

December 31, 2019

By Electronic Submission via www.regulations.gov

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1720-P
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue SW
Washington, DC 20201

Re: CMS-1720-P: Proposed Rule Regarding Modernizing and Clarifying the Physician Self-Referral Regulations

Dear Administrator Verma:

On behalf of the members of the Advanced Medical Technology Association (AdvaMed), we are writing to provide comments in response to the proposed rule (Proposed Rule) regarding the physician self-referral law (also known as the “Stark Law”),¹ published by the Centers for Medicare & Medicaid Services (CMS) of the Department of Health and Human Services (HHS) at 84 Fed. Reg. 55766 (October 17, 2019).

I. INTRODUCTION

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 and life-saving health care technology purchased annually in the United States and globally. AdvaMed members range from the largest to the smallest medical technology producers and include hundreds of small companies with fewer than 20 employees. 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 and its members are uniquely positioned to engage with providers, payors, and others in beneficial value-based arrangements to improve care and reduce costs and are at the forefront of the development of collaborations intended to advance the objectives of value-based care. Our members support ongoing efforts by HHS to transform the health care system into one that pays

¹ Section 1877 of the Social Security Act, 42 C.F.R. Part 411.

for value and to remove unnecessary governmental obstacles to value-based care and care coordination, including as a result of the Stark Law.

As a result, AdvaMed and its members have been strong advocates for regulatory reform in this area for some time. We greatly appreciate CMS's efforts to establish new and modernized exceptions under the Stark Law to encourage and protect legitimate, good-faith arrangements necessary to coordinate care, control costs, and improve patient outcomes, and we appreciate the opportunity to comment on the Proposed Rule.

We also appreciate that CMS has coordinated closely with the Office of Inspector General (OIG) of HHS in developing some of the proposals included in the Proposed Rule and that it will consider comments submitted to OIG, as applicable.² We agree with CMS's aim to promote alignment across the agencies' proposed rules to ease the compliance burden on the regulated industry.³ Indeed, in the comments AdvaMed submitted to CMS in response to CMS's Request for Information (RFI) preceding this Proposed Rule, we discussed the importance of updating the Stark Law, the federal Anti-Kickback Statute (AKS),⁴ and the Civil Monetary Penalty Rules Regarding Beneficiary Inducements (Beneficiary Inducements CMP)⁵ in a parallel fashion in order to permit the transformation to value-based care.⁶

We include below comments regarding the following recommendations in response to the Proposed Rule:

- We support CMS's approach under the Proposed Rule to allow medical technology manufacturers, including manufacturers, distributors, and suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS), to participate in protected value-based arrangements. In particular, we agree with CMS's proposed definition of VBE participant, which does not exclude any medical technology manufacturers nor DMEPOS manufacturers, distributors, and suppliers. We also agree with CMS's proposal with respect to the exception for indirect compensation arrangements, which would not exclude any medical technology manufacturers, including DMEPOS manufacturers, distributors, or suppliers, from participating in value-based arrangements.
- In contrast to medical technology manufacturers, physician-owned distributors (PODs) pose significant fraud and abuse concerns, including the program integrity concerns CMS discusses in the Proposed Rule. 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. As such, CMS should finalize the definition of VBE participant to exclude PODs, and

² 84 Fed. Reg. 55766, 55776 (Oct. 17, 2019).

³ 84 Fed. Reg. 55772.

⁴ 42 U.S.C. § 1320a-7b(b).

⁵ 42 U.S.C. § 1320a-7a.

⁶ AdvaMed letter to the Honorable Seema Verma, Administrator of CMS, dated August 24, 2018, *available at* https://www.advamed.org/sites/default/files/resource/advamed_comments_re_stark_law_rfi.pdf (AdvaMed Comments to the Stark RFI).

also exclude PODs from participating in value-based arrangements eligible for protection under the exception for indirect compensation arrangements.

- We agree with CMS's proposed approach of requiring that the value-based activities be directly connected to, or reasonably designed to achieve, any of the enumerated value-based purposes and recommend that CMS finalize this approach. Further, we believe all four of the proposed value-based purposes are appropriate and should be finalized as proposed.
- We agree with CMS's proposed approach with respect to the proposed exception for cybersecurity technology and related services, which would not restrict manufacturers from making cybersecurity donations. Medical technology companies play a central role in the delivery of health care, including value-based health care, and should be permitted to make appropriate donations of cybersecurity technology and related services.

