

October 26, 2018

**By Electronic Submission via [www.regulations.gov](http://www.regulations.gov)**

Ms. Susan Edwards  
Office of Inspector General  
Department of Health and Human Services  
Attention: OIG-0803-N  
Room 5513, Cohen Building  
330 Independence Avenue SW  
Washington, D.C. 20201

**Re: OIG-0803-N: Request for Information Regarding the Anti-Kickback Statute and Beneficiary Inducements CMP**

Dear Ms. Edwards:

The Advanced Medical Technology Association (AdvaMed) appreciates this opportunity to submit comments in response to the Request for Information (RFI) regarding the federal Anti-Kickback Statute (AKS)<sup>1</sup> and Beneficiary Inducements CMP,<sup>2</sup> published by the Office of the Inspector General of the Department of Health and Human Services (OIG) at 83 Fed. Reg. 43607 (August 27, 2018).

### **AdvaMed**

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

### **Overview of the RFI and AdvaMed's Response**

OIG notes in the RFI that the Department of Health and Human Services (HHS) is working to transform the health care system into one that pays for value, and that as part of these efforts a key priority for HHS is removing unnecessary governmental obstacles to value-based care and care coordination. OIG states that it has identified the broad reach of the AKS and the Beneficiary Inducements CMP as potential impediments to arrangements that would advance coordinated care. Accordingly, it seeks to identify ways in which it might modify or add new safe harbors to the AKS or modify the definition of "remuneration" under the Beneficiary Inducements CMP in order

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

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

to foster arrangements that would promote care coordination and advance the delivery of value-based care, while also protecting against the harms caused by fraud and abuse. OIG states that it has issued the RFI to inform its efforts, and the RFI sets forth a variety of specific topics on which OIG invites public input.

AdvaMed and its members support this initiative. The breadth of and lack of clarity with respect to the AKS and, to a lesser degree, the prohibitions of the Beneficiary Inducements CMP, have both (1) strongly deterred manufacturers, providers, payors and others from engaging in beneficial value-based arrangements to improve care and reduce costs and (2) inhibited development of collaborations intended to advance the objectives of value-based care.

As we note in greater detail below, the safe harbors under the AKS have not been updated to keep pace with the enormous changes to reimbursement under federal health care programs, which are increasingly focused upon various forms of capitated reimbursement and payment for *outcomes* instead of the fee-for-service reimbursement system payment for *volume* for which they were designed. Further, the explosion of *qui tam* litigation premised upon purported violations of the AKS creates real-world risk for all participants in the health care system (including health care providers owned or managed by U.S. states and/or their municipalities) when engaging in legitimate, good-faith arrangements necessary to coordinate care, control costs and improve outcomes, absent clearer safe-harbor protection.

AdvaMed and its members have been strong advocates for regulatory reform in this area for some time. In particular, in response to the OIG's annual solicitation of new AKS safe harbors for each of the past two years, AdvaMed has proposed that OIG promulgate new safe harbors to protect value-based pricing arrangements and value-based warranty arrangements.<sup>3</sup> Similarly, in response to the recent request for information by the Centers for Medicare and Medicaid Services (CMS) regarding the physician self-referral law (Stark Law), we recommended that CMS adopt parallel modifications to the Stark Law regulations for these types of value-based arrangements.<sup>4</sup>

We continue to believe that new safe harbors establishing criteria for permissible value-based arrangements are both appropriate and necessary to achieve the transformation to value-based care that HHS envisions, including improvements in patient clinical outcomes and the cost management objectives of the federal, state and municipal governments. As such, our response to this RFI reiterates our previous safe harbor proposals with some modifications, as set forth in detail below, and also includes an additional new proposed safe harbor for value-based risk-sharing arrangements. We also address a number of the specific topics on which OIG has requested input.

## **Promoting Care Coordination and Value-Based Care**

### The Role of Medical Technology Manufacturers

Medical technology manufacturers have a key role to play in achieving the system's transition to value-based care. Manufacturers are experts in how their technologies can impact clinical

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<sup>3</sup> AdvaMed letters to OIG dated Feb. 27, 2017 and Feb. 26, 2018, available at <https://www.advamed.org/resource-center/advamed-2017-aks-safe-harbor-proposals-value-based-arrangements> and <https://www.advamed.org/resource-center/advamed-2018-aks-safe-harbor-proposals-value-based-arrangements>.

<sup>4</sup> AdvaMed letter to CMS dated Aug. 24, 2018, available at [https://www.advamed.org/sites/default/files/resource/advamed\\_comments\\_re\\_stark\\_law\\_rfi.pdf](https://www.advamed.org/sites/default/files/resource/advamed_comments_re_stark_law_rfi.pdf).

outcomes and have the specialized knowledge to design, and/or collaborate with providers in the design of, solutions to optimize care in a cost-effective manner—often using data generated from the devices to help facilitate care coordination.

Accomplishing these improvements requires providing tools and services (beyond selling a device) to help coordinate and optimize care, in order to further establish shared accountability across the continuum. Examples of these tools and services include education, training, care pathways, protocols, data analytics, supply-chain optimization, and care coordination services, which may involve nurse call centers, monitoring and/or diagnostic technology. Medical technology manufacturers also recognize that to significantly address cost inefficiencies within a system, providers often need support in identifying the opportunities for cost-saving efficiencies and care improvements, and in designing and operationalizing systems and arrangements to realize such 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 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. The end goal of all of this is to achieve much needed coordination and shared accountability in an otherwise fragmented delivery environment.

While we believe such active participation of medical technology companies is essential to improve outcomes and control costs within our health care system (and also believe that many providers fully share this view), AdvaMed and its members also strongly support a legal framework that protects against fraud and abuse. That commitment is reflected in, among other things, our development of the AdvaMed Code of Ethics<sup>5</sup> 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. What's more, AdvaMed members employ many highly-skilled compliance professionals who engage regularly in relevant trainings and monitoring across their respective organizations.

#### Regulatory Impediments to Value-Based Arrangements

Many of the barriers faced by parties desiring to enter into value-based arrangements stem from decades-old provisions contained in existing safe harbors that have not been updated to accommodate new and innovative technologies, to account for the government's drive to transition the system to value-based care, or to clearly and appropriately take into account the numerous changes in health care payment and reimbursement occurring since they were originally adopted. As a result, limitations and lack of clarity in the existing safe harbors effectively discourage progressive arrangements and undermine the government's own push toward value-based care.

