

December 24, 2019

By Electronic Submission via www.regulations.gov

Ms. Joanne Chiedi
Acting Inspector General
Office of Inspector General
Department of Health and Human Services
Attention: OIG-0936-AA10-P
Room 5521, Cohen Building
330 Independence Avenue SW
Washington, D.C. 20201

Re: OIG-0936-AA10-P: Proposed Rule Regarding Fraud and Abuse Revisions to Safe Harbors Under the Anti-Kickback Statute and Beneficiary Inducements CMP

Dear Ms. Chiedi:

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 fraud and abuse revisions to safe harbors under the federal Anti-Kickback Statute (AKS)¹ and the Civil Monetary Penalty Rules Regarding Beneficiary Inducements (Beneficiary Inducements CMP),² published by the Office of the Inspector General (OIG) of the Department of Health and Human Services (HHS) at 84 Fed. Reg. 55694 (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. As further discussed below, our members support ongoing efforts by HHS to transform the health care system into one that pays for value and to remove unnecessary governmental obstacles to value-based care and care coordination, including as a result of the AKS and the Beneficiary Inducements CMP.

¹ Section 1128B(b) of the Social Security Act, 42 U.S.C. § 1320a-7b(b).

² Section 1128A(a)(5) of the Social Security Act, 42 U.S.C. § 1320a-7a(a)(5) (Beneficiary Inducements CMP).

As a result, AdvaMed and its members have been strong advocates for regulatory reform in this area for some time. We greatly appreciate OIG's efforts to establish new and modernized safe harbors under the AKS 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.

II. OVERVIEW

Medical Device ("Device") manufacturers should be included among those entities that are able to utilize all of the final rule's value-based AKS safe harbors because Device manufacturers can make necessary contributions to advance value-based health care, and concerns about the risk of abuse can be effectively managed through an activity/arrangement-based framework.

- (1) Device 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, process, and tools) to achieve the goals of value-based health care.**
 - **Value-based health care depends on data, and Device 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. Device 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.
 - **Device 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.
 - **Device manufacturers see how people, processes, and tools³ are working together in hospitals.** Device 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. Device manufacturers also supply prominent hardware and software components of health information systems from remote patient monitoring systems, picture archiving

³ 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>.

and communications systems (PACS),⁴ Radiology Information Systems (RIS),⁵ and electronic health records (EHR).

- **Device manufacturers have unique expertise to analyze the big data picture and design solutions.** Device 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.
 - Data Analytics and Operational Expertise– Device 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– Device 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.
- **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 “widgets” (e.g., first-generation implants) 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.

⁴ 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

⁵ 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).

- The evolution to integrate health technologies and solutions also spans the subsets of Devices that include implants and those that are classified as Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS).
- Excluding DMEPOS and Device manufacturers by definition would exclude the vast majority of “health technologies”⁶ recognized by the OIG for the clear value and promise they bring to improving the coordination and management of care, some of which are regulated as Devices themselves.

(2) Patients, providers, and payors all want Device manufacturers to share in the accountability for outcomes.

(3) More Device 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.

(4) 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.

(5) Any unique abuse risks presented by Device manufacturers are best managed with an activity/arrangement-based framework.

- As supported above and further by the detailed comments below, value-based safe harbor protection eligibility for Device manufacturers 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 implants and 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 Device manufacturer participation in value-based arrangements.
- Activity/arrangement-based safeguards would more effectively and appropriately address any unique abuse risks presented by Device manufacturers since the functional difference posed by Device manufacturers 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

⁶ 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.

current framework: physician-owned distributors (“PODs”).

The detailed comments in the next section also address a number of other aspects of the Proposed Rule. Some highlights of these comments include the following:

- **Proposed Rule Section III.J.3.a:** Under the revisions to the safe harbor for personal services and management agreements, outcomes-based payments to an agent should be permitted when the targeted outcome is internal cost savings for the principal, so long as patient outcomes are not adversely affected. Similarly, there also should not be a requirement for reduction in “payor” costs. Where improvement in patient outcomes is targeted, there should not be a requirement that it occur across care settings—improvement in the care setting of the principal should be sufficient. Further, the language of the Proposed Rule should be revised, consistent with OIG’s discussion, to allow “penalty” payments from an agent to a principal when an outcomes target has not been met.
- **Proposed Rule Section III.J.3.g:** OIG should clarify the criteria under which it would consider the methodology for determining an outcomes-based payment to be consistent with fair market value. An outcomes-based payment methodology should be determined to be consistent with fair market value using the same criteria as apply to fair market value determinations generally—*i.e.*, that the methodology is consistent with arms-length bargaining between unrelated parties. Since comparable transactions where the payment amount is determined based upon the outcome achieved often will likely not be available, OIG should describe permissible ways to make a fair market value determination when that is the case. These should include recognizing that a methodology is consistent with fair market value when the given payment levels for each outcome are economically rational for, or otherwise further a legitimate business interest of, each party.
- **Proposed Rule Section III.B.6:** We recommend that the proposed definition of “coordination and management of care” be revised to more clearly encompass patient monitoring, communication, diagnosis, and treatment.
- **Proposed Rule Section III.C.6:** OIG should not finalize any recipient contribution requirement under the care coordination arrangements safe harbor.
- The safe harbors should be revised to protect remuneration related to legitimate pre-arrangement activities necessary to evaluate and structure a value-based arrangement in order to meet the goals of any such arrangement.
- **Proposed Rule Section III.K:** Protection for warranties on bundled product and service offerings should not be limited to bundles under which all reimbursable items and services are reimbursed under the “same program, same payment” or “same program, same methodology,” as these requirements are unworkable given the myriad of reimbursement arrangements to which providers are subject today. There also should not be a prohibition on exclusive or minimum purchasing requirements, which are frequently an essential feature of outcomes-based arrangements. Moreover, warranty safe harbor reporting requirements should be updated to apply only when the buyer actually has a reporting requirement under the applicable Federal health care program.

AdvaMed applauds OIG for undertaking this effort and appreciates the opportunity to provide these comments. Removing unnecessary obstacles to beneficial value-based arrangements is essential to achieving the goals of improved care at lower cost. We strongly believe that this can be done in a manner fully compliant with the principles of the AKS and the Beneficiary Inducements CMP, within the general parameters proposed by OIG.

III.COMMENTS

A. Proposed Rule Section III.B.5: Proposed Value-Based Terminology - VBE Participant

Our comments in this section relate to the definition of value-based enterprise participant OIG has proposed at 42 C.F.R. § 1001.952(ee), which is a term that is used in several of the proposed safe harbors. As indicated in the section below on the proposed modifications to the safe harbor for personal services and management contracts relative to outcomes-based payments (at 42 C.F.R. § 1001.952(d)(2)), these comments also relate to the portions of that safe harbor relating to potential exclusion of DMEPOS manufacturers, distributors, and suppliers, and consideration of other potential exclusions.

1. Medical technology manufacturers play a critical role in coordinating and managing care for patients

Under the Proposed Rule, medical technology manufacturers can be considered as “value-based enterprise participants” or “VBE participants.”

AdvaMed appreciates OIG’s recognition of the important contributions that medical technology can make to advancing value-based care and the promise they offer in improving care coordination and health outcomes. In the Proposed Rule, OIG states:

“We are mindful that a growing number of companies are providing mobile health and digital technologies to physicians, hospitals, patients, and others for the coordination and management of patients and their healthcare, and such companies are eligible to be VBE participants under the proposed definition. These companies provide a range of services such as 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. These companies also furnish a variety of devices, technologies, software, and applications that support their services... These technologies hold promise for improving care coordination and health outcomes through monitoring of real-time patient data and detection and prevention of health problems.”⁷

OIG recognized in the Proposed Rule that companies providing mobile health and digital technologies, as well as related devices, software and applications, provide “a range of services” that are used “to coordinate and manage care, improve the quality and safety of care, and increase efficiency,” and stated that “such companies are eligible to be VBE participants under the proposed definition.”⁸

Care coordination and management improvements depend on data—capturing, producing, processing, aggregating, analyzing, and sharing patient and operational data. Data is needed to establish baselines, design solutions, and measure performance relative to targeted outcome measures. Data is also needed for clinicians and patients to make better decisions and take action earlier. Device manufacturers are integral to each segment of the data ecosystem—capturing, generating, collecting, aggregating, processing, analyzing, reporting, and sharing data and are more experienced than non-traditional, digital companies at honoring and securing the privacy of patient data.

⁷ 84 Fed. Reg. 55694, 55705 (Oct. 17, 2019).

⁸ 84 Fed. Reg. 55705.

In addition to the technologies with obvious roles for coordinating and managing care, many other Devices capture clinical and operational data or are integrated with other technologies and services to generate, collect, aggregate, analyze, and share data. Some Devices, like Picture Archiving Communications Systems (PACS),⁹ also serve as a platform to share, process, and analyze data. Device manufacturers also produce other platforms that integrate PACS with other functions and data. For example, Radiology Information Systems (RIS) integrate with PACS and manage radiology department operational functions, such as patient scheduling and tracking, workflow and resource management, results distribution, and procedure billing. Together these platforms generate and collect a wealth of clinical and operational data from connected Devices, other technologies, and services that can be used to formulate solutions to improve health outcomes, improve the quality and safety of care, and lower costs. Some Device manufacturers also produce EHR platforms that integrate with RIS and other platforms that manage services that are directly involved in managing patient care. For example, *in vitro* diagnostics (“IVDs”) have an essential role in clinical practice and influence about two-thirds of clinical decisions.¹⁰ In addition to manufacturing *in vitro* diagnostic platforms, Device manufacturers also produce Laboratory Information Management Systems (“LIMS”), which track equipment, samples, and test results, manage their workflows/protocols, create compliance reports, and analyze findings.

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. Device 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. Device 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 coordinating and managing care. Accomplishing these improvements with a VBA often involves providing tools and services (beyond selling a Device) to help coordinate and optimize care as part of the shared accountability to achieve the outcome target. Examples of these tools and services include education, training, care pathways, protocols, and care coordination services, which may involve nurse call centers, digital, monitoring, and/or diagnostic technology.

In addition, providers often need support in identifying the opportunities for care improvements and cost-saving efficiencies, and in designing and operationalizing systems and arrangements to realize such

⁹ See footnote 4.

¹⁰ Rohr U-P, et. al., The Value of In Vitro Diagnostic Testing in Medical Practice: A Status Report, PLoS ONE 11(3): e0149856 (2016), available at: <https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0149856>. (“The present study confirms the widespread belief that IVDs play an important role in clinical practice, as they influence 66% of clinical decision-making. This verifies the statement from the Lewin Group, which reported this number to be between 60–70%, which was a central aim of our study. Our investigation shows that clinical chemistry and hematology assessments play a pivotal role for clinical decision making in the initial patient work-up phase. This holds true for both the cardiology and oncology disease areas. Major differences in the use of molecular testing between the oncology and cardiology settings illustrates the excellent progress made in the field of personalized healthcare in cancer management but concerns remain over the low use of molecular testing in the cardiology field... Conclusion[:] *IVDs are an indispensable tool in clinical practice as they govern approximately 66% of clinical decision-making while accounting for approximately 2.3% and 1.4% of healthcare spending in the US and Germany, respectively.*”) (emphasis added)

improvements and efficiencies. Manufacturers are well-positioned to help in this regard as their equipment has countless touchpoints with patients and clinicians daily. As such, manufacturers may help to identify workflow efficiencies and improvements to management and communications processes, and in some cases can offer the support of health care economists, reimbursement and health policy specialists, supply chain experts, data analysts, systems experts, and others to help facilitate the development and evolution of efficient and effective health delivery networks to responsibly achieve the goals of value-based care.

