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August 24, 2018

By Electronic Submission via www.regulations.gov

The Honorable Seema Verma
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1720-NC
P.O. Box 8013
Baltimore, MD 21244-8013

Re: CMS-1720-NC: Request for Information Regarding the Physician Self-Referral Law

Dear Administrator Verma:

The Advanced Medical Technology Association (AdvaMed) appreciates this opportunity to submit comments on the physician self-referral law, Section 1877 of the Social Security Act (also known as the “Stark Law”), in response to the Request for Information (RFI) published by the Centers for Medicare & Medicaid Services (CMS) at 83 Fed. Reg. 29524 (June 25, 2018).

AdvaMed

AdvaMed is a trade association that represents the world’s leading innovators and manufacturers of medical devices, diagnostic products, digital health technologies, and health information systems. Together, our members manufacture much of the life-enhancing health care technology purchased annually in the United States and globally. Our members are committed to the development of new technologies and services that allow patients to lead longer, healthier, and more productive lives. The devices made by AdvaMed members help patients stay healthier longer and recover more quickly after treatment and enable clinicians to detect disease earlier and treat patients as effectively and efficiently as possible.

AdvaMed’s medical technology manufacturer members are well-positioned to support the ongoing transformation of the healthcare industry to value-based care. Manufacturers are experts in how their technologies impact clinical outcomes and have the specialized knowledge to design solutions to optimize care in a cost-effective manner—often using data generated from their devices to help facilitate care coordination. Medical technology manufacturers understand the importance of training, support services, data analytics, workflow efficiencies, and other aspects necessary for patients, providers and payors to realize the potential of technology and its ability to deliver value by improving outcomes that matter to patients and reducing costs and waste in the system.

AdvaMed and its members support a legal framework that protects patients and the federal health care reimbursement programs from fraud and abuse. Our member companies further recognize



the importance of ensuring ethical interactions between medtech companies and providers so that medical decisions are centered on the best interests of the patient. That is why AdvaMed developed a [Code of Ethics](#)¹ (also known as the “AdvaMed Code”) to distinguish beneficial interactions from those that may inappropriately influence medical decision-making.

Summary of Key Points

Our comments below include the following specific recommendations:

- The regulations under the Stark Law, the federal Anti-Kickback Statute, 42 U.S.C. 1320a-7b(b) (AKS), and the beneficiary inducement provisions of the Civil Monetary Penalty Law, 42 U.S. Code § 1320a-7a, all need to be updated to permit the transformation to value-based care that Congress and the Administration envision. To address one legal provision, without considering the fraud and abuse legal framework in its entirety, will not sufficiently enable the individual healthcare stakeholders to work together, coordinate care, and deliver the value that is now expected of them.
- In particular, the regulations under both the Stark Law and the AKS should contain parallel safe harbors setting forth terms and conditions under which value-based price adjustments and value-based services can be provided without violating the broad prohibitions of these two statutes. Absent these changes, these laws create significant impediments to implementation of measures needed to coordinate care, share risk, and otherwise improve clinical outcomes while controlling costs. The system is being called on to deliver value and measured outcomes. As a result, payors, providers, suppliers, and other stakeholders are now transacting commercial relationships by exchanging the new “currency” of measured outcomes and value, instead of services and dollars. We have attached to this letter a draft amendment to the Stark Law regulations which we believe would accomplish these goals subject to appropriate fraud and abuse protections; that amendment conforms to the safe harbor under the AKS which we proposed to OIG earlier this year.²
- Additionally, CMS should revise the Stark Law regulations to appropriately restrict physician-owned distributors—a type of arrangement that has repeatedly been identified as posing significant fraud and abuse concerns. We propose below text for two alternative regulatory changes to address this longstanding issue.