We have separately submitted comments to OIG in response to OIG's proposed rule regarding revisions to safe harbors under the AKS and Beneficiary Inducements CMP.⁷ Many of our comments in response to OIG's proposed rule are applicable to the Proposed Rule. We, therefore, request that CMS also review and consider such comments in the context of the Proposed Rule, as applicable.⁸

II. COMMENTS

A. Proposed Rule Section II.A.2.a: Proposed Definitions - VBE Participant

- 1. Medical technology manufacturers, including manufacturers of DMEPOS (which often also serve as distributors and suppliers), play a critical role in coordinating and managing care for patients and should be able to qualify as a VBE participant.**

Under the Proposed Rule, CMS proposes to define the term "VBE participant" as an individual or entity that engages in at least one value-based activity as part of a value-based enterprise.⁹ However, CMS notes that it is considering whether to exclude from the definition of VBE participant, among others, DMEPOS manufacturers, distributors, and suppliers or, in the alternative, whether to include in the exceptions related to arrangements that facilitate value-based health care delivery and payment (to be finalized at 42 C.F.R. § 411.357(aa)) a requirement that the arrangement cannot be between a physician (or immediate family member of a physician) and, among others, a DMEPOS manufacturer, distributor, or supplier.¹⁰

We agree with CMS's proposed definition of VBE participant, which does not exclude any medical technology manufacturers nor DMEPOS manufacturers, distributors, and suppliers. As further discussed below and in AdvaMed's Comments to OIG's Proposed Rule and AdvaMed's

⁷ Published at 84 Fed. Reg. 55694 (October 17, 2019).

⁸ https://www.advamed.org/sites/default/files/resource/advamed_comments_re_oig_vb_aks_sh_nprm_2019-12-24.pdf (AdvaMed Comments to OIG Proposed Rule Regarding Fraud and Abuse Revisions to Safe Harbors Under the Anti-Kickback Statute and Beneficiary Inducements CMP (OIG-0936-AA10-P))

⁹ 84 Fed. Reg. 55775 (to be finalized at 42 C.F.R. § 411.351).

¹⁰ 84 Fed. Reg. 55775-76.

Comments to the Stark RFI, such entities can and do play a critical role in patient care coordination and in value-based delivery and payment models. Such entities may also have direct patient contacts that justify their inclusion as parties working under a protected value-based arrangement to achieve the type of patient-centered care that is a core tenet of care coordination and a value-based health care system. Further, any unique abuse risks can be effectively managed through an activity/arrangement-based framework. As such, ***we recommend that CMS finalize the definition of VBE participant as proposed such that all medical technology manufacturers, and DMEPOS manufacturers, distributors, and suppliers, may qualify as a VBE participant.*** We have made the same recommendation in AdvaMed’s Comments to OIG’s Proposed Rule.

- **Medical Device (“Device”) manufacturers are now also health technology & solutions providers (medical technology manufacturers).**
 - Many may not be aware of how Device manufacturers have evolved from manufacturing stand-alone Devices into providers of health care solutions that integrate “traditional” Devices with digital, software, cloud, remote monitoring, telehealth, patient portal, and analytics technologies and services to tackle the clinical and operational challenges a provider and payor may face to improve health outcomes and lower costs.
 - Device manufacturers are now also sophisticated digital technology companies through the evolution of “traditional” manufacturers to integrate tech company capabilities and services.
 - The evolution to integrate health technologies and solutions also spans the subset of Devices that include those that are classified as Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS).
 - Excluding medical technology manufacturers, and manufacturers of DMEPOS (which often also serve as DMEPOS distributors or suppliers), by definition would exclude the vast majority of “health technologies”¹¹ recognized for the clear value and promise they bring to improving the coordination and management of care.
- **Medical technology manufacturers provide doctors and other clinicians with the data, platforms, and analytics to improve care coordination and management and have outsized potential to impact each aspect of organizational change (people, processes, and tools) to achieve the goals of value-based health care.**
 - **Value-based health care depends on data, and medical technology manufacturers are the backbone of the data ecosystem.** Value-based arrangements that focus on improving care coordination and management depend on capturing, producing, aggregating, analyzing, and sharing patient and operational data to improve health outcomes and reduce costs. Data is needed to establish baselines, design solutions, and measure performance. Data is also needed for clinicians and patients to make better decisions and take action earlier. Medical

¹¹ e.g., remote monitoring, predictive analytics, data analytics, care consultations, patient portals, and telehealth and other communications that may be used by providers, clinicians, payors, patients, and others to coordinate and manage care, improve the quality and safety of care, and increase efficiency. 84 Fed. Reg. 55694, 55705.

technology manufacturers are integral to each segment of the data ecosystem—generating, collecting, aggregating, reporting, analyzing, and sharing data and are more experienced than non-traditional digital companies at honoring and securing the privacy of patient data.