For example, the discount safe harbor references the specific federal health care programs and types of reimbursement in place at the time it was drafted (last amended in 1999) and has not been updated to reflect the new programs and myriad reimbursement schemes established since that

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<sup>5</sup> 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](https://www.advamed.org/sites/default/files/resource/112_112_code_of_ethics_0.pdf)

time. While the safe harbor makes reference to health maintenance organizations and competitive medical plans acting in accordance with a risk contract under Section 1876(g) or 1903(m) of the Social Security Act, or under another State health care program, as types of “buyers,”<sup>6</sup> it does not even specifically address Medicare Part D plans, created by Congress in 2003 and operational since 2006.<sup>7</sup>

Similarly, many provisions of the discount safe harbor are focused upon making sure that buyers which report their costs on a cost report appropriately reflect the discounted price on such report. While AdvaMed supports the need for appropriate cost-reporting, the safe harbor’s provisions requiring sellers to notify buyers of their cost-reporting obligations are often misplaced in today’s complicated reimbursement environment under which products or services may be reimbursed in numerous different ways, under various programs. These include, among others, various prospective payment systems under Medicare and state Medicaid programs, the Medicare Shared Savings Program, numerous demonstration programs and Medicaid waiver programs, and various reimbursement arrangements under Medicare Advantage and managed Medicaid programs. Given this reality, in practice sellers often comply with this requirement by notifying buyers that they must comply with their cost-reporting obligations, if any—because only the buyer knows the cost-reporting obligations to which it is subject, under the various programs which ultimately provide reimbursement for the patients it serves.

Moreover, the current discount safe harbor requirement that discounts relating to bundled items and/or services must be reimbursed by the same program using the same methodology is also outdated and unworkable in today’s complicated reimbursement environment. In order to improve clinical or cost outcomes it is often essential to craft value-based arrangements around a combination of items and/or services. However, it is frequently impossible to determine that the same program/methodology criteria will be satisfied with respect to every patient. For example, OIG’s recent Advisory Opinion 18-10 noted that portions of the product bundle covered by the proposed warranty arrangement under consideration there were sometimes separately reimbursable under state Medicaid programs, even though they were covered by a bundled payment under the Medicare Inpatient Prospective Payment System.<sup>8</sup> While OIG nevertheless approved the arrangement, situations such as these often make it impossible to know whether this safe harbor requirement will be satisfied. In light of these issues, we believe the “same program, same methodology” requirement should not be included in new safe harbors, and have not included such a requirement in any of the new safe harbors we propose.

Other outdated requirements similarly preclude safe harbor protection for the very types of systemic value-based improvements contemplated by the government. For example, under the current AKS framework, a cost-reporting buyer is limited to earning a discount “based on purchases of that same good or service bought within a single fiscal year of the buyer,” and the

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<sup>6</sup> In addition to providers and payors, we note that in certain cases a patient is appropriately treated as a buyer under certain types of value-based arrangements. This is reflected in our proposed safe harbor for value-based warranties, where “buyer” is defined to include Federal health care program beneficiaries, to accommodate arrangements where a value-based warranty is provided to the beneficiary.

<sup>7</sup> We note that, despite this shortcoming in the safe harbor, protection for discounts provided to Part D plans is available under the statutory discount exception to the AKS at 42 U.S.C. 1320a-7b(b)(3).

<sup>8</sup> OIG Advisory Opinion 18-10, at p. 3, footnote 5.

buyer must “claim the benefit of the discount in the fiscal year in which the discount is earned or the following year.”<sup>9</sup> However, in a value-based environment, providers, payors, and patients may benefit when clinical outcomes are measured over a longer period of time. In certain cases, it is not possible to satisfy these criteria for an outcomes-based payment because the payment determination will occur more than a year after a buyer’s purchase of the relevant product, due to the need to measure patients’ clinical outcomes over a longer timeframe. While such a narrowly timed requirement likely made sense in last century’s reimbursement system under which cost reimbursement was a primary feature, the reality today is that it is rare for providers to be reimbursed based upon their own costs for a specific product/service; instead, they are generally paid a fixed amount for a given service (including all necessary products), with cost-reporting coming into play (if at all) only on an aggregated basis across all providers for purposes of setting fixed reimbursement amounts in future periods.

We believe it is also appropriate to note that many courts’ interpretation and treatment of certain safe harbor requirements has further confused the issues, compounding risks for our member companies and fragmenting rules across our various states/circuits. For example, in one case, a federal district court declined to apply the discount safe harbor to protect discounts provided by a manufacturer to a buyer/supplier because there was no showing “that [the buyer] has provided certain information concerning the discounts to a government agency pursuant to its request”—even though there had been no allegation that any governmental agency had ever made such a request, as necessary to trigger such disclosure obligation for the charge-based buyer at issue under the discount safe harbor.<sup>10</sup>

More generally, the practices of the government itself have created an environment in which the safe harbors are not always “safe” in practice, despite the parties acting in good faith. For example, the Department of Justice has stated in litigation filings that protection under the discount safe harbor and the statutory discount exception to the AKS is unavailable if the discount is conditioned upon anything other than a simple purchase—a requirement found nowhere in the safe harbor or statute itself.<sup>11</sup> In effect, parties to an arrangement are under a threat of having the judicially-developed “one-purpose test” applied to an arrangement even if it is, based upon the specific criteria in a safe harbor, supposed to be permissible as a matter of law. In order to remove this real-world barrier to value-based arrangements it is *essential that OIG make clear through its regulatory authority that arrangements satisfying all safe harbor requirements are not subject to challenge under the AKS*, in *qui tam* actions or otherwise, even if included among the purposes of the arrangement is one to induce the purchase or prescription of a manufacturer’s technology. The nature of value-based arrangements often includes inducing or rewarding the appropriate use of quality-enhancing or cost-reducing technology and protocols. For example, an arrangement targeted at improving outcomes across a population would require the implementation of a protocol for appropriately identifying each patient that has a significant likelihood of benefiting

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<sup>9</sup> 42 C.F.R. § 1001.952(h)(1)(ii).

<sup>10</sup> *United States ex rel. Herman et al. v. Coloplast Corp. et al.*, Case 1:11-cv-12131-RWZ (D. Mass), Opinion and Order (Aug. 24, 2016), at 3.