Organizational change management experts often employ a People, Process, Tools (PPT) framework to assess operations and implement change to improve performance.¹¹ Applying the PPT framework to improving care coordination and management involves optimizing and balancing three components—People, Processes, and Tools. Medical technology manufacturers provide many of the Tools to manage and coordinate care. Through their network of technologies (including diagnostics, monitoring, and telehealth Devices) and platforms described above, medical technology manufacturers offer valuable perspectives on the Process component of PPT. Medical technology manufacturers also provide training on the safe and effective use of their Devices and can directly impact the People component through that training and harnessing insights obtained through training across institutions. Medical technology manufacturers provide doctors and other clinicians with the data, platforms, analytics, tools, and training that can be used to improve care coordination and management. Through this involvement and perspective, medical technology manufacturers have outsized potential to impact each component of organizational change (people, process, and tools) to improve the coordination and management of care.

There are numerous 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 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

¹¹ See footnote 3.

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.¹²
- 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,

¹² 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.

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 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.

Importantly, there is no meaningful, rational distinction between "health technology companies" and "traditional medical device manufacturers." As the following additional examples illustrate, traditional medical device manufacturers, including manufacturers of implantable devices, are often at the forefront in providing the types of technologies that OIG expressly recognizes as beneficial in promoting improved patient monitoring, care coordination, and patient treatment, among other things.

- 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 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.

2. OIG should not distinguish between the types of medical technology manufacturers that may be VBE participants

Under the Proposed Rule, the term "VBE participant" would expressly exclude manufacturers, distributors, or suppliers of DMEPOS, among other entities. As such, DMEPOS manufacturers, distributors, and suppliers would not be permitted to participate in protected value-based arrangements. We do not agree with this approach.

As noted above, the 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). As such, we believe *all* – not just a subset of – medical technology manufacturers should be permitted to participate in VBEs and value-based arrangements, for the reasons further discussed below.

First, among OIG’s cited reasons for proposing to exclude such entities is its assumption that manufacturers, distributors, and suppliers of DMEPOS are less likely to be on the front line of care coordination and treatment decisions in the same way as other types of proposed value-based enterprise (VBE) entities.¹³ This assumption is not correct. As many of the examples noted above illustrate, medical technology manufacturers are often directly involved in care coordination and improving patient outcomes. As those examples illustrate, the Device industry evolution to integrate health technologies and solutions also spans the subset of Devices that are classified as DMEPOS.

The detrimental impact of excluding DMEPOS is highlighted by the “diabetes management services” example that OIG provided to illustrate 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.¹⁴ OIG noted that the diabetes management services, “leverage 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.”¹⁵ The device that attaches to the body to monitor blood sugar levels and transmit that data is a continuous glucose monitor (CGM). This is similar to the “artificial-pancreas device system” example that combines a CGM 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” or providing an “outcomes-based payment,” manufacturers of such 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%.¹⁶ 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.

Second, OIG’s proposed approach of excluding manufacturers, distributors, or suppliers of DMEPOS from the definition of VBE participant could also exclude companies that engage in such activities somewhere within their organization from engaging in arrangement relating to technology that does not involve DMEPOS. Companies may include corporate affiliates or business units that OIG would characterize as

¹³ 84 Fed. Reg. 55704.

¹⁴ 84 Fed. Reg. 55705

¹⁵ *I.d.*

¹⁶ <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>

traditional medical device manufacturers, other affiliates or units that OIG would characterize as health technology companies, and still others that may focus on DMEPOS. Further, there are medical technology manufacturers that also manufacture pharmaceutical products.¹⁷ Excluding such companies from safe harbor protection would discourage beneficial and appropriate value-based arrangements. Moreover, since we believe there is no good reason for the exclusion of DMEPOS companies in the first place (as discussed further below), there is no clear basis for excluding an entity that has some activities relating to DMEPOS from engaging in an arrangement that does not relate to DMEPOS.

To the extent that OIG retains any categorical exclusions in the final definition of VBE participant, we recommend that OIG clarify that parties will not be excluded as VBE participants on the basis of corporate affiliates or other business operations engaging in the excluded activity, when the arrangement itself does not relate to the excluded activity (e.g., DMEPOS).

Third, in the preamble to the Proposed Rule, OIG notes that its proposal to exclude certain entities from the definition of VBE participant is based on historical enforcement and oversight experience, and in particular its concern that some of the entities proposed to be excluded might misuse the safe harbors as a means of offering remuneration to practitioners and patients to market their products, rather than as a means to create value for patients and payors by improving the coordination and management of patient care, reducing inefficiencies, or lowering health care costs.¹⁸ The OIG is also concerned that these entities might create arrangements styled as value-based arrangements in order to “tether” clinicians or patients to a particular product when a different product could be more clinically effective for the patient.¹⁹

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 Ethics²⁰ to help ensure that interactions between manufacturers and providers are consistent with the AKS 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 will be subject not only to the appropriate safeguards the OIG has proposed under the value-based arrangement safe harbors, but also to the AdvaMed Code of Ethics.

Further, the OIG’s concern with “tethering” ignores the fact that improved cost and clinical outcomes through value-based care often involves standardizing the use of a superior technology or practice, as determined by credible evidence. While nothing requires a VBE participant to pick a single device or system for its patients, we believe that any restriction on doing so would undermine the goals of the Proposed Rule. For example, when clinical evidence dictates that a particular practice not currently in use would vastly improve outcomes, and that practice requires the purchase and use of a particular medical device, the VBE should be empowered to require the use of that medical device under the safe harbor.

¹⁷ For example, many medical devices contain in their instructions for use (IFU) the requirement to use certain pharmaceutical products, which may also be manufactured and sold by the medical device manufacturer. Or items that “look like” devices, such as pre-surgical sterilization wipes, may actually be approved as pharmaceutical products because of their active ingredient.

¹⁸ 84 Fed. Reg. 55703-4.

¹⁹ *I.d.*

²⁰ 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.

Active participation of medical technology manufacturers in value-based arrangements is essential to improve outcomes, control costs, and encourage innovation within our health care system. But such active participation is more cumbersome and at-risk of being stifled if parties are unable to enter into value-based arrangements with the assurance that such arrangements are protected and consistent with applicable law. ***As such, we recommend that in finalizing the definition of VBE participant, OIG not categorically exclude any medical technology manufacturers, including manufacturers of implants and DMEPOS manufacturers, distributors, or suppliers.***

In the Proposed Rule, OIG also solicits comments on alternative approaches to excluding categories of entities from the definition of VBE participant and additional safeguards that could be included in the safe harbors to mitigate any potential or perceived risk of abuse.²¹ We offer the following alternative suggestions in response to the same.

- OIG could adopt an activity-based exclusion approach as opposed to an entity-based exclusion approach. That is, instead of excluding any or all categories of medical technology manufacturers or other entities from the definition of VBE participant, OIG could consider exclusions according to the type of arrangement at issue, if the circumstances merit doing so. As noted above, medical technology manufacturers can and do play an important role in coordinating and managing patient care and health outcomes. They should, at a minimum, be permitted as participants in VBEs, even if they are ultimately excluded from participation in select value-based arrangements or not specifically protected under an applicable safe harbor.²²
- In order to protect independent clinical decision making about products that are in the patient's best medical interests, OIG could add a requirement that in all value-based arrangements, a patient's health care provider must be ultimately responsible for making all decisions with regard to patient care and safety and that the VBE and other VBE participants must not interfere with such health care provider's medical judgment and the health care provider-relationship. Such a requirement could be memorialized in the required signed writing currently included in the proposed safe harbors.

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

As noted above, we believe all medical technology manufacturers should be permitted to participate in VBEs and value-based arrangements, consistent with appropriate standards finalized for the value-based safe harbors. However, we agree with OIG that medical technology manufacturers, including legitimate, innovator manufacturers with physician ownership, must be distinguished from physician-owned distributors (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 such arrangements permit the physician owners to profit from selling products 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

²¹ 84 Fed. Reg. 55706.

²² Indeed, meeting the definition of VBE participant is in fact only the first of many "hurdles" necessary to qualify for protection under the proposed value-based safe harbors. That is, even if an entity meets the definition of a VBE participant, the arrangements it seeks to enter into will not be protected unless all of the standards of an applicable safe harbor are met.

situation when personal financial incentives are dependent on the choice of treatment options with no counterweighing incentive to achieve certain clinical outcomes and reduce costs.

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. *As such, we share OIG's concerns with PODs, as discussed in the Proposed Rule and elsewhere, and recommend that OIG categorically exclude PODs from the definition of VBE participant.*

B. Proposed Rule Section III.J: Personal Services and Management Contracts and Outcomes-Based Payment Arrangements (1001.952(d))

Our comments in this section relate to the changes OIG has proposed to the personal services and management contracts safe harbor at 42 C.F.R. § 1001.952(d).

1. Proposed Rule Section III.J.1 and III.J.2: Elimination of Requirement To Set Aggregate Compensation in Advance and To Specify Schedule of Part-Time Arrangements

Under the Proposed Rule, OIG proposes to modify the existing requirement for "aggregate compensation" paid by a principal to an agent under a contract to be set in advance, consistent with fair market value and not determined in a manner that takes into account the volume or value of referrals or business otherwise generated for which payment may be made under a Federal health care program. Rather, the "methodology for determining the compensation" paid to the agent would have to meet these requirements. OIG also proposes to delete the requirement for agreements providing for services on a periodic, sporadic, or part-time basis to specify the exact schedule and length of such intervals and the charge for each.

AdvaMed supports these changes. Each of these requirements has, in practice, often created challenges for legitimate, non-abusive arrangements to qualify for protection under this safe harbor. For example, contractual arrangements under which compensation is paid at a fair market value rate but the exact volume and schedule of services required is not known in advance, and as a result, the aggregate compensation cannot be specified in advance, could not satisfy these requirements—even though the aggregate compensation paid based upon such rate was consistent with fair market value.