As we describe below, medical technology manufacturers have a key role to play in achieving the transformation to value-based care. Indeed, recent federal, state and private payor reimbursement initiatives have led our members’ health system and other provider customers to look to them for solutions to improve outcomes while controlling costs—and appropriately so, given our members’ deep knowledge regarding the conditions their products diagnose and treat. In many cases accomplishing these improvements requires going beyond a manufacturer’s core medical devices by providing tools and services to coordinate and optimize care. While many medical technology manufacturers may not be directly subject to the Stark Law, their customers typically are. It is

¹ AdvaMed Code of Ethics on Interactions with Health Care Professionals, https://www.advamed.org/sites/default/files/resource/112_112_code_of_ethics_0.pdf

² Comment Letter from AdvaMed to OIG (February 26, 2018), <https://www.advamed.org/resource-center/advamed-2018-aks-safe-harbor-proposals-value-based-arrangements>.

critical that the entire continuum of healthcare delivery participants has appropriate flexibility under the Stark Law and other fraud and abuse laws, to enter into value-based arrangements in order to deliver the value which is expected of them in today's environment.³

Modernizing Regulations to Promote Value-Based Care Solutions

CMS notes in the RFI that the Department of Health and Human Services (HHS) is working to transform the healthcare system into one that pays for value, and that as part of these efforts a key priority for HHS is removing unnecessary governmental obstacles to these efforts and to care coordination. AdvaMed and its members support this initiative. We offer below our insights into certain unnecessary regulatory barriers and suggest steps CMS should take to remove them, consistent with continuing to achieve the core goals of the Stark Law.

The Role of Medical Technology Manufacturers in Advancing Value-Based Care

Medical technology manufacturers long ago evolved from being mere “widget producers” into organizations that partner with providers, payers and other organizations to help provide care that results in better outcomes for lower costs. While manufacturers continue to improve the safety and effectiveness of devices themselves, our members have recognized that realizing the potential of medical technology often requires that providers and their patients have the support they need to address complex medical needs and navigate a complicated and frequently fragmented care delivery system. This includes, for example, care coordination services involving nurse call centers, monitoring and diagnostic technology, and management and communications processes.

Notably, realizing the goals of value-based care is often dependent upon actionable data. Medical devices often generate data on their own which functions as a key input to better coordinate care and enable providers and patients to redeploy resources where they are needed and avoid unnecessary costs. Medical technology is a crucial element in the creation of data ecosystems that empower providers and patients to implement value-based solutions and coordinate care in a cost-efficient manner.

Manufacturers also recognize that providers often need support in identifying the opportunities for cost-saving efficiencies consistent with high-quality patient outcomes, and in designing and operationalizing systems and arrangements to realize these efficiencies within complicated value-based reimbursement arrangements, consistent with applicable law. As such, manufacturers may offer the support of health care economists, reimbursement and health policy specialists, data analysts, and others to help facilitate the development and evolution of efficient and effective health delivery networks to achieve the goals of value-based care.

³ Additionally, some of our members provide Designated Health Services, as defined at 42 U.S.C. 1395nn(h)(6) and 42 C.F.R. 411.351. While our comments are not focused upon direct manufacturer-physician value-based arrangements, we believe that the draft exception to the Stark Law regulations for value-based pricing arrangements attached as Attachment A includes appropriate fraud and abuse protections to permit such arrangements.

Past Exclusion of Manufacturers from Fraud & Abuse Waivers to Promote Value-Based Initiatives

While medical device manufacturers can play a key role in advancing value-based care, outdated fraud and abuse regulations often act as barrier to them doing so. These include the regulations implementing the AKS, and the Stark Law.

CMS and the HHS Office of Inspector General (OIG) have recognized these issues, and as a result have issued conditional waivers from enforcement for certain entities and activities in connection with participation in many of the key value-based payment initiatives which CMS has rolled out in recent years. For example, in connection with the Medicare shared savings program which created Accountable Care Organizations (ACOs), CMS and OIG issued waivers in 2011, which were later updated in 2015.⁴ Unfortunately, manufacturers were excluded from eligibility for key aspects of these waivers. In particular, the pre-participation waiver, which protects arrangements for items, services, facilities or goods used to create or develop an ACO, such as care coordination mechanisms, quality improvement mechanisms, network development and management, and information technology, does not cover arrangements involving drug and device manufacturers.⁵ CMS and OIG claimed this exclusion was justified by the fact that manufacturers “are not Medicare enrolled suppliers and providers” and by unspecified “continuing program integrity risks,” but provided no logical explanation of why manufacturers should not be permitted to provide assistance in creating and developing ACOs, subject to the same protections as apply to ACO participants.⁶

This and other unsupported exclusions of manufacturers from protections designed to facilitate value-based initiatives have limited both their adoption and potential for success. In order to achieve CMS’s goals, all participants in the health care system—including payors, hospitals, physicians, other providers, and device and drug manufacturers—should be clearly permitted to tie the value of what they provide or pay for to its clinical or cost outcomes, and provide or receive value-based services designed to facilitate those outcomes, if they satisfy relevant requirements. Without promoting such arrangements and the healthcare industry will never be equipped to unlock the full potential of value-based care.