<sup>11</sup> *United States ex rel. Herman et al. v. Coloplast Corp. et al.*, Case 1:11-cv-12131-RWZ (D. Mass.), United States’ Statement of Interest Regarding Plaintiff’s Motion for Reconsideration of the Court’s Dismissal of CCS (Aug. 8, 2016), at 2 (“If a reduction in price is conditioned on more than a simple purchase, it is not a mere ‘discount,’ but rather a form of remuneration whose legitimacy must be evaluated under the anti-kickback statute separate and apart from the statutory discount exception or regulatory discount safe harbor.”).



from the use of a particular technology, and failure to implement such a protocol may restrict available value-based payment if targeted outcomes are not achieved.

Providers, manufacturers and others may also seek to enter value-based risk-sharing arrangements for the purposes of identifying and achieving improvements in clinical outcomes and/or cost savings, for compensation determined on a risk-sharing basis independent of any product pricing or warranties. These value-based risk-sharing arrangements may be vital to identifying and meaningfully addressing inefficiencies and process improvements necessary to control costs and improve outcomes, but may not clearly fit within the framework of the currently-existing personal services and management contracts safe harbor. For example, the personal services safe harbor requires that the aggregate compensation paid over the term of the agreement must be set in advance and consistent with fair market value in arms-length transactions.<sup>12</sup> Where compensation is determined based upon some sharing of the savings achieved or reimbursement bonuses realized due to improved outcomes, this requirement may be interpreted to preclude protection under that safe harbor. This safe harbor requirement is particularly inappropriate where the true “value” of the services provided to the recipient is intrinsically dependent upon whether and how much savings or the like are in fact achieved—i.e., a fixed fee set in advance may be less consistent with the core “fair market value” requirement of the personal services safe harbor than a fee based upon percentage of savings resulting from the services provided. These are not theoretical concerns; to the contrary, providers are often understandably reluctant to pay significant fixed fees for consulting services where the intended improvements may not in fact be realized.

Similarly, with respect to these types of arrangements, it is not the aggregate compensation that should be set forth in writing in advance, but the compensation formula (e.g., percentage of savings or bonus payments). Moreover, the parties should be free to agree that if the service provider’s recommendations ultimately fail to realize the intended system improvements and result in increased costs or do not improve clinical outcomes, the service provider will pay the recipient of the services an underperformance payment in light of such increased costs or unrealized clinical improvements—i.e., the parties will share both the upside and the downside. While these types of risk-sharing arrangements clearly make sense and typically pose little real-world risk of fraud and abuse, the highly limiting requirements under the existing safe harbor may be seen to preclude safe harbor protection.

Unfortunately, providers’ ability to implement value-based solutions necessitated by the evolution of CMS reimbursement is constrained by AKS provisions that are inconsistent with, or fail to contemplate the means to realize, a value-based system’s objectives and thereby seriously restrain and chill the delivery of improved or expanded care opportunities and/or significant potential cost reductions to their patient populations and their taxpayers.

#### Proposed Safe Harbors for Value-Based Pricing, Warranty, and Risk-Sharing Arrangements

Consistent with our proposals in response to the OIG’s annual safe harbor solicitations, AdvaMed recommends that OIG adopt three new safe harbors, for “value-based pricing arrangements,” “value-based warranty arrangements,” and “value-based risk-sharing arrangements.” The text of each of these proposed safe harbors is set forth in Attachment A, Attachment B, and Attachment C,

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<sup>12</sup> 42 C.F.R. § 1001.952(d)(5).

respectively, to this letter. We have also included in each of these Attachments a hypothetical scenario that illustrates the types of arrangements that each of our proposed safe harbors would protect. To be clear, while these hypotheticals may be permissible under existing safe harbors, our proposed new safe harbors will provide more clarity and certainty to enable the entire industry to operate in a consistent and predictable fashion.

The proposed safe harbors for value-based pricing and warranty arrangements generally conform to the safe harbors we proposed in our February 26, 2018 submission to OIG, with a few refinements. We have not previously proposed text for a safe harbor for value-based risk-sharing arrangements, but are doing so in response to this RFI as well as the increasing demand from providers struggling to effectively advance value-based care to meaningfully reduce costs and/or improve outcomes, as further discussed below.

While we are open to revising the existing safe harbors to remove the impediments to value-based arrangements and care coordination which, as currently drafted, they fail to address, we believe that the most straightforward way to accomplish this goal (without confusing the generally settled understanding of existing safe harbors) is to create these new safe harbors specifically designed to permit such arrangements. In particular, while value-based arrangements may include discounts or warranties, they may also involve other elements outside of these concepts.

Most notably, value-based arrangements frequently involve a suite of services, software and/or equipment which are provided in conjunction with a given product or service to achieve the targeted outcome(s). These product and services offerings are necessary to realize the goals of value-based care. For example, coordinated and high-quality pre-operative education and planning, post-operative monitoring and ongoing care may be critical to a patient's successful recovery; in order to achieve this goal, medical technology manufacturers may make available mobile apps, patient support services, provider training, and related services and equipment. We believe that sellers' provision of such services for no individualized charge(s) is conceptually consistent with OIG's treatment of similar services as having no independent value to the buyer and effectively constituting a part of the reimbursable product(s) to which they relate. Such services do not constitute a "discount" to the buyer with respect to the product purchased, but instead are part of combined product-and-services offering to diagnose or treat the disease(s)/condition(s) at issue. However, in the context of value-based arrangements, we believe the relevant fraud and abuse standard should not be a general "no independent value" test, inasmuch as buyers may in various ways derive some ancillary form of benefit from these types of services (e.g., through reimbursement bonuses due to improved patient outcomes, or cost savings from more efficient procedures). Instead, so long as the services relate to achieving the same clinical and/or cost outcome as the related product, treating them as an integrated offering should be more clearly permitted.<sup>13</sup>

Similarly, value-based arrangements often require analysis, software, equipment or services to develop or operationalize the arrangement itself. For example, a seller may offer (or, with increasing frequency, a buyer may demand) that the price for a given product or service be subject to adjustment, up or down, based upon the outcome(s) experienced by the patients receiving such product or service. Such outcomes-based economics reflect a critical and fundamental element of

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<sup>13</sup> As set forth in our proposed safe harbor, appropriate cost-reporting for the bundled offering should be required.

value-based care, and our proposed safe harbor for value-based pricing arrangements includes appropriate fraud and abuse standards for such pricing adjustments themselves (e.g., requiring appropriate cost-reporting). However, determining what metrics make sense for a given pricing adjustment (including associated criteria for the patients to be evaluated), and then measuring those metrics (and/or isolating each metric's respective contribution), applying relevant criteria and reporting the results, can be an involved and costly process. While we believe characterizing the payment for or provision of such analysis, software, equipment or services as illegal remuneration is unfounded, absent clearer safe harbor protection there is always a risk of an AKS challenge (typically by a *qui tam* relator). As a result, parties are unreasonably restrained and discouraged from moving forward with value-based arrangements due to such risks. Consequently, the government's intended benefits are not being realized.