While we support these changes, we also recommend that OIG provide additional clarity regarding exactly how the new requirement is to be applied. First, we note that in CMS's companion proposed rule under the physician self-referral law, CMS discusses at length the "volume or value standard" and "other business

generated standard,” and proposes revised regulatory text with respect to these standards.²³ Under CMS’s proposed changes, “only when the mathematical formula used to calculate the amount of the compensation includes as a variable the referrals or other business generated, and the amount of compensation correlates with the number or value of the physician’s referrals to or the physician’s generation of other business for the entity, is the compensation considered to take into account the volume or value of referrals or take into account the volume or value of other business generated.”²⁴ We believe the same standards as described in the CMS-proposed rules are appropriate under the AKS safe harbors, particularly in light of OIG’s stated desire to harmonize such safe harbors with the self-referral regulations to the extent practicable, such that an arrangement that complies with the self-referral regulations will also comply with the AKS safe harbor. ***Accordingly, we recommend that OIG clarify in the final rule that it interprets the “volume or value standard” and “other business generated standard” in the AKS safe harbors consistent with the equivalent standards under the self-referral law regulations.***

Similarly, CMS’s proposed self-referral law regulations include a definition of “commercially reasonable”—a term also used in the existing personal services and management agreement safe harbor, and in OIG’s proposed addition for outcomes-based payments. CMS proposes to define that term to mean “that the particular arrangement furthers a legitimate business purpose of the parties and is on similar conditions as like arrangements. An arrangement may be commercially reasonable even if it does not result in profit for one or more of the parties.” For the same reasons as noted above, we recommend that OIG confirm in the final rule that it is permissible to interpret the term “commercially reasonable” as used in the AKS safe harbor consistent with the definition of such term as finalized in the CMS self-referral law regulations.

We also believe that OIG can and should provide clarification regarding the proposed requirement that the “methodology for determining the compensation paid [be] consistent with fair market value in arms-length transactions . . .” We recognize that OIG is statutorily prohibited from determining in an advisory opinion “[w]hether the fair market value shall be, or was paid or received for any goods, services or property,”²⁵ but we see no reason that OIG could not indicate types of compensation methodologies that could fall within the regulatory standard, as OIG interprets the safe harbor. For example, while we presume that an hourly rate for providing services could constitute a fair market value methodology (depending upon the services at issue), an affirmative OIG statement to that effect would materially reduce industry uncertainty about its permissibility.

2. Proposed Rule Section III.J.3: Proposal to Protect Outcomes-Based Payments

In the Proposed Rule, OIG has proposed a new subparagraph to the personal services and management contracts safe harbor to protect “outcomes-based payments,” subject to the satisfaction of the relevant safe harbor standards. Outcomes-based payments would be defined as payments from a principal to an agent that: (i) reward the agent for improving (or maintaining improvement in) patient or population health by achieving one or more outcome measures that effectively and efficiently coordinate care across care settings; or (ii) achieve one or more outcomes measures that appropriately reduce payor costs while improving, or maintaining the improved quality of care for patients. The proposed definition would exclude payments that relate solely to the achievement of internal cost saving for the principal, in addition to the

²³ 84 Fed. Reg. 55791-95.

²⁴ 84 Fed. Reg. 55793.

²⁵ 42 U.S.C. § 1320a-7d(b)(3)(A).

payments made by the same list of entities that OIG has proposed to exclude from the definition of VBE participant—including manufacturers of DMEPOS.²⁶

AdvaMed supports the proposed safe harbor for outcomes-based payments, with certain modifications and clarifications. Overall, we believe it is entirely appropriate for safe harbor protection to extend to arrangements under which agents provide services to improve patient outcomes or to control costs without negatively affecting patient outcomes, in exchange for payments tied to an appropriate outcome metric. Such arrangements are crucial to facilitating the transformation to value-based care. Moreover, the proposed safe harbor standards (refined as we recommend below) would ensure that only non-abusive arrangements would receive protection.

Our comments on specific issues are set forth below.

a. Proposed Rule Section III.J.3.a: Outcomes-Based Payments

AdvaMed recommends that OIG revise the proposed safe harbor to allow for an outcomes-based payment based upon satisfaction of one or more outcome-measures reflecting either (i) an improvement (or maintenance of an improvement) in patient outcomes, or (ii) a reduction in the costs of health care delivery, without adversely affecting patient outcomes in a material manner. These are, fundamentally, the goals of outcomes-based care—payment for outcomes and lower costs. Accordingly, we believe certain aspects of the proposed safe harbor should be revised, as described below.

First, we do not agree with OIG’s proposed prohibition on outcomes-based payments “that relate solely to the achievement of internal cost savings for the principal,” or with the related language that would require an outcomes-based payment to “[a]ppropriately and materially reduc[e] costs to, or growth in expenditures of, payors.” These requirements effectively would preclude providers who accept risk through capitation from receiving protection for outcomes-based payments paid to agents for services to help reduce the provider’s costs of providing care (while maintaining or improving patient outcomes)—specifically, the payor’s costs would not be affected, because the payor would still pay the capitation amount. Capitation is one of the most fundamental and prevalent forms of value-based reimbursement; OIG would significantly undermine the goals of value-based care if the safe harbor excluded protection for outcomes-based payments made by providers subject to capitation arrangements.

More generally, we believe that the proposed language relating to payor costs and expenditures is likely to make the safe harbor unworkable in practice. As a starting point, what “payors” must be taken into account? Providers are reimbursed by scores of different payors of various types (governmental and commercial), under a dizzying array of reimbursement arrangements. Indeed, some of these may involve increased costs for a payor when a desired outcome is achieved, such as where a payor gives a provider a reimbursement bonus for achieving improved patient outcomes. More generally, providers and other parties to an outcomes-based payment arrangement are typically not in a position to determine whether an arrangement results in reduced costs or expenditures for specific payors, particularly where expected savings are based upon preventing adverse health outcomes for which payment may be made at a later date, perhaps to a different provider (e.g., reduced hospitalizations).

In discussing these proposed requirements, OIG gives the example of an arrangement between a hospital and physician group under which they share financial risk or gain only with respect to items or services reimbursed to the hospital under the Medicare Part A inpatient prospective payment system (IPPS), stating

²⁶ 84 Fed. Reg. 55745.

that the arrangement would not be protected because “the savings under the arrangement would not accrue to the payor.”²⁷ In our view, this result demonstrates clearly that the proposed exclusion is inappropriate. The point of the IPPS is to shift financial risk for delivery of care to hospitals, so as to require hospitals to manage costs across their population in a manner that will enable them to provide quality care at the prospective payment amount efficiently. If a hospital can enter into an arrangement with a physician group to reduce costs without negatively affecting patient outcomes, such an arrangement should be protected and, in fact, encouraged. Notably, the proposed safe harbor would require, among other things, that the agreement not induce any party to reduce or limit medically necessary items or services to patients—a requirement that AdvaMed supports.

Additionally, the portions of OIG’s proposed language that would require payor costs or growth in expenditures to be “appropriately and materially” reduced are inherently subjective, and as such, could prevent parties from ever being sure that their arrangement qualified for safe harbor protection. For example, would a 1 percent expected reduction in costs be deemed material or immaterial? If expected growth in expenditures over three years is reduced from 10 percent to 8.5 percent, is that sufficient? Similarly, what makes a reduction in costs “appropriate”? ***AdvaMed believes that the safe harbor will be workable only if, in addition to removing the requirement that the costs being reduced are those of a “payor,” OIG also eliminates the “appropriately and materially” qualifiers.***

Second, with respect to the improved care portion of the language, the proposed definition of outcomes-based payments would require that the payment “reward the agent for improving (or maintaining the improvement in) patient or population health by achieving one or more outcome measures that effectively and efficiently coordinate care across care settings.” ***We see no reason to mandate coordination of care across settings so long as an appropriate value-based purpose is defined, and we recommend that this requirement be removed.*** For example, an arrangement under which a hospital principal rewards an agent for improving patient outcomes from surgeries performed solely in the hospital setting is desirable, even though it does not require any changes with respect to coordination of care in other contexts. It is entirely appropriate that such an agreement compensate the agent through an outcomes-based payment that is calculated based upon the extent to which the targeted improvement in patient outcomes, in the hospital setting, has been achieved.

More generally, the proposed safe harbor appears to use somewhat different standards with regard to improved patient outcomes in different portions of its language—standards that we believe should be consistent throughout the safe harbor. Specifically, the proposed definition refers to improvements in “patient or population health by achieving one or more outcomes measures,” whereas the beginning of the proposed safe harbor refers to satisfying an outcome measure related to improvements in “patient care.” ***We recommend that OIG consistently refer to an improvement (or maintenance of an improvement) in patient or population outcome, as determined using one or more appropriate metrics.***²⁸

²⁷ 84 Fed. Reg. 55745-6.

²⁸ We agree with OIG’s proposed requirement that the metric be selected based upon either clinical evidence or credible medical support. We suggest that this requirement be stated only once and the separate references to “evidence-based” and “valid” measures be removed, so as to avoid a construction that credible medical support is not sufficient where appropriate clinical evidence is not available so as to make a metric “evidence-based,” even though it is backed up by credible medical support.

Another example of conflicting definitions involves principal and agent payments. While OIG states that it intends to protect a shared losses payment “from a principal to a payor or from a downstream agent to a principal to repay the payor for a portion of the payor’s losses incurred . . . when a principal’s expenditures for the patient population for the applicable performance period exceed specific performance benchmarks,”²⁹ the proposed definition of outcomes-based payment states that it is “limited to payments from a principal to an agent . . .” Accordingly, as drafted, the safe harbor would not appear to protect such reverse-flow payments from the agent to the principal. *AdvaMed therefore recommends that OIG revise the definition to also protect payments from an agent to a principal, when a targeted outcome or cost metric has not been satisfied.*

b. Proposed Rule Section III.J.3.b: Entities Not Included

For the same reasons set forth in our comments in Section III.A. above relating to the proposed definition of VBE participant, we believe that OIG should not exclude safe harbor protection for outcomes-based payments made by a manufacturer, supplier or distributor of DMEPOS. While we will not repeat at length here all of the points that we made in that portion of this letter,³⁰ we note that such an exclusion is particularly inappropriate in the context of the safe harbor for personal services and management agreements. Many device manufacturers currently provide services to health systems and other provider customers to assist them in improving patient outcomes and controlling costs without adversely affecting patient care, sometimes through consulting divisions for which this is a core business. Such manufacturers and their customers frequently desire to tie the compensation level to the achievement of the targeted outcome—precisely the type of outcomes-based payment service arrangement that this safe harbor contemplates. For example:

- A medical device manufacturer of post-operative therapies (which also provides DMEPOS products) offers a risk stratification solution that integrates with a hospital’s electronic medical record system to identify patients at risk of surgical site infection and other surgical complications. The risk algorithm provides guidance on the appropriate post-operative care protocol per patient. The hospital agrees to use the manufacturer’s recommended therapy on all high-risk patients, and the manufacturer agrees to a penalty (or to cover certain products and services) for any readmission due to surgical complications. In each circumstance, the arrangement involves products reimbursed under a DRG; none of the manufacturer’s DMEPOS products are included in the arrangement.

Where such arrangements constitute fair market value (as further discussed below) and meet the other proposed safe harbor standards, they should be protected, just as arrangements with any other type of entity would be.

Moreover, device manufacturers (including manufacturers of DMEPOS) are frequently at the forefront of companies “providing mobile health and digital technologies to physicians, hospitals, patients and others for coordination and management of care,” including “a range of services such as 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”—*i.e.*, the very companies that

²⁹ 84 Fed. Reg. 55745.