- **Medical technology manufacturers generate and collect clinical and operational data.** Aside from the obvious diagnostic and monitoring Devices, many other Devices generate data on their own or are integrated with digital, remote monitoring, software, cloud, and patient engagement technologies and services to generate, collect, and aggregate clinical and operational data.
- **Medical technology manufacturers see how people, processes, and tools¹² are working together in hospitals.** Medical technology manufacturers aggregate data across their Devices, which can integrate information from other connected Devices, technologies, and services into large data sets that can provide insights into clinical and operational practices within a health system. Medical technology manufacturers also supply prominent hardware and software components of health information systems from remote patient monitoring systems, picture archiving and communications systems (PACS),¹³ Radiology Information Systems (RIS),¹⁴ and electronic health records (EHR).
- **Medical technology manufacturers have unique expertise to analyze the big data picture and design solutions.** Medical technology manufacturers have clinical and operational expertise from developing, testing, and manufacturing Devices, along with studying continuing Device use, patient experience, and outcomes across provider approaches, to analyze globally aggregated data and design solutions to improve health outcomes, reduce costs, and improve the patient experience.

¹² Organizational change management experts utilize the People, Process, Tools/Technology (PPT) framework to assess an organization's operations and implement change to improve performance. People, Process, and Tools are the components of the “golden triangle,” or triple constraint, where modifying one component impacts the others, and balancing the components and maintaining good relationships among them is sought to achieve organizational efficiency. See *Everything You Need to Know about the People, Process, Technology Framework*, Smartsheet, available at: <https://www.smartsheet.com/content/people-process-technology>.

¹³ A Picture Archiving Communications System (PACS) provides one or more capabilities relating to the acceptance, transfer, display, storage, and digital processing of medical images and is regulated as a Class 2 medical device. Its hardware components may include workstations, digitizers, communications devices, computers, video monitors, magnetic, optical disk, or other digital data storage devices, and hardcopy devices. The software components may provide functions for performing operations related to image manipulation, enhancement, compression or quantification. medical devices. 21 C.F.R. 892.2050

¹⁴ Radiology Information System (RIS) functions include patient scheduling and tracking, workflow and resource management, examination performance tracking, examination interpretation, results distribution, and procedure billing, and record data such as when patients are scheduled for an MRI, when patients arrive, when the scanning starts, when the images become ready for interpretation by radiologists, when radiologist reports are finalized, and all of the intermediate steps. See McEnery, K. W., *Coordinating Patient Care Within Radiology and Across the Enterprise*, Journal of the American College of Radiology, Vol. 11, Issue 12, 1217–1225 (2014).

- Data Analytics and Operational Expertise– Medical technology manufacturers have built extensive expertise to improve systems and processes for research, development, manufacturing, and operations using advanced analytics capabilities that can be leveraged to develop solutions that improve the quality and efficiency of care.
 - Clinical Expertise- Medical technology manufacturers are experts in how their technologies affect clinical outcomes through the work of dedicated medical, clinical, quality, and health economics specialists, years of testing, scientific studies, and clinician feedback on Device performance. This specialized knowledge is applied to design solutions that improve health outcomes.
- **Patients, providers, and payors all want medical technology manufacturers to share in the accountability for outcomes.**
 - **More medical technology manufacturers will be willing to take on financial risk to achieve outcome targets and engage in more comprehensive, patient-centered Value-Based Arrangements (“VBAs”), stimulating innovation, and accelerating the transformation to paying only for the value delivered in the results that are achieved.**
 - **Several VBA design elements mitigate the potential for fraud and abuse.**
 - VBA programs require outcomes targets that are established and documented in advance of the VBA program implementation. Throughout the VBA implementation, the outcomes measures are tracked and documented in order to evaluate whether the proposed target is achieved or not. This requires a significant amount of cooperation by all parties to make sure that the VBA program is operationalized as intended. In light of the grounded data parameters and the significant amount of input and participation from all parties, the hands-on nature of these arrangements leads to less opportunity for any one participant or the group of participants to “game” the program and engage in fraudulent behaviors.
 - **Any unique abuse risks presented by medical technology manufacturers or DMEPOS manufacturers, distributors, or suppliers are best managed with an activity/arrangement-based framework.**
 - As supported above and further by the detailed comments below, value-based exception eligibility for medical technology manufacturers, and DMEPOS manufacturers, distributors, and suppliers, in the final rule, will give patients, providers, and payors substantially augmented opportunities for improving care coordination and management. Example VBAs are integrated into the comments below, highlighting the various ways that manufacturers of all types of medical devices, including DMEPOS, are on the front lines of care coordination and management. These examples also show how health technologies are integrated with “traditional” and DMEPOS Devices and the value proposition of medical technology manufacturer participation in value-based arrangements.
 - Activity/arrangement-based safeguards would more effectively and appropriately address any unique abuse risks presented by medical technology manufacturers or