We agree with CMS that coordinating care is crucial to realizing the potential of value-based care arrangements. The expertise and resources our members can bring to developing arrangements to enable care coordination among all parties relevant to an episode of care can limit the need for isolated providers to continually reinvent the wheel—often at a cost that outweighs the potential upside from successful participation in the value-based arrangement. This is particularly true for rural health care providers and with respect to population health initiatives.

Recommendations for Stark Law Regulatory Reform Related to Value-Based Arrangements

We believe that CMS should design new exceptions to permit value-based arrangements regardless of the underlying payer reimbursement model, rather than attempting to design new exceptions

⁴ 76 Fed.Reg. 67992 (Nov. 2, 2012); 80 Fed.Reg. 66726 (Oct. 29, 2015).

⁵ 80 Fed.Reg. at 66731-2, 66742 (Oct. 29, 2015).

⁶ *Id.*

around specific alternative payment models which are currently in use or contemplated today. These models—and the healthcare system itself—are constantly and dynamically evolving.

These changes include managed care organization acquisition of various types of provider organizations, including integrated delivery systems, with physician integration and value-based compensation often a key element for success. Pharmacies, integrated delivery systems and managed care organizations are increasingly pursuing initiatives to provide care of various types in less-expensive settings than traditional medical facilities and physician offices, such as retail medical clinics and urgent care centers. Similarly, drug and device manufacturers are increasingly becoming involved in efforts to promote optimal care delivery and coordination, including through arrangements with suppliers and clinics, as well as by making available care-related software and various types of patient and provider support.

By the same token, payers have been adjusting reimbursement models with increasing frequency to reflect value-based arrangements and provide appropriate financial incentives at various levels of the system. These include initiatives such as oncology care pathways focused upon use of evidence-based therapies, with reimbursement incentives designed to promote appropriate use of cost-effective treatments—which may, in turn, be tied to outcomes-based pricing from manufacturers, as well as manufacturer provision of patient support. Moreover, the many current and contemplated innovations under the Medicaid program at the state and federal level—including the Medicare/Medicaid financial alignment demonstration, major increases in Medicaid managed care organization enrollment and numerous waivers for various types of initiatives—are sure to continue.

In light of these and similar developments, we ask that CMS consider revising the Stark Law regulations to broadly permit financial relationships resulting from value-based arrangements. In particular, we recommend that CMS modify the definition of “remuneration” at 42 C.F.R. 411.351 to expand the existing exclusions in that regulation to include value-based reimbursement or price adjustments provided to or by a physician, and value-based services provided to or for the benefit of the physician or the physician’s patients, so long as set criteria are satisfied. These would include documentation and, as appropriate, disclosure of the arrangement, in advance of payments being made or services being provided.

Relevant definitions should limit the characteristics of the price adjustments and services that would qualify for the applicable exception. For example, the permitted price adjustments could exclude those that knowingly induce the physician to reduce or limit the provision of medically necessary items or services to the physician’s patients. The permitted services could be subject to requirements that such services promote value-based care in defined ways, such as analysis for developing and software for operationalizing the value-based arrangement, or equipment and services for optimizing clinical outcomes through care coordination or otherwise.

We believe this type of approach would have the virtue of cutting through the clutter of the current Stark Law regulations to clearly delineate criteria for value-based arrangements that, once satisfied, would ensure that any Stark Law concerns have been addressed. These criteria should parallel those for a new safe harbor under the AKS, given the overlap between these two major fraud and abuse laws. AdvaMed submitted proposals for new value-based safe harbors to the AKS

in response to the OIG annual solicitation for new safe harbors.⁷ Attached for your consideration please find as Attachment A a proposed parallel Stark Exception that would support value-based pricing arrangements, associating payments with outcomes, by permitting price adjustments based on whether specified clinical or cost outcome targets were achieved (*e.g.*, performance or penalty payments) when certain conditions are met.

