320a-7b(b). In the case of a POD, the physician owner receives remuneration in form of a return on investment in exchange for referring patients to a hospital where a procedure is performed using a POD product. The physician owner who also performs the procedure using the POD’s product may even get to “double dip” into the payment pool: that is, he/she is not only paid the return on investment, but he or she is also paid by the hospital or by a third-party payer for actually performing the procedure.
compensation exception. Further, AdvaMed recommends that the Stark Law should incorporate a definition of PODs that distinguishes clearly between inappropriate distributor arrangements from legitimate innovator companies. To these points, AdvaMed offers two specific recommendations.

First, given that POD arrangements with hospitals involve remuneration that invokes the Stark Law as described above, AdvaMed recommends that the Stark Law include clear language that POD arrangements are not subject to an exception under Stark, thereby prohibiting them. AdvaMed recommends adding the following to Section 1395nn(e) of 42 U.S.C.:

(9) Physician-Owned Distributors
Payments made to a physician holding an ownership or investment interest in a Physician-Owned Distributor, as defined in subsection (h) of this section, are not subject to the exception for compensation arrangements.

Second, AdvaMed urges Congress to include a definition of “physician-owned distributor” that focuses specifically on those arrangements that pose the most concerns under the law.

In general, the Stark Law does not apply to legitimate, innovator manufacturers operating within the medical device supply chain. Indeed, there are clear distinctions between legitimate, innovator manufacturers with physician ownership for legitimate business reasons apart from the ability to generate referrals to the manufacturer on the one hand and PODs (as defined below) on the other hand.

Many start-up manufacturers that create innovative, groundbreaking technology have an element of physician ownership (e.g., as a result of a founding investment, a transfer of equity in exchange for bona fide consulting services, or a contribution of novel, significant, or innovative intellectual property, etc.). Innovative manufacturers’ revenue, however, is not tied to physician owners, their referrals, or the procedures they perform using the manufacturer’s products. Physician ownership interests in these innovator manufacturers, in fact, generally form an insignificant portion of the manufacturer’s total equity. These medical device manufacturers, which are subject to FDA regulations on the development, marketing, and production of devices and subject to FDA inspection of production facilities, compete based upon innovation and market and sell (or expect to market and sell) products widely rather than primarily to health care facilities where the physician-owners refer patients or perform procedures.

PODs, on the other hand, simply sell or arrange for the sale of existing implantable devices and are not innovators of new products. PODs tend to sell only to a handful of entities, frequently even just one entity, and a majority of a suspect POD’s revenue is derived from its physician owners, their referrals, and/or the procedures they perform using POD-distributed devices. In fact, the primary purpose of the POD itself is to benefit the physician owners.

Accordingly (and generally speaking), innovator manufacturers do not pose the same Anti-Kickback Statute risks as PODs or undermine the public policy concerns the Stark Law intended to address as PODs do.14 Therefore, it is imperative for any definition of “POD” to distinguish clearly

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14 Legitimate manufacturers of medical devices do not exhibit the “suspect characteristics” of a POD that the OIG enumerates in its 2013 Special Fraud Alert. According to the OIG, PODs exhibit the following “suspect characteristics” under the Anti-Kickback Statute:

- The size of the investment offered to each physician varies with the expected or actual volume or value of devices used by the physician.
- Distributions are not made in proportion to ownership interest, or physician-owners pay different prices for their ownership interests, because of the expected or actual volume or value of devices used by the physicians.
between inappropriate POD arrangements and legitimate innovator manufacturers.

AdvaMed recommends including the following definition at 42 U.S.C. § 1395nn(h):

"Physician-Owned Distributor" or "POD" is defined as any entity, or any affiliate of an entity, in the medical device supply chain that has physician ownership, including ownership by individual physicians, a physician's immediate family members or agents, trusts, partnerships, limited liability companies, corporations, unincorporated associations, or any other entity established by or on behalf of physicians ("Physician Owner(s)") and that meets each of the following:

i. The entity derives any proportion of its revenue from (a) selling or arranging for the sale of medical devices ordered by Physician Owners for use in procedures using products distributed by the POD and performed by a Physician Owner or any other physician affiliated with the POD or affiliated with

- Physician-owners condition their referrals to hospitals or ASCs on their purchase of the POD’s devices through coercion or promises, for example, by stating or implying they will perform surgeries or refer patients elsewhere if a hospital or an ASC does not purchase devices from the POD, by promising or implying they will move surgeries to the hospital or ASC if it purchases devices from the POD, or by requiring a hospital or an ASC to enter into an exclusive purchase arrangement with the POD.