DMEPOS manufacturers, distributors, or suppliers since the functional difference posed by these entities would be the range of remuneration that could be offered. However, AdvaMed agrees that one narrow category of Device distributor should be excluded because the fraud and abuse risks posed would not be addressed sufficiently in the current framework: physician-owned distributors (“PODs”).

There are numerous other examples of how medical technology manufacturers participate in the coordination and management of care for patients and otherwise improve health outcomes in a climate of disparate implementation of clinical practice nationwide. The following are just a few examples:

- A medical device manufacturer of automated external defibrillators (AEDs) and cardiac monitoring devices with transmitting capabilities also has a software solution that permits coordination among EMS/ambulance providers, emergency rooms, and catheterization laboratories. Specifically, the software enables receiving hospitals to access cardiac data from the EMS devices in real-time; receive advance notice of patients en-route; and empowers appropriate clinicians to provide consultation back to EMS personnel to direct target location (*e.g.*, local emergency room, the emergency room at a specialized hospital, cath lab).
 - The software is device-agnostic and has been intentionally designed for collaboration across AED manufacturers so that information can be relayed from the ambulance to the hospital regardless of brand. The coordination opportunities as a result of the software will lead to improved diagnosis, triage, and care of patients suffering myocardial infarctions to reduce response times and improve patient outcomes.
 - For certain classes of patients, reducing the time between myocardial infarction and patient catheterization to less than 90-minutes has been associated with improved patient outcomes and reduction of cardiac cell death. In leveraging the manufacturer’s device capabilities to transmit real-time data among the EMS crew, emergency room clinicians, and cardiologists, clinicians have detailed advance notice of a patient’s arrival and an unrivaled set of emergent data to coordinate and manage their care, thus significantly reducing the time to treat. In contrast, without this technology and appropriate intervention, patients arrive at the emergency room, and there is a delay while information is verbally transmitted from EMS personnel to the admitting staff; the emergency room then is likely to engage in its own triage and testing, performing an EKG itself (because it does not have the relevant information at hand), and coordinating with the cath lab as appropriate, all while the patient waits in the emergency room as critical time is passing.
- A DMEPOS manufacturer of advanced diabetes technologies (*e.g.*, an “artificial-pancreas device system” (APDS) combining an insulin pump, continuous glucose monitors (CGM), and specialized algorithms) collaborates with a payor and leverages machine learning and artificial intelligence to more effectively customize patient support and improve outcomes for patients struggling with diabetes management. In turn, payors experience reduced costs. Technologies such as this are critical in facilitating the transition to value-based care. One in five Americans aged 65 or older has been diagnosed with diabetes, and

effectively managing this disease is crucial to improving health and controlling Medicare costs.¹⁵