³⁰ All of the points made in section III.A. of this letter shall be deemed included as comments on the proposed exclusions of specified types of entities from the definition of outcomes-based payment.

OIG describes as “health technology companies” that should be eligible to act as VBE participants.³¹ In fact, DMEPOS manufacturers frequently leverage data from the DMEPOS items themselves for patient monitoring to improve care as part of the services they provide—often a role that no other entity in the health care system can perform. Again, consider OIG’s own example of the health technology company providing diabetes management services.

We recommend that in finalizing the new safe harbor to protect outcomes-based payments, OIG not categorically exclude DMEPOS manufacturers, suppliers, and distributors, or pharmaceutical manufacturers. All medical technology manufacturers should be permitted to participate in protected outcomes-based payment arrangements, consistent with appropriate standards finalized for the safe harbor. Moreover, we see no rationale for the categorical exclusion of an entity that has some operations that manufacturer pharmaceuticals—which may include combination products that include both a device and a drug.

c. Proposed Rule Section III.J.3.f: Outcome Measures

In the Proposed Rule, OIG proposes that, for each outcome measure under the agreement, the parties “periodically rebase during the term of the agreement, to the extent applicable,” and it solicits comments on whether a specific timeframe should be included for when parties must rebase benchmarks.³²

While we recognize in principle OIG’s concern that “evergreen” outcomes arrangements “could be used as a vehicle to reward referrals well after the desired provider behavior change or savings benchmark has been met,” we do not believe that it is possible to establish any requirement for rebasing that would be appropriate in all cases.

Where an outcome is tied to a baseline performance level, the period for determination of whether the given outcome target has been achieved can vary substantially. For example, a measure relating to the recurrence of heart attacks might appropriately require three years of outcomes data to evaluate against the given target metric, whereas metrics relating to other conditions (e.g., diarrhea) might appropriately be evaluated over a period of less than a year. Setting the appropriate timeframe also requires a recognition that rebasing too frequently can result in savings growth goals at an unattainable and unrealistically steep trajectory, particularly for historically efficient providers.

Moreover, as reflected in OIG’s proposed language to the effect that an outcomes-based payment may be for “maintaining improvement in” quality of patient care, the fact that an outcomes measure has been attained does not necessarily mean that the targets for the outcomes-based payment should be increased—instead, continuing to meet the original outcome target may require maintenance of the same level of effort.

We believe that any requirement for rebasing is appropriately captured in the requirement that the outcomes-based payment methodology is commercially reasonable and consistent with fair market value, further discussed below. Specifically, if the agent’s performance of the given services is no longer needed to continue to achieve the original outcome target, then payment of the original outcomes-based payment amount for those services presumably would not be commercially reasonable, and would not reflect fair market value for the services provided.

We recommend that OIG either remove the proposed rebasing standard (in reliance upon the separate commercial reasonableness and fair market value standards) or modify it to require that the outcome

³¹ 84 Fed. Reg. 55705.

³² 84 Fed. Reg. 55747.

targets be rebased only if and to the extent necessary for the methodology to continue to be commercially reasonable and consistent with fair market value. In the latter case, the requirement to rebase should apply within a reasonable period after both (i) the completion of the initial performance period and (ii) the methodology for determination of the outcomes-based payment is no longer commercially reasonable and/or consistent with fair market value. In particular, parties should not be required to change the terms of a payment methodology mid-stream, before the initial performance period has ended, simply because the agent is succeeding in meeting the target.

d. Proposed Rule Section III.J.3.g: Methodology

In the Proposed Rule, OIG proposes that the aggregate compensation (including any outcomes-based payments) constitute fair market value, but also acknowledges that this “may pose challenges to the extent there are not industry standards yet developed to determine fair market value for some outcomes-based payment arrangements” OIG anticipates that “the industry will evolve and adapt to assess fair market value for value-driven outcomes-based payment arrangements” and solicits comment on this approach, noting that it is considering whether to substitute a different safeguard (without indicating what that safeguard might be).³³

AdvaMed supports a requirement that the methodology for determining an outcomes-based payment be consistent with fair market value, but we recommend that OIG clarify the criteria under which it would interpret such a methodology to be consistent with fair market value. Absent such clarification, parties will not be able to rely upon the safe harbor, given the potential for enforcement authorities, *qui tam* relators, or courts to later allege or determine that the criteria applied were incorrect or inadequate.

In general terms, we believe that an outcomes-based payment methodology should be determined to be consistent (or inconsistent) with fair market value using the same criteria as apply to fair market value determinations generally—*i.e.*, that the methodology is consistent with arms-length bargaining between unrelated parties.

We note that, conceptually, there is nothing about an outcomes-based payment that is inconsistent with a fair market value test. To the contrary, a payment determined based upon the outcome achieved may be the only amount that is economically attractive to both parties and therefore representative of fair market value compensation, since the principal pays only for what it actually receives (*i.e.*, the targeted outcome). Put differently, a principal logically should be willing to pay more for given services if the desired outcome is achieved than if it is not. By the same token, an agent may be willing to condition its right to receive a higher payment level on a targeted outcome being achieved, so as to earn that higher compensation level. Consequently, an outcomes-based payment can represent a win-win payment structure. If the principal would not be willing to pay a fee regardless of whether the desired outcome is, in fact, achieved, the only compensation level that could constitute fair market value (paid by a willing buyer to a willing seller) would be an outcomes-based payment. Moreover, it is worth noting that conditioning or calculating a compensation level based upon the extent to which a desired result is achieved by the service provider regularly occurs in numerous industries outside of health care.

The points that we believe OIG should clarify relative to the methodology for determining aggregate compensation are as follows:

- Requirements relative to commercial reasonableness and the payment not being determined in a manner that directly takes into account the volume or value of any referrals or business otherwise

³³ 84 Fed. Reg. 55747.

generated by the parties outside of the arrangement for which payment may be made in whole or in part under a Federal health care program are distinct from the requirement that a payment or methodology constitute fair market value.³⁴

- Where comparable transactions are not available to evaluate what constitutes a range of fair market value payment levels for given outcomes—as may often be the case for novel outcomes-based payment arrangements—other criteria may be used to evaluate whether the overall compensation level and any outcomes-based payment methodology are consistent with fair market value. These may include:
 - Use of comparable arrangements where compensation is not conditioned or calculated based upon an outcome, with the addition of a premium for the achievement of the outcome or a discount for failure to satisfy the outcome.
 - Consideration of whether the given payment levels associated with each outcome appear economically rational for, or otherwise further a legitimate business interest of, each party. In particular, would it make business sense for a principal to agree to pay the specified outcomes-based payment amount to the agent, if the principal knows the given outcome target will be achieved? Similarly, would it make business sense for an agent to accept the risk associated with lower value-based payment amounts (or reverse-flow payments back to the principal) given the level of probability that the outcome target will not be achieved? While the existence of one or more outcome targets that may be unlikely to be achieved should not be precluded, the principal focus in such a case should be on whether the payment level for the most likely outcome is economically rational for the agent.
 - Along the same lines, an outcomes-based payment that is zero if the outcome target is not achieved should not be categorically precluded, but such terms should be evaluated relative to the cost incurred by the agent and the potential positive payment that the agent may receive. For example, automated services that require little or no marginal cost for an agent to provide to the given principal may make economic sense even if the outcome target is unlikely to be satisfied, so long as the expected compensation from those principals for which the outcome target is satisfied results in the arrangement that, taken as a whole, makes rational business sense for the agent.
 - Where the agreement allows for a reverse-flow payment from the agent back to the principal if the targeted outcome is not achieved, the agent should be able to provide a reasonable basis for concluding that such an outcome is unlikely. However, here as well, the arrangement should be evaluated as a whole to determine whether it makes rational business sense. For example, an agent could reasonably accept a 25 percent chance of having to make a relatively small reverse-flow payment to a principal in exchange for the opportunity to earn a bonus for achieving a positive outcome for which there is also a 25 percent probability (with a 50 percent likelihood of an outcome for which the payment would constitute fair market value under conventional measures). Similarly, if the principal has had to make a significant investment in order to

³⁴ This is consistent with CMS' proposed rule under the physician self-referral law. *See* 84 Fed. Reg. 55766, 55789 (Oct. 17, 2019). With regard to the volume or value test, we note and agree with OIG's statement recognizing that "parties may need to establish payment methodologies that at least indirectly take into account the volume or value of other business generated between the parties." 84 Fed. Reg. 55747. We request that OIG clarify that its use of "otherwise generated between the parties" refers to referrals or business generated outside of the outcomes-based payment agreement.

effectively make use of agent's services (such as designation of physical space, reallocation and training of personnel, or adoption of certain information systems) and the targeted outcome is not achieved, it may make economic sense for the agent to pay the principal in whole or in part for the lost investment.

- ***Overall, we request that OIG reiterate in the final rule its statement that it “recognize[s] that outcomes-based payment arrangements may vary in structure and [we] strive to provide flexibility for parties to design arrangements to achieve appropriate quality of patient care as well as appropriate efficiency and cost savings goals.”³⁵***

e. Proposed Rule Section III.J.3.i: Impact on Patient Quality of Care

OIG proposes as a standard that the agreement could “neither limit[] any party’s ability to make decisions in their patients’ best interest nor induce[] any party to reduce or limit medically necessary items or services.” While we support these conditions, we believe that the first portion of this language would benefit from clarification. In particular, many value-based arrangements, by their nature, involve standardization on a given system and/or protocol to improve efficiencies and better coordinate and deliver care. Indeed, many outcomes-based arrangements are expressly premised upon use of a specified system, with the outcomes-based payment available only if it is used comprehensively or for some minimum number of patients—requirements that are frequently necessary for the improvement to work as intended, or for the outcome metric to be statistically valid.³⁶

As an example, consider the following scenario:

- Nearly 70% of all retained surgical instruments are surgical sponges, and the current standard of care is to use a manual count alone to confirm that sponges are not retained. A medical device manufacturer offers a product designed to use technology to track surgical sponges (in addition to a manual count) and prevent retained surgical sponges. The system consists of a surgical sponge counter, barcoded sponges, and software that, when used collectively and consistently, is designed to prevent the surgical never-event of a retained surgical sponge. If such a system is used exclusively in a customer’s operating rooms and correctly in accordance with its IFU, the device manufacturer will indemnify its customer up to an identified amount for complications arising from any retained surgical sponge. The device manufacturer will also rebate the customer the incremental cost of implementing the system (capital and disposables) over the customer’s previous three-year sponge spend. In this case, exclusivity is appropriate because the presence of any other sponge increases the risk of a retained sponge.

While a standardized system or protocol should not prevent any party from making decisions in their patients’ best interests, ***we recommend that OIG expressly confirm that a requirement of exclusive or minimum level of use for an outcomes-based payment to be available is not prohibited by this language, so long as the principal determines that such a requirement will not preclude it from making decisions in its patients’ best interests.*** We believe that, in practice, providers only agree to an exclusivity or minimum use criteria when they believe such a requirement has been met.

³⁵ 84 Fed. Reg. 55747.