In addition to value-based pricing and warranty arrangements where the pricing or warranty remedy is based on outcomes measures, parties may also or at the same time seek to enter into consulting or similar services arrangements to improve provider efficiencies and assist providers in improving patient outcomes. Such arrangements often make the most sense when the compensation is based on clinical and/or cost improvements actually realized, instead of the aggregate amount fixed-in-advance fee justified using traditional fair market value methodologies, as required under the current personal services and management contracts safe harbor.

For these and other reasons, we believe promulgation of new safe harbors with provisions tailored specifically to value-based pricing, warranty, and risk-sharing arrangements are both appropriate and overdue. Under each of these proposed safe harbors, a value-based arrangement would be required to satisfy appropriate fraud and abuse safeguards for the participants to enjoy safe harbor protection. Some of the key points can be summarized as follows:

- The value-based pricing arrangements safe harbor would protect value-based pricing adjustments, defined as a payment made by a seller to a buyer (or by a buyer to a seller) that is conditioned and/or calculated based upon one or more clinical and/or cost outcomes (determined using one or more measurable metrics) that are associated with the value of seller's reimbursable items and/or services when appropriately used.<sup>14</sup>
  - Eligible “buyers” would include providers and payors, and eligible “sellers” would include manufacturers, suppliers and providers.
  - The safe harbor would protect a wide variety of value-based price adjustments, including, but not limited to, rebates provided by manufacturers to payors or providers if the manufacturer's product fails to meet a clinical goal, and value-based reimbursement arrangements between payors and providers.
  - Included in Attachment A is a hypothetical scenario related to this new value-based pricing arrangements safe harbor.

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<sup>14</sup> “Base” discounts provided under the arrangement—i.e., those not dependent upon a clinical/cost outcome—would also be included in the definition of value-based pricing adjustments, so that they would also be subject to protection, subject to satisfaction of the same cost-reporting and other requirements. See paragraph (\*) (5) (F) (i), below.



- The value-based warranty safe harbor would allow sellers to make certain clinical or cost assurances with respect to their products, and provide an appropriate “value-based warranty remedy” if the warranted outcome is not achieved.
  - A value-based warranty remedy could be a warranty price adjustment and/or warranty replacement items and/or services. The latter category may include the seller’s 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, if such items/services are not billed by any person to any Federal health care program and are medically appropriate.
  - Included in Attachment B is a hypothetical scenario related to this new value-based warranty safe harbor.
- The value-based risk-sharing arrangements safe harbor would protect certain transfers of value under the arrangement where required criteria are satisfied.
  - A value-based risk-sharing arrangement is a written agreement under which participants agree to (i) contribute to the achievement of pre-identified and measurable clinical and/or economic target endpoints designed to promote improved patient outcomes or reduce costs (without negatively affecting outcomes), (ii) implement associated processes and procedures to optimize the delivery, efficiency and/or quality of patient-centered care, and (iii) assume an allocation of the financial risk in achieving the targeted endpoints, with consideration of the participants’ respective contributions thereto.
  - The transfer of value under the arrangement must be intended to drive or promote accountability, cost, coordination and overall care of patient populations, manage and coordinate care for patients through arrangements approved and administered, furnished or arranged by the parties, or encourage efficient deployment and utilization of infrastructure and/or facilitate redesign or care process workflow to achieve higher quality and/or more efficient service delivery for patients, in each case consistent with quality of care, physician medical judgment and patient freedom of choice.
  - Among other requirements, the methodology to determine financial risk must be set forth in writing and in advance of the performance of the specific risk-sharing arrangement and shall not be dependent upon the volume or value of any referrals or the purchase of any participant’s goods or services which do not contribute to the achievement of pre-identified clinical and/or economic target metrics.
  - Included in Attachment C is a hypothetical scenario related to this new value-based risk-sharing arrangements safe harbor.
- The first two safe harbors would allow for provision of “value-based services,” defined to include analysis, software, equipment, information and/or services reasonably necessary or appropriate for the purposes of determining the terms of the arrangement, operationalizing

the arrangement (e.g., measuring and reporting relevant outcomes metrics), optimizing the effectiveness and clinical utility of the products or services at issue, or otherwise achieving the clinical or cost outcomes upon which the arrangement is based (including through provision of software, equipment, information or services to patients and providers).

- Similarly, the third safe harbor would allow for participant activities reasonably necessary or appropriate to determine the terms of the value-based risk-sharing arrangement, including determining the metrics to be used in the arrangement, and to measure, collect, calculate and/or report such metrics or the resulting economic benefit or exposure.
- The value-based pricing and warranty arrangement safe harbors would permit bundled arrangements subject to specified conditions, and appropriate cost-reporting required (with the seller's assistance in providing reasonable allocations, when requested by the buyer).
- Other requirements must be satisfied, including setting forth in writing the terms and conditions of the arrangement and the services to be provided, and compliance with prohibitions on duplicative reimbursement claims.

Overall, the proposed safe harbors include many features of existing safe harbors, but are cast in terms consistent with the value-based arrangements envisioned and encouraged by today's health care reimbursement system, using provisions less likely to cause confusion regarding their requirements and to remove the chill presented by the current safe harbors that were fashioned without contemplation of value-based care systems. For example, we have omitted the numerous discount safe harbor requirements for the seller to "report" discounts to a buyer, inasmuch as the parties will each be well aware of a value-based pricing adjustment when one makes payment to the other in accordance with the required pre-existing writing specifying when such pricing adjustment is payable.

Some of the many benefits we believe will result from adoption of these safe harbors include:

- Improvement of health care quality by better enabling manufacturers and other sellers to provide solutions tailored to improve clinical outcomes;
- Expansion of health care opportunity to underserved segments of populations;
- Better control of costs by facilitating arrangements that put the seller or services provider at economic risk for achievement of defined clinical and/or cost outcomes;
- Reduction of inefficient allocation of resources, by clearly aligning regulatory frameworks to government objectives; and
- Promoting competition on the most relevant bases—value and outcomes, not just nominal costs.