- A medical device manufacturer partners with health systems, integrated delivery networks (IDNs), accountable care organizations (ACOs) and payors to help them coordinate and manage the care for a patient population by aggregating data from multiple sources to provide insights into how patients are utilizing the health care system so that providers can proactively intervene and develop longitudinal care plans that meet the care needs of multiple types of patients over a longer period and create solutions that scale. Specifically, the medical device manufacturer leverages a suite of care coordination and engagement solutions and pathways, including software and tools (*e.g.*, tablet, emergency response pendant, medication dispenser) that provide automated support for patients, so that patients with a complex care regimen gain independence.
- A manufacturer of DMEPOS and Devices enters into a bundled service arrangement with an outpatient clinic chain to provide patient risk stratification analytics services, and a suite of 30-day product/therapy bundles to be selected by the clinic's physicians based on a patient's condition (may include both DME and non-DME products and services). The manufacturer bears the risk for any excess supplies (DME and non-DME) needed during the period of care. As part of the service arrangement, patients are provided access to a mobile patient application developed and offered by the device manufacturer to better engage in their care, and to electronically deliver clinical progress on their treatment securely back to the manufacturer, who aggregates this data and runs analytics, both of which are reported to the outpatient clinic physicians to provide them with additional information about the evolution of the patient's condition under the selected product/therapy bundle and how well the patient is tolerating and following the prescribed therapy.
- A medical device manufacturer of pressure injury prevention/treatment devices also offers a data analysis service to track clinical practices, clinical outcomes, and patient impact as they relate to hospital- or healthcare-acquired pressure injuries to the heel or sacrum. Patients who are bed bound and immobile are at increased risk for developing pressure injuries (*i.e.*, bedsores), especially on the sacrum and heels. These injuries can result in infections and almost always result in extended lengths of stay in the care environment. Under the program, the manufacturer trains nursing staff, helps develop and implement treatment protocols, and coordinates with clinical staff to review outcomes data in order to reduce hospital- or healthcare-acquired pressure injuries to the heel or sacrum, helping to prevent extended lengths of stay in the care setting, thereby reducing the risk of exposure to further healthcare-associated conditions.
- For a particular condition, numerous studies demonstrate that improving a patient's compliance with his/her therapy above a specific threshold results in (1) a reduction in the total number of days needed of therapy and (2) substantial health care cost savings, when

¹⁵ CMS Medicare Current Beneficiary Survey Data Highlight, September 2017, available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/MCBS/Downloads/Diabetes_DataBrief_2017.pdf.

monitoring services are performed, both at the individual patient level over an episode of care and aggregated for an identified target patient population. A DMEPOS manufacturer participates in care coordination with payors and providers through the use of its remote therapy monitoring solution, currently provided -- for commercial payers only -- for a daily fee in conjunction with its DMEPOS item that is utilized in the patient's daily therapy regimen. Therapy utilization data is transmitted securely from the patient's home and interpreted by therapy specialists employed by the DMEPOS manufacturer. If monitoring identifies therapy utilization falling below the clinically specified threshold, therapy specialists call the patient and/or caregiver for additional information to inform the care team and patient about the most appropriate options to improve therapy compliance.

- A medical device manufacturer of orthopedic and spinal implants also sells a surgical planning tool aimed at improving spine surgery by providing solutions for the full continuum of patient care. Specifically, the manufacturer partners with health care providers to support the pre-, peri-, and post-operative process by enabling surgeons to measure and document skeletal parameters that aid in the selection of implants and appropriate treatment as well as by providing caregivers with information for procedural precertification from payors to reduce unnecessary delays. Under the program, a tracking tool collects outcomes data that could potentially be used for predictive analytics.
- A medical device manufacturer of an implantable, life-saving device that treats a life-threatening disease that cannot be corrected by drug therapy also offers a device-agnostic software technology that identifies patients with the life-threatening disease well before they are referred to a specialist, or even to an implanting physician. The technology, combining specialized software and consultation services uses standard imaging to identify these potential patients (despite the disease state often being mistaken by both the patients and general physicians as the normal signs of aging), send their diagnostic information to specialty physicians for review, diagnosis and referral, and then can follow them through the system when they are in fact referred to a specialty physician. Partnerships with hospital systems and providers can help improve patient health outcomes and produce efficiencies that drive down costs.

Active participation of medical technology manufacturers in value-based arrangements is essential to improve outcomes and control costs within our health care system (a view we believe many providers fully share). Among CMS's cited reasons for considering excluding DMEPOS suppliers from the definition of VBE participants is its lack of clarity with respect to whether such entities have direct patient contact in order to justify including them in protected value-based arrangements.¹⁶ As many of the examples noted above illustrate, medical technology manufacturers – including DMEPOS suppliers - are often directly involved in care coordination and improving patient outcomes.