³⁶ Such requirements may also reflect a product’s FDA approval/clearance, comprehensive IFUs and/or specific training requirements intended to ensure the safe and effective use of a product.

C. Proposed Rule Section III.B: Proposed Value-Based Terminology – Accountable Body; Governing Document; Value-Based Purpose; and Coordination and Management of Care/Coordinating and Managing Care

1. Proposed Rule Section III.B.1.c. Accountable Body³⁷

a. The VBE Oversight Body Should be Accountable, but Does not Need to be a Separate Legal Entity.

Requiring the accountable body or compliance officer to be independent of the interest of individual VBE participants is not necessary in order to appropriately manage the compliance risk. The legal concepts of duty of loyalty and fiduciary duty are well established in corporate law. It is possible for a compliance officer, corporate governing board, or corporate compliance committee to consider and uphold its fiduciary duty to more than one entity simultaneously. It is not necessary to mandate that a VBE create a new governing board that is separate and apart from the VBE participant governing boards in order to ensure that the responsible decision-makers of the VBE will act in the best interest of the VBE. Establishing additional requirements for VBEs also would be an unnecessary barrier to participation.

b. Practical Governance and Oversight of VBE Arrangements

Instead of imposing overly prescriptive reporting requirements or the creation of a new, independent entity to oversee the value-based arrangement, the OIG should consider allowing each VBE participant to certify compliance of the VBE and its various arrangements during the term the VBE is active.

c. Compliance Program Requirements for VBEs

AdvaMed applauds the OIG's consideration of a compliance mechanism that would ensure that the requirements of safe harbors are actually met. AdvaMed supports a requirement that the VBE participants confirm commitment to an appropriate code of ethics that covers instances necessitating compliance operational oversight (e.g., compliant interactions with health care professionals, clinical research compliance, off-label marketing compliance).

2. Proposed Rule Section III.B.1.d. VBE Governing Document³⁸

AdvaMed is generally in agreement with the OIG's requirement that each VBE has a governing document that describes the VBE and how the VBE participants intend to achieve the value-based purposes. However, AdvaMed believes that the OIG should clarify that the contract forming the basis of a contractual VBE can itself constitute the governing document.

3. Proposed Rule Section III.B.6. Value-Based Purpose and Care Coordination and Management³⁹

Under the Proposed Rule, the term "value-based purpose" is defined to mean four identified purposes, the first of which is the coordination and management of care for a TPP.⁴⁰ Each of the proposed value-based

³⁷ 84 Fed. Reg. 55701

³⁸ *I.d.*

³⁹ 84 Fed. Reg. 55706-55707

⁴⁰ The other three proposed purposes are: (i) improving the quality of care for a target patient population; (ii) appropriately reducing the costs to, or growth in expenditures of, payors without reducing the quality of care for a TPP; and (iii) transitioning from healthcare 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 a TPP.

safe harbors requires that the protected arrangement includes value-based activities that directly further at least this purpose. Therefore, this definition is used in multiple places throughout the Proposed Rule.

In the Proposed Rule, OIG proposes to define “coordination and management of care” and “coordinating and managing care” to mean the deliberate organization of patient care activities and sharing of information between two or more VBE participants or VBE participants and patients, tailored to improving the health outcomes of the TPP in order to achieve safer and more effective care for the TPP. OIG notes that coordinating and managing care could include using care managers, providing care or medication management, creating a patient-centered medical home, helping with transitions of care, sharing and using health data to improve outcomes, or sharing accountability for the care of a patient across a continuum of care.⁴¹

AdvaMed believes the proposed definition of “coordination and management of care” is unnecessarily limiting in that it does not appear to include the provision of care, *i.e.*, patient monitoring, patient diagnosis and patient treatment, and related communication or information for such purposes. For example, in the context of the new proposed care coordination safe harbor, discussed further below, the OIG uses the example of a value-based arrangement between a hospital and a skilled nursing facility (SNF), in which the hospital provides a behavioral health nurse to follow designated inpatients with mental health disorders in the event of discharge to the SNF. Under the proposed definition of coordination and management of care, it appears that the nurse could not actually provide care for patients – only coordinate it. Similarly, as an example of the technologies and services made available by “health technology companies,” OIG states that it is aware of “companies that provide diabetes management services, leveraging 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.”⁴² While AdvaMed certainly agrees that the provision of such remote monitoring technologies should be permitted under the safe harbors proposed by OIG, they are not fundamentally about “organization of patient care activities,” but instead about patient monitoring, diagnosis, and treatment itself. Given the pervasive use of this defined term throughout the proposed safe harbors, it is important that it not be interpreted as allowing only patient scheduling software.

Patient monitoring, diagnosis, and treatment, together with related communications to facilitate these activities, have a clear and significant impact on patient care quality, health outcomes, and costs. Broadening the definition of coordination and management of care to include patient monitoring, diagnosis, and treatment is not likely to result in or encourage fraudulent and abusive practices. *As such, we recommend that the final definition of coordination and management of care be revised to more clearly encompass patient monitoring, communication, diagnosis, and treatment.*

D. Proposed Rule Section III.C: Care Coordination Arrangements to Improve Quality, Health Outcomes, and Efficiency Safe Harbor (42 CFR 1001.952(ee))

Our comments in this section relate to the new proposed safe harbor for care coordination arrangements to improve quality, health outcomes, and efficiency at 42 C.F.R. § 1001.952(ee).

1. Proposed Rule Section III.C.4.d: No Remuneration From Individuals or Entities Outside the Applicable VBE

⁴¹ 84 Fed. Reg. 55707.

⁴² 84 Fed. Reg. 55705.

Under the Proposed Rule, one of the proposed standards for the new care coordination arrangements safe harbor is that the remuneration exchanged cannot be funded by, or result from contributions of, individuals or entities outside of the VBE.

We recommend that OIG clarify that this requirement will not prohibit or preclude a VBE participant from providing to other VBE participants in-kind remuneration received from a non-VBE participant that such VBE participant obtained in a compliant manner (e.g., under another safe harbor). For example, a hospital system VBE participant should be permitted to share with a physician practice VBE participant who is in the same VBE, care coordination software provided by a manufacturer to the hospital system as part of a bundled sale under the discount safe harbor (to the extent allowed under manufacturer software license terms).⁴³

Further, while this proposed safe harbor would not protect a non-compliant transaction between an entity outside of the VBE and a VBE participant, a VBE participant that receives remuneration from another VBE participant should not lose protection under this safe harbor because of the manner in which the other VBE participant obtained the remuneration.

We also recommend that OIG confirm that this proposed standard will not prohibit or preclude an affiliate or division of a VBE participant from funding or contributing remuneration to other VBE participants in the ordinary course of business, consistent with the other requirements of the safe harbor. Many of the entities that will qualify as VBE participants, including medical technology manufacturers, are diversified entities comprised of multiple legal entities and/or divisions. Such entities and/or divisions regularly exchange remuneration in the ordinary course of business. Such financial support (such as shared office space or shared personnel resources) among corporate affiliates should not in itself violate the prohibition against remuneration from entities outside a VBE, unless the exchange is done exclusively for the purpose of the VBE inconsistent with ordinary corporate practice.

2. Proposed Rule Section III.C.6: Contribution Requirement

As proposed, protection under the new care coordination arrangements safe harbor would only be available if the recipient paid at least 15 percent of the offeror's cost for the in-kind remuneration.

We recommend that OIG not finalize any contribution standard under the new care coordination safe harbor. First, such a standard may prevent parties from entering into beneficial and important arrangements that would otherwise be protected by this safe harbor. Recipient VBE participants may not have the funds available for the contribution or may question whether they will receive sufficient financial return from the use of care coordination remuneration to merit such contributions.

Second, the contribution standard is not necessary since the other standards proposed under the safe harbor are sufficient to reduce any potential fraud and abuse risk, regardless of whether the recipient has made a contribution. In particular, the new safe harbor includes a separate standard that the remuneration be used

⁴³ Such a clarification is consistent with OIG's position with respect to a similar requirement under the new proposed safe harbor for patient engagement and support tools. The proposed patient engagement tools and support safe harbor provides that no individual or entity outside of the applicable VBE may fund or otherwise contribute to the provision of the patient engagement tool or support. In the preamble to the Proposed Rule and with respect to this specific requirement, OIG notes that "this proposed safe harbor does not address, or otherwise prohibit, arrangements between VBE participants and others (including vendors and manufacturers) for the purchase and sale of tools and supports that the VBE participant would furnish under the safe harbor. Such arrangements must be assessed on a case-by-case basis for compliance with the Federal anti-kickback statute and any other applicable law." 84 Fed. Reg. 55726-7.

primarily to engage in value-based activities that are directly connected to the coordination and management of care.

According to OIG, this contribution standard is intended to mirror that set forth in the current electronic health records (EHR) items and services safe harbor at 42 C.F.R. § 1001.952(y). However, the EHR safe harbor contains far less stringent standards than those proposed under this new safe harbor. Further, while a contribution standard may make sense in the context of the EHR safe harbor (where the EHR remuneration is of clear independent value to the recipient), in the context of this new safe harbor, care coordination for the overall benefit of patients and the health care system is the overriding purpose of the safe harbor (similar to the proposed new cybersecurity safe harbor, which does not include a proposed contribution standard).

Finally, and practically, the cost may be difficult to determine and apply. In the case of medical technology manufacturers, the offeror's cost may be difficult to determine with respect to tools or programs that the manufacturer develops internally and makes available. For example, the manufacturer may have substantial development costs but small marginal costs for each individual recipient/user. In addition, cost points are often subject to proprietary and confidentiality obligations.

Therefore, to the extent a contribution standard is retained in the final rule, we recommend that there be an option to determine the required contribution amount based on the price charged by the offeror to purchasers outside of the VBE, rather than cost.

E. Proposed Rule Section III.D: Value-Based Arrangements With Substantial Downside Financial Risk (1001.952(ff))

Our comments in this section relate to the new safe harbor OIG has proposed at 42 C.F.R. § 1001.952(ff) for certain value-based arrangements involving VBEs that assume substantial downside financial risk from a payor.

1. Definition of Substantial Downside Financial Risk

The proposed new safe harbor for value-based arrangements with substantial downside financial risk requires, among other standards, that the VBE assume substantial downside financial risk from a payor. In the Proposed Rule, OIG has proposed to define substantial downside financial risk based on specific methodologies or benchmarks, and it solicits comments on the same, including whether the proposed benchmarks should be higher or lower to ensure appropriate incentive.⁴⁴

AdvaMed submits that the proposed benchmarks for substantial downside financial risk are too high. For example, under the proposed definition of substantial downside financial risk, one of the categories is that the capitated payment reflects a discount equal to at least 60 percent of the total expected fee-for-service payments. Such a proposal is unrealistic and excessive. As proposed, parties will be prohibited from taking advantage of the protections offered under the new safe harbor because they will be unable to realistically assume the definitional risk proposed. We believe this will particularly be the case for smaller providers and entities which seek to participate in appropriate and beneficial value-based activities and arrangements but will be unable to assume the level of risk proposed by OIG. At the levels of risk proposed by OIG under this new safe harbor, whole groups of providers and entities will be practically excluded from participating in these proposed value-based arrangements. ***We recommend that in the final rule, the benchmarks included in the definition of substantial downside financial risk be adjusted to more realistic levels.***

⁴⁴ 84 Fed. Reg. 55717.