Modernizing Regulations to Address Physician-Owned Distributors

In addition to the recommendations we offer above, AdvaMed also believes that CMS should revise the Stark Law regulations to more clearly address the parameters of physician-owned distributors (PODs) further to its efforts to promote value-based care solutions while protecting the integrity of the Medicare program. As further discussed below, PODs create certain self-serving incentives that directly conflict with the goals of value-based arrangements, which include encouraging care coordination and appropriate incentives across the entire health care continuum. We offer below our insights into PODs, including how they discourage value-based care and create conflicts of interest and ethical concerns, as well as our recommendations for improving the Stark Law regulations to address the same.

Background Information Related to Physician-Owned Distributors

In general, PODs are entities that derive revenue from selling, or arranging for the sale of, devices ordered by their physician-owners for use in procedures the physician owners perform on their own patients.

PODs pose the type of serious, problematic violation of the Stark Law that the law was originally intended to combat. PODs are created primarily to allow treating physicians to enter the medical device supply chain for the physician owners to profit from selling product to hospitals at which the POD's physician owners treat their patients.

PODs pose conflicts of interest and ethical concerns that are incompatible not only with the AKS, 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 with no counterweighing incentive to achieve certain clinical outcomes and reduce costs. The federal government's own reports recognize the negative impact that PODs may have.⁸

⁷ Comment Letter from AdvaMed to OIG (February 26, 2018), <https://www.advamed.org/resource-center/advamed-2018-aks-safe-harbor-proposals-value-based-arrangements>.

⁸ See, *e.g.*, U.S. Department of Health and Human Services, Office of Inspector General, *Special Fraud Alert: Physician Owned Entities*, Mar. 26, 2013, available at http://www.oig.hhs.gov/fraud/docs/alertsandbulletins/2013/POD_Special_Fraud_Alert.pdf (OIG Special Fraud Alert) (PODs “pose dangers to patient safety,” “produce substantial risk of fraud and abuse,” and are “inherently suspect”); U.S. Senate Finance Committee, *Physician Owned Distributorships: An Update on Key Issues and Areas of Congressional Concern*, May 2016, available at <http://www.finance.senate.gov/imo/media/doc/Combined%20PODs%20report%202.24.16.pdf> (Senate Finance Committee Report) (“the Committee remains highly concerned about the damage that PODs have done, and are continuing to do, to patient safety and federal healthcare programs”); MedPAC, *Report to the Congress: Medicare and the Health Care Delivery System*, June 2018, available at http://medpac.gov/docs/default-source/reports/jun18_medpacreporttocongress_sec.pdf?...0 (MedPAC Report) (“PODs have the ability to distort the supply chain for medical devices— potentially resulting in an increase in the volume of surgeries performed on beneficiaries, higher costs for hospitals and the Medicare program, and inappropriate care”); U.S. Department

Of course, not all physician-owned businesses are problematic.⁹ 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.¹⁰

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). 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.

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. PODs have no incentive to participate in value-based arrangements that seek to encourage cost savings across the continuum of care, and in fact their model specifically discourages value-based initiatives that may create cost savings at the point-of-sale.

Accordingly (and generally speaking), innovator manufacturers do not pose the same AKS risks as PODs or undermine the public policy concerns the Stark Law intended to address as PODs do.

Current Application of the Stark Law to Physician-Owned Distributors

As you know, under the Stark Law, a physician cannot make referrals for “designated health services” (DHS) to entities with which the provider (or an immediate family member) has a direct or indirect financial relationship. CMS has previously indicated that DHS includes inpatient and outpatient hospital services that involve surgical implants.¹¹ By agreeing to purchase implantable

of Health and Human Services, Office of Inspector General, *Spinal Devices Supplied by Physician-Owned Distributor: Overview of Prevalence and Use, Executive Summary*, Oct. 2013, available at <http://oig.hhs.gov/oei/reports/oei-01-11-00660.asp> (OIG Spinal Device Report).