CMS also cites as a potential reason to exclude from the definition of VBE participant DMEPOS manufacturers, distributors, and suppliers its (and its law enforcement partners') program integrity concerns about potentially abusive arrangements between certain types of entities that furnish

¹⁶ 84 Fed. Reg. 55775.

designated health services (DHS) or otherwise participate in the health care system.¹⁷ AdvaMed and its members strongly support a legal framework that protects against fraud and abuse. That commitment is reflected in, among other things, our early development of the AdvaMed Code of Ethics¹⁸ to help ensure that interactions between manufacturers and providers are consistent with fraud and abuse laws and do not inappropriately influence medical decision-making, so that medical decisions are centered on the best interests of the patient. If permitted to be VBE participants, medical technology manufacturers, including those that are DMEPOS manufacturers, distributors, and suppliers, will be subject not only to the appropriate safeguards CMS and OIG have proposed under the value-based arrangement exceptions and safe harbors, but also to the AdvaMed Code of Ethics.

The detrimental impact of excluding DMEPOS is highlighted by the “artificial-pancreas device system” example above provided that illustrates the integration of devices, technologies, software, applications, and services to coordinate and monitor patient care and health outcomes (for individuals and populations), manage treatment, and communicate and access patient medical information.¹⁹ This example, “leverage[s] devices that can be worn or attached to the body to monitor blood sugar levels and transmit that data, through an application to a cloud storage service, for review by patients and the clinicians managing the patients’ diabetes care.”²⁰ The device that attaches to the body to monitor blood sugar levels and transmit that data is a continuous glucose monitor (CGM), which is combined with an insulin pump and specialized algorithms. Both CGMs and insulin pumps are classified as durable medical equipment (DME) under Medicare. Because the Proposed Rule would categorically exclude manufacturers, distributors and suppliers of DMEPOS from acting as a “VBE participant,” manufacturers of such health technologies would be precluded from participating in nearly all of the value-based arrangements contemplated by the Proposed Rule, even though they would be able to provide valuable data, analytics, monitoring, and telehealth capabilities. This value proposition is not merely hypothetical. The impact of such technologies in value-based health care arrangements with private payors is already visible. For example, at the end of the first year of implementation of one program, patients had reduced the incidence of diabetes-related preventable hospital admissions by 27%.²¹ The exclusion of DMEPOS manufacturers (which often also serve as suppliers or distributors) in the Proposed Rule, would deter manufacturers from entering into similar or more robust value-based arrangements with payers or providers serving, for example, Medicare beneficiaries.

¹⁷ 84 Fed. Reg. 55775-76.

¹⁸ AdvaMed Code of Ethics on Interactions with U.S. Health Care Professionals, <https://www.advamed.org/resource-center/advamed-code-ethics-2020>; The AdvaMed Code of Ethics Certification program is open to both AdvaMed member and non-member medical technology companies, including manufacturers and distributors. For more information about the certification program, visit <https://www.advamed.org/issues/code-ethics/code-ethics>

¹⁹ 84 Fed. Reg. 55705

²⁰ *I.d.*

²¹ <https://www.globenewswire.com/news-release/2018/07/10/1535429/0/en/First-Year-Results-from-Medtronic-and-UnitedHealthcare-Value-Based-Relationship-Demonstrate-Cost-Savings-and-Reduced-Hospital-Admissions.html>

For additional information regarding the important role of medical technology manufacturers, and DMEPOS manufacturers, distributors, and suppliers, in value-based arrangements, as well as information in response to CMS's program integrity concerns, please see AdvaMed's Comments to OIG's Proposed Rule,²² as well as AdvaMed's Comments to the Stark RFI.²³

2. PODs should be excluded from the definition of VBE Participant

As noted above, we believe all medical technology manufacturers, including DMEPOS manufacturers, distributors, and suppliers, should be permitted to participate in VBEs and value-based arrangements as VBE participants, consistent with appropriate standards finalized for the value-based exceptions. In contrast, *we recommend that CMS categorically exclude physician-owned distributors (PODs) from the definition of VBE participant, or otherwise finalize the Stark Law regulations to appropriately restrict PODs.*

Medical technology manufacturers, including legitimate, innovator manufacturers with physician ownership, must be distinguished from PODs. 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 are created primarily to allow treating physicians to enter the medical device supply chain and permit the physician owners to profit from selling a 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 Stark Law, but also with the AKS, 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. PODs pose the type of serious, problematic violation of the Stark Law that the law was originally intended to combat, and federal government reports recognize the negative impact that PODs may have.²⁴