Importantly, we are convinced that adoption of these safe harbors would not be likely to result in overutilization, underutilization, skewed medical decision-making, unfair competition or other fraud and abuse concerns. Nothing in these safe harbors would create an incentive for providers

to over-utilize products or services. Relative to under-utilization, we note that the proposed definition of “value-based pricing adjustment” expressly requires that the arrangement “not knowingly induce the buyer to reduce or limit medically necessary items or services to the buyer’s patients.” Similarly, the definition of value-based risk-sharing arrangement requires that target endpoints be specifically designed to promote improved patient outcomes or reduce the costs of healthcare delivery while avoiding negatively affecting patient outcomes. Medical decision-making will be more appropriate, not less, given the increased flexibility to make decisions based upon value and outcomes, not just nominal price. And competition will be more fair, not less, as value is increasingly taken into account.

### **Other RFI Issues**

In addition to the points and proposals made above, we also had the following comments in response to the RFI.

#### Critical Terminology

In the RFI, the OIG seeks thoughts on definitions for a series of terms it believes are critical in the context of health care delivery reform, payment reform, and the AKS. In general, we believe these terms are most appropriately defined in relation to the specific safe harbors or other regulations to which they are intended to apply. In this regard, we have defined and used certain terms similar to those identified by the OIG in our proposed safe harbors below.

With respect to the terms identified by the OIG in the RFI, we offer below additional context and information for OIG’s consideration.

*Value-Based Care.* We consider value-based care to be that which is designed to improve health outcomes for patients and/or to reduce the costs and inefficiencies of health care delivery without negatively affecting patient outcomes. Value-based care represents a more targeted harmonization and shared accountability<sup>15</sup> of health care cost/effort and health care quality.

Value-based care may take a variety of different forms. For example, value-based reimbursement models include capitated payments to providers for a suite of services, thereby making the provider responsible for controlling costs while achieving quality standards, or adjusting reimbursement based upon quality and/or cost criteria (e.g., Medicare Shared Savings Program and the MACRA Merit-based Incentive Payment System (MIPS)). Value-based care also includes arrangements between providers, manufacturers, patients, and/or payors to provide a suite of services to accomplish targeted outcomes, to condition or calculate a price for a health care product or service based upon achievement (or failure to achieve) targeted outcomes, or to provide a warranty remedy if one or more targeted outcomes is not achieved. Value-based care also includes risk-sharing arrangements between various participants in the health care system, such as those where consulting or similar services are provided for compensation tied to achievement of clinical

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<sup>15</sup> This concept of shared accountability recognizes that value-based care may include risk-sharing arrangements that encompass upside and/or downside risk for the participants, based upon achievement (or failure to achieve) targeted clinical and/or cost outcomes. This principle is reflected in our proposed value-based safe harbors.

and/or cost outcomes.

*Outcomes-Based Care.* In our view, outcomes-based care is a derivative of value-based care (as described above) and is the metric by which value is measured. As the foregoing reflects, “value” is often determined through achievement (or failure to achieve) one or more targeted clinical and/or cost outcomes. Accordingly, this concept is used repeatedly in the safe harbors we have proposed.

While we certainly believe that the concept of outcomes applies in the context of direct patient care, we also believe the term applies more broadly to include processes and procedures that optimize the delivery and efficiency of care either to control costs, expand opportunities for care, or that may ultimately lead to (indirect) improvements with respect to patient care. For example, reduction in surgical time, reduction in excess inventory, or supply chain savings.

*Risk Sharing.* We believe that risk sharing arrangements may take countless forms, each of which includes a sharing by the parties of a responsibility to achieve agreed-upon clinical or cost outcomes, as well as a sharing of the risk of not achieving the outcomes and/or the benefit of surpassing the outcomes. Risk sharing arrangements may incorporate a higher up-front price to account in part for the risk exposure.

*Cost Outcomes.* We make reference to cost outcomes in our proposed safe harbors. In considering such concept, we suggest the OIG consider that relevant outcomes may include those beyond the cost of directly treating any individual patient. For example, demonstrated savings through reduction of inventory, logistics or supply chain work-flow and staffing efficiencies, reduction in time necessary to complete an intervention, and diminishment in days lost to employee absence through improved safety initiatives might all be targeted cost outcomes.

As the OIG considers defining these and other terms, we encourage it to keep in mind that all participants in the health care continuum, including manufacturers, must be considered and included in whatever definitions the OIG ultimately develops. In addition, we believe that these terms should be defined consistently across all applicable regulations, which may include regulations promulgated by CMS. Finally, we believe that these issues are most appropriately addressed through updated regulation, as opposed to agency guidance. Such an approach ensures a notice and comment opportunity for all interested parties and also ensures that all health care stakeholders can work together to coordinate care and deliver the value that is expected of them without fear of inadvertently running afoul of fraud and abuse laws.

### Beneficiary Engagement

We note that our proposed safe harbors to the AKS may involve provision of value-based services to beneficiaries (e.g., mobile apps, patient counseling, etc.), and that beneficiaries themselves could be recipients of value-based warranties (and associated warranty remedies) under our proposed safe harbor for value-based warranties. In light of the cross-reference to the AKS safe

harbors under the definition of “remuneration” pursuant to the Beneficiary Inducements CMP,<sup>16</sup> we do not believe it is necessary to propose companion changes to the CMP provisions, with respect to these value-based arrangements.

### Application Across Multiple CMS Programs

OIG invites feedback regarding the pros and cons of fraud and abuse protections (e.g., waivers or safe harbors) that are uniform across different types of CMS-sponsored models, initiatives and programs (Section 3.A.i.e).

AdvaMed believes that it is necessary to provide a uniform set of fraud and abuse protections that is applicable not only to different types of CMS-sponsored models, initiatives and programs, but to all types of models, initiatives and programs to which the AKS or Beneficiary CMP could potentially apply. This would include, among other things, the numerous innovative programs under state Medicaid programs (including demonstrations and waivers, and under managed Medicaid plans), Medicare Advantage plans, the Medicare/Medicaid financial alignment demonstration, and otherwise. Realistically, the health care community cannot keep track of the myriad variations under these numerous programs; similarly, it is unrealistic to think that OIG could do so, and timely provide waivers or similar protections specific to each, as each continually evolves. We believe that a common set of principles can provide the protections necessary to substantially reduce many of the significant current barriers to value-based arrangements.

### Cybersecurity-Related Items and Services

In the RFI, OIG requests information regarding cybersecurity-related items and services; particularly, the donation or subsidization of the same.<sup>17</sup> Generally, we believe that to the extent cybersecurity items and services are part of a value-based arrangements solution, such items and services should be protected under the proposed safe harbors we include below.