2. Remuneration Exchanged Between VBE Participants

The proposed new safe harbor for value-based arrangements with substantial financial downside risk would protect remuneration exchanged between a VBE and a VBE participant. In the preamble to the Proposed Rule, OIG notes that it is considering whether and how to extend this safe harbor to remuneration that passes from one VBE participant to another.⁴⁵

We recommend that OIG finalize the new safe harbor for value-based arrangements with substantial financial downside risk to extend to remuneration exchanged between and among VBE participants.⁴⁶

In the Proposed Rule, OIG notes that it is concerned about extending this safe harbor to remuneration that passes from one VBE participant to another because the VBE participant receiving the remuneration may have assumed little or no financial risk and may be billing for his or her services on a fee-for-service (FFS) basis, thus retaining FFS incentives with respect to ordering or arranging for items and services for patients.⁴⁷ However, this concern disregards the fact that under the proposed safe harbor, VBE participants must meaningfully share in the VBE's substantial downside financial risk.

3. Ownership or Investment Interest and related Distributions

The Proposed Rule provides that remuneration protected under this safe harbor does not include the offer or receipt of an ownership or investment interest in an entity or any distributions related to such ownership or investment interest. OIG solicits comments on this approach and whether it presents any operational challenges with respect to the creation of a VBE as a separate legal entity.

We recommend that this proposed restriction be eliminated or, in the alternative, recommend that OIG clarify that it does not intend to prohibit VBE participants from establishing a corporate structure for a VBE in which the participants may each receive some equity. Without further clarification from OIG, the proposed approach creates operational challenges and unnecessarily restricts the ability of individuals and entities to dictate the corporate structure of VBEs they may choose to create. Parties should be allowed to receive on a protected basis any ownership or investment interest or related distributions from the VBE. The safe harbor requires the parties to assume substantial financial risk; they should be permitted to benefit from any related financial upside.

4. Writing Standard

One of the proposed standards under the new safe harbor for value-based arrangements with substantial financial downside risk is that the VBE and the VBE participant set forth in a signed writing all material terms of the value-based arrangement, including the "type and the offeror's cost of the remuneration."

We recommend that in finalizing this safe harbor, the OIG remove as a material term required to be included in the signed writing the type and the offeror's cost of the remuneration. It is not clear why such a term would need to be identified. This proposed safe harbor does not include a contribution requirement. As such, the offeror's cost of the remuneration is not material to the arrangement. Moreover, as noted above,

⁴⁵ *I.d.*

⁴⁶ When we refer to VBE participant here, we are not including those VBE participants that wholly assume risk on behalf of a VBE and therefore may qualify as an agent of the VBE. We understand that the safe harbor as proposed would protect remuneration exchanged between the VBE participant acting in its capacity as agent of the VBE and another VBE participant. See 84 Fed. Reg. 55717.

⁴⁷ 84 Fed. Reg. 55717.

with respect to the new care coordination safe harbor, the offeror's cost may be difficult to determine.⁴⁸

5. Pre-Arrangement Activities

The proposed new safe harbor for value-based arrangements with substantial downside financial risk would require the assumption of risk, or a contractual obligation to assume the required risk, within six months. OIG states that it proposed this six month grace period during which arrangements would be protected prior to the date the VBE actually assumes the required risk in order to balance the need to protect startup arrangements while also limiting potential program integrity risks.⁴⁹ In the Proposed Rule, OIG solicits comments on whether six months is a sufficient timeframe.

While we appreciate OIG's recognition that some lead time may be necessary to structure a VBE or value-based arrangement, particularly where the assumption of risk will be undertaken, we believe that the current proposal is not sufficient to 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.

However, OIG's proposal would only protect pre-arrangement remuneration if, at the time, such remuneration is provided, the VBE has already assumed or is contractually obligated to assume substantial financial downside risk within the next 6 months. Consequently, remuneration for start-up needs prior to entering into a payor contract for substantial downside financial risk would not be protected. Further, after good faith efforts, if the start-up activities indicate that the contemplated assumption of risk is not feasible or would not satisfy the safe harbor criteria established by OIG such that the parties decide not to pursue the contemplated VBE, related remuneration would also not be protected.

We recommend that the final rule be modified to extend safe harbor protection to all legitimate pre-arrangement activities, not just those undertaken once a contractual obligation is in place. Further, work performed by the parties in a good faith effort to set up a VBE or value-based arrangement should be protected, even if the arrangement ultimately does not move forward. To the extent that the OIG is concerned about an open-ended timeframe for parties to engage in good faith efforts to set up a VBE or value-based arrangement, OIG could impose a timeline by which the parties must make a decision whether to move forward with the VBE or value-based arrangement, such as eighteen (18) months.⁵⁰

F. Proposed Rule Section III.E: Value-Based Arrangements With Full Financial Risk (1001.952(gg))

Our comments in this section relate to the new safe harbor OIG has proposed at 42 C.F.R. § 1001.952(gg)

⁴⁸ Therefore, to the extent that the OIG maintains the writing standard as proposed, we recommend that OIG revise the standard to permit the parties to alternatively identify the offeror's contribution based on price, rather than cost, for the same reasons discussed above with respect to the new care coordination safe harbor.

⁴⁹ 84 Fed. Reg. 55717.

⁵⁰ Our comments and recommendations with respect to protecting appropriate pre-arrangement activities as discussed here in the context of the new safe harbor for value-based arrangements with substantial financial downside risk apply to ***all*** of the proposed VBE safe harbors, as well as the proposed personal services safe harbor subparagraph for outcomes-based payments. For the same reasons discussed here, we recommend that OIG modify or clarify all VBE safe harbors and the personal services safe harbor accordingly.

for certain value-based arrangements involving VBEs that assume full financial risk.

This new safe harbor would protect certain arrangements involving VBEs that have assumed “full financial risk” from a payor for a TPP. In the Proposed Rule, OIG states that a VBE would be at “full financial risk” if it is financially responsible for the cost of all items and services covered by an applicable payor for each patient in the TPP.

AdvaMed submits that the proposed definition of full financial risk is too restrictive and should be modified. We believe a comprehensive assumption of risk such as that proposed by OIG is rare, and that very few parties would be able to meet the proposed definition. For example, very few if any provider groups are in a position to assume the risk for all items and services covered under Medicaid. Thus, the new safe harbor, if not modified, would have limited utility. This will have significant ramifications in underserved populations. ***We recommend that in the final rule, OIG modify the definition of full financial risk in order to ensure that individuals and entities can and will participate in protected value-based arrangements, as discussed below.***

Apart from the definitional threshold of the level of risk required to be assumed, many of the standards proposed under this new safe harbor for full financial risk are the same as those proposed under the new safe harbor for value-based arrangements with substantial downside financial risk, discussed above. For those shared standards, and for the reasons enunciated earlier, we reiterate the same comments as shared above. Specifically:

- *We recommend that OIG extend protection under the new safe harbor for value-based arrangements with full financial risk to include remuneration that passes from one VBE participant to another.*
- *We recommend that OIG not finalize the proposed requirement that the remuneration protected under the new safe harbor for value-based arrangements with full financial risk not include the offer or receipt of an ownership or investment interest in an entity or any distributions related to such ownership or investment interest.*
- *We recommend that OIG extend safe harbor protection to remuneration related to pre-arrangement activities reasonable and necessary for determining the terms of an arrangement to be protected by this safe harbor, and for operationalizing the same.*

G. Proposed Rule Section III.K: Warranties (1001.952(g))

AdvaMed supports most of the revisions that OIG has proposed to the warranties safe harbor at 42 C.F.R. § 1001.952(g). We particularly note and applaud OIG’s indication that its revised definition of “warranty” would “provide protection for warranty arrangements conditioned on clinical outcome guarantees” if the safe harbor requirements are satisfied.⁵¹ However, we believe that certain of the proposed requirements are overly restrictive, and additional changes are needed to appropriately enable manufacturers to stand behind their products and related services through outcomes-based warranties.

1. Proposed Rule Section III.K.1: Bundled Warranties

⁵¹ 84 Fed. Reg. 55750. We note that we read the proposed warranty language to also allow for a warranty based upon a cost outcome, and request that OIG expressly confirm in the final rule that it agrees with that interpretation.

OIG has proposed that a warranty may relate to one or more items or services, so long as it covers at least one item.⁵² However, it has also proposed a requirement that “the federally reimbursable items and services subject to the warranty must be reimbursed by the same Federal health care program and in the same Federal health care program payment.” OIG requests comment on this proposal, noting among other things, that “the proposed requirement might inhibit warranties conditioned on the collective performance of warranted items across a patient population (population-based warranties) because these items would not be reimbursed in the same payment.”⁵³

We recommend that bundled warranties be permitted with no requirement that for all reimbursable items and services in the bundle to be reimbursed under either the “same program, same payment” or “same program, same methodology.” Health care providers are reimbursed under myriad reimbursement schemes for federally-reimbursable items and services, including traditional Medicare, CMS Innovation Center models and demonstrations, advanced payment methodologies, various Medicare Advantage plan reimbursement arrangements, state Medicaid fee-for-service (both traditional and under waivers and demonstrations), and Medicaid managed care organization reimbursement schemes, among others. A manufacturer or supplier that wishes to make available a warranty program seldom knows all of the ways in which providers might be reimbursed for items and services included in a bundled warranty arrangement. Among other issues, frequently, these reimbursement terms are confidential business terms between providers and managed care organizations. As OIG notes, even in the context of the bundled warranty arrangement that OIG approved under Advisory Opinion 18-10, some of the items in the bundle were separately reimbursable under certain states’ Medicaid programs.⁵⁴ Moreover, in many cases items or services included in a bundle are not reimbursed specifically, but might be deemed reimbursed indirectly as part of a payment for another item or service; in such cases, there might be numerous potential payments or reimbursement methodologies that could be viewed as providing such indirect reimbursement. As a practical matter, it generally would not possible for a manufacturer to be confident that this requirement was satisfied, making this safe harbor effectively unavailable for bundled item and service offerings.

We also question whether the issues identified by OIG as the reason for proposing this requirement constitute real-world problems. OIG states explicitly that the revised warranties safe harbor would not protect a manufacturer’s or supplier’s sale of the items and services as a bundle.⁵⁵ Consequently, OIG and other enforcement agencies retain the ability to challenge bundled sales that they believe are problematic due to some item or service being separately reimbursable or constituting independent value, regardless of whether a warranty on the bundle would be within the safe harbor. Further, the existence of a warranty on a bundle does not present the same concerns as a bundled sale itself—fundamentally, the warranty only

⁵² OIG states at 84 Fed. Reg. 55724 (in text and footnote 37) that the phrases “item and services” and “items or services,” as used in the safe harbor regulations, are not subject to the definition at 42 C.F.R. § 1003.110, and as such are not limited to items and services that are reimbursable under a Federal health care program. While that discussion was in the context of the proposed safe harbor for patient engagement and support tools, we request that OIG make clear that the warranty safe harbor is similarly not limited to items and services reimbursable under a Federal health care program. This is particularly relevant to medical equipment used by providers that often is not directly reimbursed under Federal health care programs, but may be deemed indirectly reimbursed as part of the payment for services performed through use of such equipment. There is no reason why the warranties safe harbor should not be available to allow manufacturers of such equipment to stand behind its performance.