²² https://www.advamed.org/sites/default/files/resource/advamed_comments_re_oig_vb_aks_sh_nprm_2019-12-24.pdf (AdvaMed Comments to OIG Proposed Rule Regarding Fraud and Abuse Revisions to Safe Harbors Under the Anti-Kickback Statute and Beneficiary Inducements CMP (OIG-0936-AA10-P))

²³ https://www.advamed.org/sites/default/files/resource/advamed_comments_re_stark_law_rfi.pdf (AdvaMed Comments responsive to CMS Request for Information Regarding the Physician Self-Referral Law (CMS-1720-NC))

²⁴ 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 (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> (“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 (“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 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>.

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 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). 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.

For additional information regarding PODs and the reasons for they should be excluded from the finalized definition of VBE participant, please see AdvaMed's Comments to OIG's Proposed Rule, as well as AdvaMed's Comments to the Stark RFI.

B. Proposed Rule Section II.A.2.a: Proposed Definitions – Value-Based Purpose

Under the Proposed Rule, only arrangements reasonably designed to achieve at least one of four enumerated value-based purposes would potentially qualify as a value-based arrangement to which the proposed exceptions related to arrangements that facilitate value-based health care delivery and payment would apply.²⁵ The four proposed value-based purposes are: (1) coordinating and managing the care of the target patient population ("TPP"); (2) improving the quality of care for the TPP; (3) appropriately reducing the costs to, or the growth in expenditures of, payors without reducing the quality of care for the TPP; and (4) transitioning from health care delivery and payment mechanisms based on the volume of items and services provided to mechanisms based on the quality of care and control of costs of care for the TPP.²⁶

CMS solicits comments on the proposed definition of value-based purpose generally as well as comments related to each of the enumerated proposed value-based purposes. With respect to value-based purpose (4) above, CMS notes that it interprets this purpose, "as a category that includes the integration of VBE participants in team-based coordinated care models; establishing the infrastructure necessary to provide patient-centered coordinated care; and accepting (or preparing to accept) increased levels of financial risk from payors or other VBE participants in value-based arrangements," but questions whether this goal lacks the precision necessary to know

²⁵ 84 Fed. Reg. 55774.

²⁶ 84 Fed. Reg. 55775.

whether the underlying purpose of an arrangement qualifies as a value-based purpose subject to protection.”²⁷

We agree with CMS’s proposed approach of requiring that the value-based activities be directly connected to, or reasonably designed to achieve, any of the enumerated value-based purposes and recommend that CMS finalize this approach. Further, we believe all four of the proposed value-based purposes are appropriate and should be finalized. We believe that all proposed purposes are important in the context of advancing the transition to value-based care, improving quality and health outcomes, and lowering health care costs. The increased flexibility of protecting arrangements involving all such value-based purposes will encourage beneficial and appropriate arrangements that accomplish these important goals.

With respect to the value-based purpose (4) above, we believe the proposed goal is appropriate and should be finalized as proposed. CMS’s proposed definition will encourage and protect beneficial and innovative arrangements, which may take many forms, including those not yet currently envisioned. Further, and importantly, this value-based purpose will protect appropriate and necessary pre-arrangement activities. In order to decide whether to pursue certain value-based arrangements and activities and to determine the terms and conditions for the same, potential VBE participants need to work together to develop the terms, conditions, and membership of the contemplated VBE. Such coordination and preparation may include the exchange of value. If the exchange of value is legitimately oriented toward establishing a VBE or the terms of a value-based arrangement (e.g., considering and establishing outcome targets or baselines), it should be protected.

C. Proposed Rule Section II.A.2.b(4): Proposed Exceptions; Indirect Compensation Arrangements to Which the Exceptions at Proposed § 411.357(aa) are Applicable (Proposed § 411.354(c)(4))

1. Medical technology manufacturers should be permitted to participate in value-based arrangements eligible for protection under the exception for indirect compensation arrangements

In the Proposed Rule, CMS identifies the circumstances under which the proposed exceptions for arrangements that facilitate value-based health care delivery and payment (at proposed new section 411.357(aa)) would apply to an indirect compensation arrangement that includes a value-based arrangement in the unbroken chain of financial relationships between the referring physician (or a member of his or her immediate family) and the entity furnishing DHS.²⁸ Specifically, CMS proposes that, when the value-based arrangement is the link in the chain closest to the physician (i.e., the physician is a direct party to the value-based arrangement), the indirect compensation arrangement would qualify as a “value-based arrangement” for purposes of applying the proposed exceptions for arrangements that facilitate value-based health care delivery and payment.²⁹ Such proposal would not exclude any medical technology manufacturers, nor DMEPOS manufacturers, distributors, or suppliers.