⁹ Indeed, the Senate Finance Committee Report acknowledges that “physician ownership in legitimate innovator companies is allowable.” Senate Finance Committee Report at 20.

¹⁰ 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.

¹¹ 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

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 AKS¹² and constitutes a prohibited compensation arrangement under the Stark Law.¹³

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 the Stark Law.¹⁴

However, the terms of this exception to the Stark Law cannot be met to exempt a POD arrangement from liability because the hospital's agreement to purchase devices from a POD is not an arm's length fair market value transaction,¹⁵ 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,¹⁶ and, as noted in the OIG Special Fraud Alert, the POD arrangement

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.”).

¹²The 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>.

¹³ See 73 Fed. Reg. 23528, 23695 (April 30, 2008) (“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).

¹⁴ For this exception to be available, the so-called “indirect compensation” received by the physician must: (1) 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; (2) be set out in writing, signed by the parties, specifying the services covered; and (3) not violate the anti-kickback statute. 42 C.F.R. § 411.357(p).

¹⁵ Stark Law regulations define “fair market value” to mean the value “in arm’s length transaction,” consistent with “general market value.” 42 C.F.R. § 411.351. “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. *Id.* Because POD owners are in a position to implicitly or explicitly 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.¹⁵ 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.

¹⁶ This is because 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. This conclusion does not change as a result of the “per click” exception at 42 C.F.R. § 411.354(d)(2), which provides 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. Whether the per-unit price varies over the course of a single year does not

with the hospital and physician owners likely represents a violation of the AKS.

Nonetheless, 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.

Recommendations for Stark Law Regulatory Reform Related to Physician-Owned Distributors

Given the inherent conflicts of interest posed by PODs, AdvaMed recommends that the Stark Law be modified to clarify that POD arrangements are not shielded by the indirect compensation exception. Further, AdvaMed recommends that the Stark Law should incorporate a definition of PODs that distinguishes clearly between inappropriate distributor arrangements that create real concerns and risks under the Stark Law, because they enable their physician owners to profit from referrals, and legitimate innovator companies that do not give rise to conflicts of interest or depend upon self-referrals for revenue. To these points, AdvaMed offers two specific recommendations for your consideration included at Attachment B.

Alternatively, AdvaMed recommends that the Stark Law regulations be revised to classify PODs as DHS entities, thereby prohibiting an owner-physician from ordering products from his or her POD, unless an exception applies.¹⁷ Proposed language related to this alternative recommendation is also included at Attachment B.

We believe implementing these revisions – (a) explicitly excluding PODs from the compensation arrangements exception to the Stark Law, (b) incorporating a definition of PODs under the Stark Law that distinguishes between POD arrangements and legitimate medical device manufacturers, or alternatively (c) classifying PODs as DHS entities – will encourage appropriate value-based arrangements and 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.

Conclusion

Due to the evolution of the healthcare system since the Stark Law was passed and implemented, current restrictions have become an unnecessary impediment to the adoption of modern value-based care arrangements. It is time to update the Stark Law regulations, ideally in concert with similar changes to the safe harbors under the AKS, to clearly permit value-based arrangements, subject to appropriate program integrity protections. In addition, the Stark Law regulations should be updated to address the conflicts of interest and ethical concerns posed by PODs.

Unlike past CMS and OIG approaches to these issues, these revisions should not exclude involvement by medical technology manufacturers, given the key role they and their technology can play in connection with arrangements to coordinate care, improve outcomes and lower costs.

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.

¹⁷ This recommendation is consistent with a potential revision included in the MedPAC Report. See MedPAC Report at 162.

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* * *

Thank you in advance for your consideration of the above proposals. We would be pleased to discuss these proposals in greater detail at your convenience. Please do not hesitate to contact me at (202) 783-8700 or cwhite@advamed.org with any questions.

Sincerely,



Christopher L. White
Chief Operating Officer and General Counsel
Advanced Medical Technology Association (AdvaMed)

ATTACHMENT A
New Stark Exception for Value-Based Arrangements

Within 42 CFR 411.351, under the definition of Remuneration, add a fourth exception to remuneration for value-based pricing adjustments and value-based services under a value-based pricing arrangement.

§ 411.351 Definitions. As used in this subpart, unless the context indicates otherwise:

...