Software and technology designed to guard against and/or enable prompt remediation of exposed cyber vulnerabilities associated with providing a value-based solution should be considered part of the solution. In addition, such items and services are often integral to a manufacturer’s product and therefore properly considered part of the product. That said, cyber risk is also presented within an environment’s IT ecosystem only a fraction of which may be within the domain of any particular device manufacturer or IT solution provider. If a manufacturer is introducing technology or services that may present risks for customers (either individually or via its operation within a larger IT environment), we believe that manufacturer should be able to agree to bear some responsibility for mitigating such risk, which may come in the form of cybersecurity-related items and/or services.

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<sup>16</sup> 42 U.S.C. § 1320a-7a(i)(6)(B).

<sup>17</sup> We note that cybersecurity is a broad topic that extends beyond the issue of value-based care, which is the subject of the RFI. Our comments here are limited to this issue in the context of value-based care. Cybersecurity-related issues more generally may be more properly addressed in response to a separate Request for Information.



### Intersection of Physician Self-Referral (Stark) Law and AKS

As reflected in the comments we recently submitted to CMS in response to the Stark RFI,<sup>18</sup> AdvaMed believes that the Stark Law and the AKS should contain parallel safe harbors setting forth terms and conditions under which value-based price adjustments and value-based warranties can be provided without violating the broad prohibitions of these two statutes. Along those lines, we proposed text for revisions to the Stark Law regulations which would parallel the AKS safe harbors for value-based pricing and warranty arrangements we are proposing here. Along the same lines, we believe the Stark Law regulations should also include a new exception allowing value-based risk-sharing arrangements subject to the same terms and conditions we have proposed here.

Importantly, while many medical technology manufacturers may not be directly subject to the Stark Law, their customers typically are. Further, in an ever-consolidating environment, Stark may be relevant to a manufacturer's affiliates as well. It is critical that the entire continuum of healthcare delivery participants has a common set of standards providing the appropriate flexibility to enter into value-based arrangements in order to deliver the value which is expected of them in today's environment.

### **Conclusion**

Due to the evolution of the health care system since the current safe harbors to the AKS were adopted and the government's stated objective to further accelerate a value-based care evolution, existing restrictions have become outdated and unnecessary impediments to the furtherance and adoption of modern value-based care arrangements. It is time to modernize and improve the AKS safe harbors, ideally in concert with similar changes to the exceptions under the Stark Law, to clearly permit and encourage value-based arrangements, subject to appropriate program integrity protections.

\* \* \*

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](mailto:cwhite@advamed.org) with any questions.

Sincerely,



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

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<sup>18</sup> See AdvaMed letter to CMS dated Aug. 24, 2018, available at [https://www.advamed.org/sites/default/files/resource/advamed\\_comments\\_re\\_stark\\_law\\_rfi.pdf](https://www.advamed.org/sites/default/files/resource/advamed_comments_re_stark_law_rfi.pdf).

## ATTACHMENT A

### **I. New AKS Safe Harbor for Value-Based Pricing Arrangements**

AdvaMed proposes that OIG adopt a safe harbor for value-based pricing arrangements as follows:

(\*) **Value-based pricing arrangements.** As used in section 1128B of the Act, “remuneration” does not include any value-based price adjustment or value-based services provided in connection with a value-based pricing arrangement, each as defined in paragraph (\*) (5) of this section, as long as the following standards (as applicable) are met—

- (1) The terms and conditions of the value-based price adjustment are fixed and disclosed in writing by the seller or buyer making such value-based price adjustment available, at or prior to the time of the buyer’s first purchase or coverage of the seller’s reimbursable items and/or services (as defined in paragraph (\*) (5) (C) of this section) under the value-based pricing arrangement. For such purposes, terms and conditions shall be deemed fixed if the formula or other objective mechanism for determining the amount of the value-based price adjustment is set forth in such written document.
- (2) The value-based services to be provided or made available by the seller as part of such value-based pricing arrangement are identified in writing and disclosed by the seller to the buyer at or prior to the time of the buyer’s first purchase or coverage of reimbursable items and/or services under the value-based pricing arrangement; provided, that with respect to value-based services described in paragraph (\*) (5) (D) (i), such value-based services shall instead be identified in writing and disclosed by the seller to the buyer at or prior to the time they are provided.
- (3) In the case of the buyer:
  - (A) If and as required under any applicable Federal health care program statute, regulation, demonstration or contract pursuant to which such buyer furnishes or provides coverage for the reimbursable items and/or services to which such value-based pricing arrangement relates, the buyer appropriately reports and/or reflects the buyer’s price and/or net cost for the reimbursable items and/or services to which the value-based pricing arrangement relates, taking into account (i) any such value-based price adjustment provided to or by the buyer as part of such value-based pricing arrangement, and (ii) the value reasonably attributed by the seller to each reimbursable item and/or service provided or made available by the seller as part of such value-based pricing arrangement, as provided by the seller under paragraph (\*) (4) below; and
  - (B) The buyer does not submit a claim for separate payment for any value-based services provided or made available by the seller under the value-based pricing arrangement apart from the buyer’s claim which includes the reimbursable items and/or services included in the value-based pricing arrangement.
- (4) In the case of a seller:
  - (A) If reasonably requested by the buyer in order to satisfy a reporting obligation of the buyer under paragraph (\*) (3) of this section, such seller provides the buyer the value