²⁷ 84 Fed. Reg. 55775.

²⁸ 84 Fed. Reg. 55786.

²⁹ *I.d.*

However, CMS notes in the Proposed Rule that it is considering whether to exclude an unbroken chain of financial relationships between an entity and a physician from the definition of “indirect value-based arrangement” if the link closest to the physician (that is, the value-based arrangement to which the physician is a party) is a compensation arrangement between the physician and a DMEPOS manufacturer, distributor, or supplier, among others, or if a DMEPOS manufacturer, distributor, or supplier, among other persons or organizations, is a party to any financial relationship in the chain of financial relationships.³⁰ CMS is also considering whether to include health technology companies in any such exclusion.³¹

We agree with CMS’s proposed approach with respect to the exception for indirect compensation arrangements, which would not exclude any medical technology manufacturers, nor DMEPOS manufacturers, distributors, or suppliers, from participating in value-based arrangements and recommend that CMS finalize the same. As discussed above in the context of the definition of VBE participant, medical technology manufacturers can and do play an important role in coordinating and managing patient care and health outcomes and should be permitted to participate in protected value-based arrangements.

Further, we note that there is no meaningful, rational distinction between “health technology companies” and medical technology manufacturer. Medical technology manufacturers now integrate “traditional” and DMEPOS Devices with digital, software, cloud, remote monitoring, telehealth, patient portal, and analytics technologies and services to tackle the clinical and operational challenges a provider and payor may face to improve health outcomes and lower costs. Medical technology manufacturers, including those that manufacture DMEPOS (which often serve as distributors and suppliers), are often at the forefront in providing the types of technologies that are beneficial in promoting improved patient monitoring, care coordination, and patient treatment, among other things.

As such, CMS should similarly not exclude health technology companies.

2. PODs should be excluded from participating in value-based arrangements eligible for protection under the exception for indirect compensation arrangements

For the same reasons discussed above in the context of the definition of VBE participant, *we recommend that in finalizing the regulations, CMS exclude PODs from participating in value-based arrangements eligible for protection under the exception for indirect compensation arrangements, or otherwise finalize the Stark Law regulations to appropriately restrict PODs*, which are a type of arrangement that has repeatedly been identified as posing significant fraud and abuse concerns.

D. Proposed Rule Section II.E.2.b: Cybersecurity Technology and Related Services (Proposed § 411.357(bb)); Conditions on Donation and Protected Donors

In the Proposed Rule, CMS does not propose to restrict the types of entities that may make cybersecurity donations under the proposed exception for cybersecurity technology and related

³⁰ 84 Fed. Reg. 55786-87.

³¹ *I.d.*

services.³² However, CMS notes that it is considering narrowing the scope of entities that may provide remuneration under the exception and solicits comments on whether particular types of entities should be excluded from donating cybersecurity technology and related services, including manufacturers.³³ In soliciting such comments, CMS distinguishes between individuals and entities that according to CMS have “direct and primary patient care relationships that have a central role in the health care delivery infrastructure,” such as hospitals and physician practices, and suppliers of ancillary services, such as laboratories, and manufacturers or vendors that “indirectly furnish items and services used in the care of patients.”³⁴

We agree with CMS’s proposed approach with respect to the proposed exception for cybersecurity technology and related services, which would not restrict manufacturers from making cybersecurity donations, and recommend that it finalize the same. Although CMS characterizes manufacturers’ role in the care of patients as “indirect,” in fact, as discussed above and in AdvaMed’s Comments to OIG’s Proposed Rule, as well as AdvaMed’s Comments to the Stark RFI, medical technology companies play a central role in the delivery of health care, including value-based health care. Medical technology companies should be permitted to make appropriate donations of cybersecurity technology and related services.

* * *

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,

/s/

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

³² 84 Fed. Reg. 55833.

³³ *I.d.*

³⁴ *I.d.*