⁵³ 84 Fed. Reg. 55749.

⁵⁴ 84 Fed. Reg. 55750.

⁵⁵ 84 Fed. Reg. 55748, footnote 83.

places the buyer in the same position as the buyer would have been if the items and services had produced the warranted outcome.

Warranties on bundled product and service offerings represent the type of competition that OIG *should* be promoting, in which providers prefer the products of manufacturers that agree to provide a remedy if a targeted outcome is not achieved. Manufacturers should not lose the opportunity for safe harbor protection of a warranty when they offer services in conjunction with a device or other product to help ensure that the warranted outcome is achieved. These types of warranty arrangements are at the core of what value-based care is all about.

2. Proposed Rule Section III.K.2: Capped Amount of Warranty Remedies; Prohibition on Exclusivity and Minimum-Purchase Requirements

Under the Proposed Rule, OIG proposes to modify the warranties safe harbor to limit the remuneration a manufacturer or supplier may pay to any individual (other than a beneficiary) or entity for any medical, surgical, or hospital expense incurred by a beneficiary to the cost of the items and services subject to the warranty.⁵⁶ We believe capping the amount of protected warranties remedies is too restrictive and will negatively impact patient care and unnecessarily stifle innovative value-based arrangements.

Sellers of products should be permitted to make certain clinical or cost assurances with respect to their products, and to provide appropriate value-based warranty remedies if warranted outcomes are not achieved. Such appropriate remedies may include the provision or payment for medical, surgical, hospital or other services and related items in connection with the replacement or supplementation of a warranted item or as an alternative or supplemental treatment, the cost of which may exceed the cost of the items or services subject to the warranty. We discussed this concept in AdvaMed's comments in response to OIG's Request for Information preceding the Proposed Rule⁵⁷ and provided the following hypothetical example of a value-based warranty arrangement:

- General Hospital (Hospital) is experiencing high post-operative surgical site infection (SSI) rates for patients undergoing procedures in the Hospital's general surgery service line. This has led to increased lengths of stay, the need for additional treatment and services, and in many cases, costly hospital readmissions after discharge. Payors are denying reimbursement for the readmissions and other services, on the basis that the costs resulting from these SSIs are avoidable. Hospital is not able to otherwise absorb these costs and considers shutting down its general surgery services line altogether. There is an opportunity to improve clinical outcomes and reduce costs materially.
- Medical Device Company (Company) develops, manufactures, and sells a comprehensive solution to address the risk of SSIs (Solution). The Solution includes the use of: (1) a suture device that is designed and developed to reduce the risk of SSIs; (2) clinical experts to conduct confidential reviews of Hospital's current clinical practices to help identify potential risks for SSIs at the Hospital; (3) customized plans to help Hospital personnel adopt and implement evidence-based infection prevention strategies and protocols and enhance compliance with Hospital policies and procedures; and (4) patient educational resources designed to engage patients in their care from pre-admission through discharge to facilitate optimal wound healing post-surgery.

⁵⁶ 84 Fed. Reg. 55750.

⁵⁷ 83 Fed. Reg. 43607 (Aug. 27, 2018). AdvaMed's comment letter in response to the Request for Information is available at https://www.advamed.org/sites/default/files/resource/advamed_letter_to_oig_re_aks_rfi.pdf.

- Company wants to offer Hospital the Solution through a value-based health care (VBHC) program that includes providing a warranty for failing to achieve patient clinical results specified as targets at the time of sale of the Solution.
- The VBHC program is negotiated and structured as follows:
 - In order to prepare for the adoption and implementation of the VBHC program, Hospital and Company will establish through a monitoring process an Infection baseline rate that includes patients who experience an SSI after undergoing a procedure in Hospital's general surgery service line during a defined 12-month measurement period (Infection Baseline Rate). Any services provided by Company to assist in determining the Baseline Infection Rate are set forth in a written document provided by Company to Hospital.
 - Company and Hospital agree that clinically, implementation of the Company's Solution should lead to a reduction in SSIs compared to the Hospital's Infection Baseline Rate.
 - Company sells the Solution to Hospital pursuant to a written agreement with a warranty providing that if the Hospital implements the Solution as set forth in the Agreement and does not achieve at least a 5% decline in SSI's compared to the Infection Baseline Rate during any subsequent 12-month measurement period, Company will compensate Hospital (in accordance with rates specified in the agreement) for specified types of documented medical, surgical, hospital or other directly related items and services provided by Hospital in treating patients who received the suture device included in the Solution and experienced an SSI, not to exceed \$X per patient; provided the following requirements are met: (a) such items and services are supplied, provided and paid for in accordance with the terms and conditions of the warranty; (b) such items and services are not billed by any person to any Federal health care program; and (c) such items and services are medically necessary.
 - The term of the agreement is 5 years, and there are 5 pre-defined 12-month SSI measurement periods.
 - If at least the 5% decline is achieved during a measurement period, no warranty remedy is available with respect to patients experiencing an SSI during that period.

Under this example, the Company could compensate the Hospital for an amount that would exceed the cost of the Solution itself if the targeted clinical outcomes of 5% reduction in SSI is not met; however, the arrangement specifically requires that such items and services not be billed by any person to any Federal health care program and that they be medically necessary.

We believe that this is an appropriate result with appropriate safeguards to protect against the concerns raised by the OIG in the Proposed Rule. As such, ***we recommend that OIG not cap the amount of warranty remedies and instead finalize the warranties safe harbor to permit manufacturers or suppliers to provide or pay for medical, surgical, hospital or other services and related items in connection with the replacement or supplementation of a warranted item or as an alternative or supplemental treatment, even if such remuneration exceeds the cost of the items and services subject to the warranty, as long as the replacement or supplementation items and services are not billed by any person to any Federal health care program and are medically appropriate.***

OIG also proposes that the manufacturer or supplier could not condition a warranty on the buyer's exclusive use of, or minimum purchase of, any of the manufacturer's or supplier's items or services. ***We believe this***

requirement is unnecessary and potentially contravenes the intent of the proposal, and therefore recommend it be removed from the final rule.

With respect to the minimum purchase requirement, many outcomes-based warranties relate to the performance of warranted items (and, where included, related services) across a patient population (described by OIG as “population-based warranties”). These typically require that there be some minimum level of use of the product (and any related services) so as to make the outcomes measure statistically meaningful. For example, a manufacturer might warrant, consistent with clinical studies, that use of its device will produce the warranted outcome at least 85 percent of the time; however, the warranty is only available if the device has been used on a large enough number of patients (typically determined through a minimum purchase requirement) to produce a statistically relevant outcome measure. OIG’s proposed requirement would preclude such outcomes-based warranties.

Similarly, an exclusive purchasing requirement is often necessary for the contemplated warranty to make sense. For example, a set of items bundled with an associated information technology system and related staff training may produce the target outcome only if the buyer standardizes on their use. As a business matter, the manufacturer or supplier could offer the outcomes-based warranty only if the buyer agrees to use the warranted items exclusively.

While OIG characterizes these types of requirements as “steering practices” that it considers “highly problematic,” that view is completely mistaken. Notably, buyers and sellers of items reimbursed under Federal health care programs are not subject to any general prohibitions on imposing exclusivity or minimum purchase requirements, as a condition of making discounts available or otherwise. While a provider obviously could not agree to an exclusive purchase requirement that would preclude it from obtaining medically necessary items for its patients, in many cases, providers can standardize on the use of any one of a number of similar, competitive products without triggering any such concerns. Exclusivity and minimum purchase requirements are features that can promote competition and lower costs, as in the case of purchase discounts conditioned on the volume of products purchased. Warranties constitute another means by which manufacturers compete against one another, by providing assurances of performance. Moreover, the fact that a warranty might be conditioned on a minimum or exclusive purchase requirement does not preclude a buyer from purchasing competitive products in violation of such requirement—the provider would simply lose the benefit of the warranty (which the manufacturer had no obligation to offer in the first place) by doing so.

3. Proposed Rule Section III.K.3: Reporting Requirements

OIG proposes that beneficiaries would be excluded from the existing safe harbor reporting requirements “since beneficiaries do not report costs to the Government,” and it solicits comments “on any burden the current reporting requirements impose and the need for more flexible reporting requirements . . . to better facilitate warranties tied to clinical outcomes.”⁵⁸

The safe harbor, as OIG has proposed to revise it, would require that the “buyer (unless the buyer is a Federal health care program beneficiary) must fully and accurately report any price reduction of an item or service (including a free item or service) that was obtained as part of the warranty, in the applicable cost reporting mechanism or claim for payment filed with the Department or a State agency.” This language was crafted when the Federal health care program reporting requirements were much different than they are today. In particular, for a vast portion of the items and services for which buyers currently are reimbursed

⁵⁸ 84 Fed. Reg. 55750.

under Federal health care programs currently, buyers have no obligations to report price reductions (or costs of any type) in either a “cost reporting mechanism” or a “claim for payment.” For example, there are no such requirements with respect to the vast bulk of items and services for which providers are reimbursed by Medicare Advantage plans or Medicaid managed care organizations.

Critically, the fact that the cost reporting mechanisms referenced in safe harbor do not exist would effectively make it impossible for buyers to comply with these requirements, and therefore would make the safe harbor unavailable as a practical matter. Put simply, in many cases, providers no more report costs to the Government than do the beneficiaries that OIG proposes to exempt from this reporting requirement.

AdvaMed recommends a simple fix to this problem: the buyer should only be required to report a price reduction or replacement product obtained as part of a warranty if it has an obligation to do so under applicable requirements of the Federal health care program payor making payment for the warranted item or service to which the price reduction relates. OIG should clarify that buyers are entitled to use any reasonable methodology for purposes of allocating a rebate that does not relate to a specific item or service across all items and services to which the warranty rebate relates. Further, as OIG notes, a cost reduction under a warranty may be received only well after the warranted item has been purchased by a provider, particularly where the clinical outcome from the use of the item may be measured several years after the initial purchase of the item. Accordingly, we recommend that OIG specifically provide that, for safe harbor purposes, such a rebate must be reported only after it is received.

H. Proposed Rule Section III.F: Arrangements for Patient Engagement and Support To Improve Quality, Health Outcomes, and Efficiency (1001.952(hh))

Our comments in this section relate to the new safe harbor OIG has proposed at 42 C.F.R. § 1001.952(hh) to protect certain arrangements for patient engagement tools and supports furnished by VBE participants.