Remuneration means any payment or other benefit made directly or indirectly, overtly or covertly, in cash or in kind, except that the following are not considered remuneration for purposes of this section:

...

(4) Any value-based price adjustment between a physician and an entity under a value-based pricing arrangement, or any value-based services provided to or for the benefit of a physician or any of such physician's patients under a value-based pricing arrangement, each as defined in paragraph (4)(iii) of this section, as long as the following standards are met—

- (i) The terms and conditions of the value-based price adjustment are set forth in writing and disclosed to the recipient of such value-based price adjustment by the entity or physician making such value-based price adjustment available, at or prior to the time of the first purchase or coverage of the reimbursable items and/or services (as defined in paragraph (4)(iii)(A) of this section) to which such value-based price adjustment relates under the value-based pricing arrangement. For such purposes, terms and conditions shall be deemed set forth in writing if the formula or other objective mechanism for determining the amount of the value-based price adjustment is set forth in such written document.
- (ii) The value-based services to be provided or made available as part of such value-based pricing arrangement are set forth in writing and disclosed by the entity to the physician at or prior to the time of the first purchase or coverage of the reimbursable items and/or services to which such value-based services relate under the value-based pricing arrangement.
- (iii) For purposes of this paragraph (4):
 - (A) The term reimbursable items and/or services means health care items and/or services (x) for which payment may be made, in whole or in part, under one or more of a Federal health care program, private health insurance coverage, or any other arrangement through which a third party provides health care coverage or services to patients, or (y) which are provided directly to patients on a private pay or charitable basis by a physician or entity;
 - (B) The term value-based services means analysis, software, equipment, information and/or services, provided or made available by an entity (or by a third party pursuant to an arrangement with the entity) as part of a value-based pricing arrangement between such entity and such physician, for a reduced charge or no charge (apart from the price or net cost for the reimbursable items and/or services to which the value-based pricing arrangement relates), for one or more of the following purposes:
 - (I) Determining the terms of such value-based pricing arrangement before such

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terms are set forth and disclosed in writing (including, without limitation, determining one or more of the metrics to be used in the value-based pricing arrangement);

- (II) Measuring, collecting, calculating and/or reporting the metric(s) upon which the value-based pricing arrangement is based and/or the resulting value-based price adjustment (if any) which is payable;
- (III) Optimizing the effectiveness and clinical utility of the reimbursable items and/or services to which the value-based pricing arrangement relates (e.g., training and/or process improvements); and/or
- (IV) Otherwise achieving the clinical and/or cost outcomes on which the value-based pricing arrangement is based, including through provision of analysis, software, equipment, information and/or services to patients to facilitate such outcomes;

Provided, that in the case of value-based services described in clauses (III) and (IV) of this definition, such services must relate to achieving clinical and/or cost outcomes in connection with conditions diagnosed or treated by one or more reimbursable items and/or services to which the value-based pricing arrangement relates, or to the use of one or more such reimbursable items and/or services (including, but not limited to, avoiding potential adverse outcomes related to such condition, diagnosis, treatment or use), in each case when such reimbursable items and/or services are appropriately used, and which do not knowingly induce the physician to reduce or limit medically necessary items or services to the physician's patients.

- (C) The term value-based pricing arrangement means an agreement or other arrangement under which an entity provides a value-based price adjustment to a physician, a physician provides a value-based price adjustment to an entity, and/or value-based services are made available to or for the benefit of a physician or any patients of such physician, in each case in accordance with the requirements of this section;
- (D) The term value-based price adjustment means a reduction to or increase in an entity's or physician's price or net cost for one or more reimbursable items and/or services to which the value-based pricing arrangement relates, consisting of one or both of the following:
 - (I) a discounted or bundled price or net cost initially payable for one or more such reimbursable items and/or services as part of a value-based pricing arrangement which also includes terms and conditions for a value-based price adjustment provided in accordance with clause (II) of this definition and/or value-based services provided in accordance with clauses (III) or (IV) of the definition of such term, in each case as set forth in the written document referenced in paragraph (4)(i) of this section; and/or
 - (II) a payment made by a physician to an entity, or by an entity to a physician, as a reduction to or increase in the recipient's price or net cost for one or more such reimbursable items and/or services, which is conditioned and/or

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New Stark Exception for Value-Based Arrangements

calculated based upon one or more clinical and/or cost outcomes (determined using one or more measurable metrics) which are associated with the value of such reimbursable items and/or services purchased under such value-based pricing arrangement when appropriately used, and which does not knowingly induce the physician to reduce or limit medically necessary items or services to the physician's patients, in accordance with terms and conditions set forth in the written document referenced in paragraph (4)(i) of this section.