- reasonably attributed by the seller to each reimbursable item and/or service provided by the seller under the value-based pricing arrangement;
- (B) The seller does not submit a claim or otherwise seek reimbursement under any Federal health care program for any reimbursable items and/or services or value-based services which it provides or makes available as part of the value-based pricing arrangement, apart from its reimbursement under such value-based pricing arrangement; and
  - (C) Such seller refrains from doing anything that would impede the buyer from meeting its obligations under paragraph (\*) (3) of this section.
- (5) For purposes of this paragraph (\*):
- (A) The term buyer means (i) an individual or entity (such as a provider or supplier) which receives reimbursement under any Federal health care program for reimbursable items and/or services furnished by such person or entity, and (ii) an entity (such as a Medicare Advantage organization or a Medicare Part D plan sponsor) which provides coverage and reimbursement for reimbursable items and/or services and is fully or partially at risk for the cost of such reimbursable items and/or services (other than on a fee-for-service basis);
  - (B) The term seller means an individual or entity which supplies to a buyer, either directly or indirectly through one or more intermediaries (such as a wholesaler), one or more reimbursable items and/or services and makes available a value-based price adjustment to the buyer, is the recipient of a value-based price adjustment made available by the buyer to the seller, and/or makes available one or more value-based services to or for the benefit of such buyer or its patients (in each case, subject to the terms and conditions of the value-based pricing arrangement);
  - (C) The term reimbursable items and/or services means items and/or services for which payment may be made, in whole or in part, under a Federal health care program;
  - (D) The term value-based services means analysis, software, equipment, information and/or services provided or made available by a seller as part of a value-based pricing arrangement, for a reduced charge or no charge (apart from the buyer's price or net cost for the reimbursable items and/or services to which the value-based pricing arrangement relates), reasonably necessary or appropriate for one or more of the following purposes:
    - (i) Determining the terms of such value-based pricing arrangement before such terms are fixed and disclosed in writing (including, without limitation, determining one or more of the metrics to be used in the value-based pricing arrangement);
    - (ii) Measuring, collecting, calculating and/or reporting the metric(s) upon which the value-based pricing arrangement is based and/or the resulting value-based price adjustment (if any) which is payable;

- (iii) Optimizing the effectiveness and clinical utility of the reimbursable items and/or services to which the value-based pricing arrangement relates (*e.g.*, training and/or process improvements); and/or
- (iv) Otherwise achieving the clinical and/or cost outcomes on which the value-based pricing arrangement is based, including through provision of analysis, software, equipment, information and/or services to patients to facilitate such outcomes;

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

- (E) The term value-based pricing arrangement means an agreement or other arrangement under which a seller provides a value-based price adjustment to a buyer, a buyer provides a value-based price adjustment to a seller, and/or a seller makes available value-based services, in each case in accordance with the requirements of this section;
- (F) The term value-based price adjustment means a reduction to or increase in a buyer's price or net cost for one or more reimbursable items and/or services supplied by a seller under a value-based pricing arrangement, consisting of:
  - (i) a discounted or bundled price or net cost initially payable by a buyer for one or more such reimbursable items and/or services, as set forth in the written document referenced in paragraph (\*) (1) of this section, as part of a value-based pricing arrangement which also includes terms and conditions for a value-based price adjustment provided in accordance with clause (ii) of this definition and/or value-based services provided in accordance with clauses (iii) or (iv) of the definition of such term; and/or
  - (ii) a payment made by a seller to a buyer, or to a buyer by a seller, as a reduction to or increase in the buyer's price or net cost for one or more such reimbursable items and/or services, which is conditioned and/or calculated based upon one or more clinical and/or cost outcomes (determined using one or more measurable metrics) which are associated with the value of the seller's reimbursable items and/or services purchased by such buyer under such value-based pricing arrangement when appropriately used, and which does not knowingly induce the buyer to reduce or limit medically necessary items or services to the buyer's patients, in accordance with terms and conditions set forth in the written document referenced in paragraph (\*) (1) of this section.

Without limitation of the foregoing, a value-based price adjustment under this paragraph (\*) (5) (F) may include, without limitation, (x) the seller's payment to a buyer of all or a portion of amounts which the buyer owes or fails to receive under a payment arrangement to which the buyer is subject with respect to reimbursable items and/or services, or of costs otherwise borne by the buyer, as a result (directly or indirectly, wholly or in part) of the intended clinical and/or cost outcome not having been achieved (or only partially achieved), or (y) the buyer's payment to the seller of all or a portion of amounts which the buyer receives under a payment arrangement to which the buyer is subject with respect to reimbursable items and/or services as a result (directly or indirectly, wholly or in part) of the intended clinical and/or cost outcome having been achieved (or partially achieved).

## **II. Hypothetical Example—Value Based Pricing Arrangement**

### **SCENARIO**

A medical technology manufacturer's capital equipment is designed to assist a surgeon in achieving better clinical outcomes from certain surgeries, and there is evidence that demonstrates that the use of this equipment can reduce expensive complication rates substantially. However, the capital equipment is expensive and its use during surgery is not separately reimbursed, so hospitals are reluctant to spend the money without additional assurances as to its value.

To incentivize investment in the capital equipment, the manufacturer is extending to hospitals a purchase agreement, which will provide for the capital equipment together with product training and on-site surgery support as well as a discount on all related consumables. The offered agreement also provides that should the complication rate not be reduced by a targeted amount compared to an established baseline within 18 months after training has been completed, then the manufacturer will provide a rebate to the hospital on the capital equipment and consumables used during surgeries performed within this period. This rebate will be calculated using a formula negotiated between the manufacturer and the hospital customer and reflected in the purchase agreement that takes into account baseline complication rates, percentage improvement required for no rebate to be payable, and requires a minimum number of cases having been completed to ensure statistical validity of the calculations. For example, if there are too few cases, the percentages may be skewed, and as such no rebate will be payable. However, the agreement also establishes that surgeons are solely responsible for determining the circumstances under which the use of the capital equipment is clinically appropriate.

In order to appropriately establish the baseline prior to the execution of the purchase agreement, the manufacturer will enter into a planning agreement with a potential customer hospital whereby the manufacturer agrees to place equipment at no charge in the hospital's operating rooms to establish an understanding of current surgical practices and calculate the baseline complication rate. The manufacturer will share this data with the hospital so that the parties may use the information in drafting the formula by which the value-based rebate will be calculated.

Both the purchase agreement and the planning agreement require the hospital to refrain from submitting a claim for separate payment to any payor for the services and information provided by



the manufacturer under those agreements, and further to appropriately report its net cost for reimbursable items and services as appropriate.

### **ANALYSIS**

This hypothetical arrangement would be permitted under the proposed safe harbor for value-based pricing arrangements.

First, pursuant to paragraph (\*) (5)(D)(i) of the proposed safe harbor, the equipment and services provided under the planning agreement constitute value-based services for the purpose of “determining the terms of such value-based pricing arrangement before such terms are fixed and disclosed in writing”, specifically, for the purpose of determining the baseline complication rate. As required under paragraph (\*) (2), those value-based services are “identified in writing and disclosed by the seller to the buyer at or prior to the time they are provided.”

Second, as required by paragraph (\*) (1), the terms and conditions of the value-based price adjustment are fixed and disclosed in writing by the seller to the buyer at or prior to the buyer’s first purchase of the reimbursable items and/or services under the arrangement, inasmuch as the “formula or other objective mechanism for determining the amount of the value-based price adjustment” is set forth in the purchase agreement executed by the manufacturer and the hospital.