- Physician-owners are required, pressured, or actively encouraged to refer, recommend, or arrange for the purchase of the devices sold by the POD or, conversely, are threatened with, or experience, negative repercussions (e.g., decreased distributions, required divestiture) for failing to use the POD’s devices for their patients.

- The POD retains the right to repurchase a physician-owner’s interest for the physician’s failure or inability (through relocation, retirement, or otherwise) to refer, recommend, or arrange for the purchase of the POD’s devices.

- The POD is a shell entity that does not conduct appropriate product evaluations, maintain or manage sufficient inventory in its own facility, or employ or otherwise contract with personnel necessary for operations.

- The POD does not maintain continuous oversight of all distribution functions.

- When a hospital or an ASC requires physicians to disclose conflicts of interest, the POD’s physician-owners either fail to inform the hospital or ASC of, or actively conceal through misrepresentations, their ownership interest in the POD.

See OIG Special Fraud Alert at p. 3.

15 In its proposed rulemaking, CMS is careful to distinguish between physician-owned companies that are "manufacturers" and those "companies that profit from the purchase and resale of products made by another organization (that is, they act as distributors) . . . ." 73 Fed. Reg. at 23694. In these latter cases, according to CMS, "the physician investors bear little, if any, economic risk" and many of these companies provide "little, if any necessary research, design, or testing services." Id. Further, these non-manufacturing companies "may serve little purpose other than providing physicians the opportunity to earn economic benefits in exchange for nothing more than ordering medical devices or other products that the physician-investors use on their own patients." Id. This clear distinction between inappropriate POD arrangements and legitimate medical device manufacturers is a crucial one.
the Physician Owner or (b) patient referrals to other physicians who perform procedures using products distributed by the POD; and

ii. Physician Owners are compensated in the form of a commission, return on investment, profit sharing, profit distribution, or other remuneration directly or indirectly derived from (a) the sale or distribution of POD devices to an entity furnishing DHS used in procedures performed by such Physician Owner or any other physician affiliated with the POD or affiliated with the Physician Owner or (b) the referral of patients by the Physician Owner to other physicians who perform procedures at an entity furnishing DHS and using products distributed by the POD.

In any such revisions, it is important for the language of the Stark Law to be narrowly tailored such that it distinguishes between those supply chain entities that create real concerns and risks under Stark, because they enable their physician owners to profit from referrals, and those manufacturers with physician ownership for legitimate business reasons apart from generating referrals. As noted above, this latter category of companies does not give rise to conflicts of interest or depend upon self-referrals for revenue and do not implicate the Stark law. In either case, DHS entities should undertake robust due diligence to understand whether an entity with which it is contemplating doing business is a POD.

Implementing these revisions – (a) incorporating a definition of PODs under Stark that distinguishes between POD arrangements and legitimate medical device manufacturers and (b) explicitly excluding PODs from the compensation arrangements exception to Stark – would significantly reduce the risk of product over-utilization and patient harm associated with the inherent conflict of interest that is at the core of PODs.

IV. CONCLUSION

AdvaMed applauds your committees’ work in this area. While modifying the Stark Law does require that drafters take special care and caution with respect to crafting these revisions, additional clarity in the area of PODs is much needed. AdvaMed is grateful to provide any additional input as the process of modifying the Stark Law moves forward including, for example, with respect to changes to address more technical violations of Stark such as missing signatures or minor paperwork violations as well as concerns associated with shared savings programs.

Thank you for the opportunity to provide our initial comments on this critical topic. If you have any questions, please feel free to contact me directly.

Sincerely,

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Advanced Medical Technology Association
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