Without limitation of the foregoing, a value-based price adjustment under this paragraph (4)(iii)(D) may include, without limitation, (x) an entity's payment to a physician of all or a portion of amounts which the entity receives or is not required to pay under a payment arrangement to which the entity is subject with respect to some or all of the reimbursable items and/or services to which the value-based payment arrangement relates, as a result (directly or indirectly, wholly or in part) of an intended clinical and/or cost outcome under such payment arrangement having been achieved (or partially achieved), and (y) a physician's payment to an entity (directly or through credit against amounts otherwise payable) of all or a portion of amounts which the entity owes or fails to receive under a payment arrangement to which the entity is subject with respect to some or all of the reimbursable items and/or services to which the value-based payment arrangement relates, or of costs otherwise borne by such entity, as a result (directly or indirectly, wholly or in part) of an intended clinical and/or cost outcome under such payment arrangement not having been achieved (or only partially achieved).

ATTACHMENT B
Stark Regulatory Revisions for Physician-Owned Distributors

Within 42 CFR 411.354, under subsection (d) regarding the special rules on compensation, add a new special rule related to PODs.

§ 411.354 Financial relationship, compensation, and ownership or investment interest.

...

(d) *Special rules on compensation.* The following special rules apply only to compensation under section 1877 of the Act and subpart J of this part:

...

(5) Payments made to a physician holding an ownership or investment interest in a Physician-Owned Distributor, as defined at §411.351, by such Physician-Owned Distributor are not eligible for the exception for indirect compensation arrangements.

In addition, within 42 CFR 411.351, add a new definition for PODs.

§ 411.351 Definitions. As used in this subpart, unless the context indicates otherwise:

...

Physician-Owned Distributor or POD –

- (1) Means any entity, or any affiliate of an entity, that has a physician owner 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 medical devices distributed by the POD and performed by a physician owner or any other physician affiliated with the POD or affiliated with the physician owner or (b) patient referrals to other physicians who perform procedures using medical devices 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 medical devices distributed by the POD 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 medical devices distributed by the POD.

ATTACHMENT B
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- (2) Does not include an entity in which the ownership or investment interest meets the requirements of the publicly traded securities exception in §411.353(a).
- (3) For purposes of this subpart, the term “physician owner” means a physician, or an immediate family member of a physician, who has an ownership or investment interest in a POD, including ownership or investment through agents, trusts, partnerships, limited liability companies, corporations, unincorporated associations, or any other entity.
- (4) For purposes of this subpart, the term “medical device” does not include a medical device for which:
 - (i) the referring physician is named as an inventor on an issued patent for the item ordered or requested by the physician, and
 - (ii) neither the referring physician, nor an immediate family member, receives any remuneration from the entity selling or arranging for the sale of the device based on the volume or value of referrals made by any such physician (or an immediate family member of any such physician), other than a return on his or her bona fide investment that is proportional to the amount of the investment.

Alternatively, within 42 CFR 411.353, add a new subsection related to PODs.

§ 411.353 Prohibition on certain referrals by physicians and limitations on billing.

...

- (h) Special rule for Physician-Owned Distributors. (1) A physician shall be deemed to have made a referral that is prohibited by paragraph (a) of this section to a POD, and the POD shall be deemed to have caused to be submitted a claim or bill prohibited by paragraph (b) of this section if –
 - (i) the designated health services include a procedure using a medical device supplied by or through the POD and performed by the referring physician or any other physician who has a financial relationship with the POD (or an immediate family member of any such physician); and
 - (ii) the physician performing the procedure or selecting the device (or an immediate family member of any such physician) has an ownership or investment interest in the POD.

In conjunction with this alternative new section, AdvaMed recommends including at 42 C.F.R 411.351 the same definition for Physician-Owned Distributor included above.