1. Proposed Rule Section III.F.2: Limitations on Recipients

As proposed, this new safe harbor would protect patient engagement tools and supports furnished only to patients in a TPP. In the Proposed Rule, OIG solicits comments on whether it should instead provide safe harbor protection to a broader universe of patients.⁵⁹ For example, OIG proposes protecting patient engagement tools and supports furnished by VBE participants to any patient, so long as the tools and supports predominately address the needs of the TPP, and the tools and supports have a direct connection to the coordination and management of care for the patient.⁶⁰ OIG also acknowledges in the Proposed Rule certain operational challenges inherent in limiting the safe harbor’s protection only to those patients within the TPP.⁶¹

We recommend that in finalizing this new safe harbor, OIG extend the universe of individuals to whom VBE participants may furnish engagement tools and supports beyond only those patients within the TPP, including to family members and caregivers of patients. We appreciate OIG’s suggestion that a broader universe of patients could benefit from the provision of patient engagement tools and supports envisioned under the proposed safe harbor. We agree that this is the case: a broader universe of patients can and should benefit from the provision of appropriate patient engagement tools and supports, particularly where the tools and supports will be provided pursuant to the other safeguards included in the proposed safe harbor.

⁵⁹ 84 Fed. Reg. 55723.

⁶⁰ *I.d.*

⁶¹ *I.d.*

We further believe that the tools and supports envisioned under the proposed safe harbor could be helpful and beneficial to a patient's family members and caregivers, and in appropriate circumstances, these should also be protected under the safe harbor. For example, it may be appropriate to provide transportation to medical appointments not just to a patient, but also to a patient's caregiver who will be accompanying the patient to such an appointment.

2. Proposed Rule Section III.F.4.d: Additional Proposed Conditions; Direct Connection

Under the Proposed Rule, the patient engagement tool or support would be required to have a "direct connection" to the coordination and management of care of the TPP, which is one of the four value-based purposes identified by OIG in the Proposed Rule. OIG notes that it is considering and seeks comments on requiring that the tools and supports be directly connected to any of the four value-based purposes, as opposed to requiring a direct connection specifically to the coordination and management of patient care.⁶²

We recommend that OIG require only that patient engagement tools and supports be directly connected to any of the four value-based purposes. We appreciate the importance of coordinating and managing care, but we also believe that the other three value-based purposes identified by OIG are equally important in the context of advancing the transition to value-based care, improving quality and health outcomes, and lowering health care costs. We believe that this increased flexibility will encourage beneficial and appropriate arrangements that accomplish these important goals.

3. Proposed Rule Section II.F.4.i: Additional Proposed Conditions; Monetary Cap

Under the proposed patient engagement and support safe harbor, the aggregate retail value of the tools and supports furnished by a VBE participant to a patient could not exceed \$500 on an annual basis, unless there was a determination of financial need. The OIG solicits comments on various aspects of this proposed standard.

First, the OIG solicits comment on whether the proposed monetary limit of \$500 is appropriate. *We believe that while the amount OIG has proposed may be reasonable in some cases, a higher amount may also be appropriate in many cases, and we, therefore, recommend that the requirement be revised to allow for a higher value when the VBE's accountable body or responsible person determines the circumstances support the same.*

Like the OIG, we believe that the new value-based safe harbors should be finalized in a manner that encourages beneficial and innovative arrangements intended to improve quality and health outcomes and produce health system efficiencies and lower costs. Recognizing that such innovative arrangements may take many forms, including those not yet currently envisioned, it is difficult to identify a specific monetary cap.

A potential solution may be to increase the annual cap amount but add a requirement to the finalized safe harbor that the VBE's accountable body or person responsible for the financial and operational oversight of the VBE review and approve the value of the tool or support to make sure that it is not excessive under the circumstances. Alternatively, OIG could finalize the safe harbor to provide that the monetary cap is \$500, unless a higher amount is approved by the VBE's accountable body or person responsible for the financial and operational oversight of the VBE.

⁶² *I.d.*

Regardless of the amount, ***if OIG finalizes a specific annual cap amount, we recommend that it also provide that such amount will automatically increase on an annual basis based on the consumer price index or some other reasonable inflation measurement,*** consistent with monetary caps included in other rules.⁶³

Second, the OIG seeks comments on how to interpret the term “retail value.” In the preamble to the Proposed Rule, OIG notes that it is considering interpreting “retail value” to mean the fair market value to the recipient or commercial value to the recipient.⁶⁴ ***We recommend that in the final rule OIG interpret “retail value” to mean commercial value to the recipient.*** This approach will ensure that patient engagement tools and supports have a consistent value, regardless of the patient at issue. Fair market value may require more onerous analysis and could result in the same tool or support provided to two different patients having a different value. Commercial value is likely a more straight-forward standard to identify and, therefore easier to operationalize and track within the arrangement.

Third, the OIG solicits comments on its proposed approach of applying the monetary cap to individual VBE participants, and on whether the requirement should instead apply to the VBE as a whole.⁶⁵ ***We agree with the approach OIG has proposed of applying the monetary cap to individual VBE participants and recommend that it be finalized in the final rule.*** The final rule should allow flexibility for innovative arrangements to achieve the stated goal of promoting value-based care, including those which may involve the provision of appropriate patient engagement tools and supports by multiple VBE participants. The proposed safe harbor includes several other standards to safeguard against potential fraud and abuse such that the arbitrary limitation of appropriate tools and supports available to patients would be unnecessary.

4. Proposed Rule Section III.F.5.d: Potential Safeguards; Retrieval of Items and Goods

In the Proposed Rule, the OIG notes that it is considering, and seeks comment on, an additional condition under the safe harbor for patient engagement tools and supports that would require offerors to engage in reasonable efforts to retrieve an item or good furnished as a tool or support in certain circumstances (*e.g.*, when the patient is no longer in the TPP; when the VBE no longer exists; or when the offeror is no longer a VBE participant).⁶⁶ OIG is also considering setting a minimum value for the item or good, above which offerors would be required to make reasonable retrieval efforts, and/or limiting any retrieval requirement to tools and supports that are practicable to recover and where harm to the patient or disproportionate expense to the VBE participant would not result.⁶⁷

We do not believe it is necessary or practical to include in the final rule a standard that offerors have an obligation to retrieve patient engagement tools and supports. Instead, we believe that parties to an arrangement should be permitted to determine whether such efforts are reasonable and necessary, as well as when and how to go about retrieving items or goods, to the extent deemed reasonable and necessary under the particular circumstances of an arrangement. For example, a VBE participant may provide a

⁶³ See, *e.g.*, 42 C.F.R. § 403.904(h)(2)(ii) (related to the Sunshine Act reporting exclusion for de minimis payments or other transfers of value); 42 C.F.R. § 411.357(k) and (m) (related to the Stark Law exceptions for non-monetary compensation and medical staff incidental benefits).

⁶⁴ 84 Fed. Reg. 55728.

⁶⁵ *I.d.*

⁶⁶ 84 Fed. Reg. 55729.

⁶⁷ 84 Fed. Reg. 55730.

patient engagement tool or support in the form of a health-related software application (e.g., monitoring tool). Software applications cannot always be deactivated remotely. It would be unfeasible to require a VBE participant to seek out the patient in order to remove or “retrieve” the application.

To the extent that the OIG finalizes a condition that would require offerors to retrieve certain items or goods furnished pursuant to this safe harbor, we recommend that OIG clarify that any such obligation is based on a standard of reasonable effort or attempt to retrieve the item or good. Offerors should not be held to an unrealistic standard to retrieve an item or good, particularly to the extent that the burden of retrieval may outweigh the value of the item or good. Further, we agree that there should be objective circumstances in which an offeror is not required to retrieve an item or good (e.g., the cost of retrieval outweighs the value of the item or good; retrieval would be overly burdensome). In order to ensure that an offeror’s decision to cease retrieval is not being driven by an attempt to inappropriately influence beneficiaries, OIG could finalize that decisions with respect to whether and how to retrieve items must be reviewed and approved by the VBE’s accountable body or person responsible for the financial and operational oversight of the VBE.

I. Proposed Rule Section III.B.3: Proposed Value-Based Terminology - Target Patient Population

Under the Proposed Rule, the term “target patient population” (TPP) is defined to mean an identified patient population selected by the VBE or its VBE participants using legitimate and verifiable criteria that are set out in writing in advance of the commencement of the value-based arrangement and further the VBE’s value-based purposes. OIG solicits comments on this definition and whether to limit it to patients with a chronic condition or shared disease state that would benefit from care coordination.

We appreciate OIG’s recognition of the challenges inherent in limiting the definition of TPP. For example, with respect to the proposed safe harbor related to patient engagement tools, we agree that operationally it would be difficult to limit the protected recipients to those in the TPP. First, as OIG notes in the Proposed Rule, some VBEs may not be able to prospectively identify the individual patients in the TPP, including in the case of certain accountable care organization arrangements. Second, patients may move in and out of a TPP during the term of a value-based arrangement, depending on how a TPP is defined or identified. The OIG should permit flexibility and fluidity with respect to the definition of TPP in order to ensure that proper arrangements can be protected. In order to do so, ***we recommend that in finalizing the definition of TPP, OIG clarify that an “identified patient population” is not necessarily a static population of patients, and that the individual patients included in a TPP may shift during the term of an arrangement. We further recommend that OIG not limit the definition of TPP to those patients with chronic conditions or shared disease states.*** While we believe identifying a relevant TPP based on legitimate and verifiable criteria is appropriate, further limiting eligible patients unnecessarily stifles patient-centric innovation.

J. Other Comments and Considerations

1. Recommended Preamble Language

We recommend that OIG include language in the preamble to the final rule stating explicitly that an arrangement or business practice that satisfies the applicable conditions set forth in a safe harbor regulation must be respected as compliant with the AKS for all purposes, including False Claims Act (FCA) actions. In particular, we recommend that the OIG make clear that the “one purpose” test applicable to conduct outside of a safe harbor is not relevant to a business practice or arrangement for which applicable safe harbor conditions are satisfied.

Such a discussion would conform to longstanding OIG policy and would bolster the real-world effectiveness of any value-based safe harbors that OIG finalizes. One of the major issues that we and other stakeholders have identified as impeding the adoption of beneficial value-based arrangements is the explosion of *qui tam* litigation initiated by financially-motivated relators and their counsel under the FCA. These cases all too often seek to characterize non-abusive and appropriate industry practices as health care fraud, based upon the extremely broad language of the AKS, as part of their efforts to pressure companies into settlements to avoid material litigation expenses.

This recommendation is consistent with our previous discussions and correspondence with Deputy Secretary Eric Hargan and his staff.⁶⁸ In such correspondence, we provided a document containing proposed preamble language for OIG to consider for inclusion in its preamble discussion of proposed and final safe harbor regulations. We offer this language again for OIG's consideration and recommend the inclusion of the same or similar language in the preamble to the final rule.

* * *

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)

⁶⁸ May 8, 2019 Letter to Deputy Secretary Eric Hargan regarding Safe Harbors for Value-Based Arrangements, available at https://www.advamed.org/sites/default/files/resource/2019-05-08_advamed_letter_re_aks_safe_harbors_for_vbas_vf_1.pdf