The arrangement relates to a bundle consisting of reimbursable items and/or services (the capital equipment and consumables) as well as the training. Notably, the capital equipment and consumables are not necessarily reimbursed under the same Federal health care program and methodology (in particular, the consumables may be deemed reimbursed as part of the payment for each surgery). The training constitutes a value-based service under paragraphs (\*) (5)(D)(iii) and (iv) as a service for the purpose of “optimizing the effectiveness and clinical utility of the reimbursable items and/or services to which the value-based pricing arrangement relates (e.g., training and/or process improvements), and for the purpose of “otherwise achieving the clinical and/or cost outcomes on which the value-based pricing arrangements are based (i.e., reduction of the complication rate). The services are appropriately included in the bundle since they “meaningfully contribute to ... the use of one or more” of the reimbursable items and/or services to which the value-based pricing arrangement relates (i.e., the equipment and consumables), including “avoiding potential adverse outcomes” related to such use (i.e., complications), when such items are appropriately used, and do not “knowingly induce the buyer to reduce or limit medically necessary items or services to the buyer’s patients.”

The value-based pricing adjustment includes both the upfront discount on the consumables (under paragraph (\*) (F)(i), as a “discounted or bundled price or net cost initially payable by a buyer”), as well as the rebate payable if the percentage reduction in complications is not achieved (under paragraph (\*) (F)(ii), as a “payment made by a seller to a buyer ... as a reduction to ... the buyer’s price or net cost ... which is conditioned and/or calculated based upon one or more clinical and/or cost outcomes (determined using one or more measurable metrics) which are associated with the value of seller’s reimbursable items and/or services when appropriately used....”). The rebate also satisfies the requirement that it “not knowingly induce the buyer to reduce or limit medically necessary items or services to the buyer’s patients....”

Finally, in order for the hospital buyer to fall within the safe harbor, it must appropriately report and/or reflect its price or net cost taking into account the value-based pricing adjustment and value-based services, if and as required under applicable Federal health care program requirements, and the buyer must not submit a claim for separate payment for any of the value-based services apart from its claim for the reimbursable items and/or services to which such services relate. In the case of the manufacturer seller, it must provide the hospital the value reasonably attributed by it to each reimbursable item and/or service (i.e., the equipment and consumables) included in the arrangement if reasonably requested by the hospital to satisfy a cost reporting obligation, it must not submit a claim for the reimbursable items and/or services or value-based services apart from its reimbursement (payment) under the value-based pricing arrangement (purchase agreement), and it must refrain from doing anything that would impede the hospital from meeting its foregoing obligations.

## ATTACHMENT B

### **I. New AKS Safe Harbor for Value-Based Warranty Arrangements**

AdvaMed proposes that OIG adopt a safe harbor for value-based warranty arrangements as follows:

(\*) **Value-based warranties.** As used in section 1128B of the Act, “remuneration” does not include any value-based warranty remedy or value-based services provided by a seller of warranted items to a buyer of such warranted items in connection with a value-based warranty, each as defined in paragraph (\*) (5) of this section, as long as the following standards (as applicable) are met—

- (1) The terms and conditions of the value-based warranty remedy are fixed and disclosed in writing by the seller making such value-based warranty available, at or prior to the time of the buyer’s first purchase or coverage of the seller’s warranted items to which the value-based warranty relates.
- (2) The value-based services to be provided or made available by the seller as part of such value-based warranty are identified in writing and disclosed by the seller to the buyer at or prior to the time of the buyer’s first purchase or coverage of the warranted items to which the value-based warranty relates; provided, that with respect to value-based services described in paragraph (\*) (5) (C) (i), such value-based services shall instead be identified in writing and disclosed by the seller to the buyer at or prior to the time they are provided.
- (3) In the case of the buyer:
  - (A) If and as required under any applicable Federal health care program statute, regulation, demonstration or contract pursuant to which such buyer furnishes or provides coverage for the warranted items to which such value-based warranty relates, the buyer appropriately reports and/or reflects the buyer’s price and/or net cost for the warranted items to which the value-based warranty relates, taking into account (i) any warranty price adjustment (as defined in paragraph (\*) (5) (G) of this section) and (ii) the value reasonably attributed by the seller to each reimbursable item and/or service provided or made available by the seller as part of such value-based warranty, as provided by the seller under paragraph (\*) (4) below;
  - (B) The buyer does not report or reflect any cost for any warranty replacement items and/or services (as defined in paragraph (\*) (5) (H) of this section) provided as part of a value-based warranty remedy under any Federal health care program, or otherwise seek reimbursement under any Federal health care program for such warranty replacement items and/or services; and
  - (C) The buyer does not submit a claim for separate payment for any value-based services provided or made available by the seller under the value-based warranty apart from the buyer’s claim which includes the warranted items to which the value-based warranty relates.

(4) In the case of the seller:

- (A) If reasonably requested by the buyer in order to satisfy a reporting obligation of the buyer under paragraph (\*) (3) of this section, such seller provides the buyer the value reasonably attributed by the seller to each reimbursable item and/or service provided by the seller under the value-based warranty;
- (B) Such seller does not submit a claim or otherwise seek reimbursement under any Federal health care program for any such value-based warranty remedy or value-based services provided or made available by it as part of the value-based warranty; and
- (C) Such seller refrains from doing anything that would impede the buyer from meeting its obligations under paragraph (\*) (3) of this section.

(5) For purposes of this paragraph (\*):

- (A) The term buyer means (i) a Federal health care program beneficiary who receives a warranted item under a Federal health care program, (ii) an individual or entity (such as a provider or supplier) which receives reimbursement under any Federal health care program for a warranted item provided or supplied by such person or entity and (iii) an entity (such as a Medicare Advantage organization or a Medicare Part D plan sponsor) which provides coverage and reimbursement for a warranted item and is fully or partially at risk for the cost of such warranted item (on other than a fee for service basis);
- (B) The term seller means an individual or entity which supplies or provides to a buyer, either directly or indirectly through one or more intermediaries (such as a wholesaler), one or more warranted items with respect to which such seller makes available a value-based warranty remedy to the buyer (subject to the terms and conditions of the value-based warranty), and may also make available one or more value-based services to or for the benefit of such buyer or its patients;
- (C) The term value-based services means analysis, software, equipment, information and/or services provided or made available by a seller as part of a value-based warranty, for a reduced charge or no charge (apart from the buyer's price or net cost for the warranted items to which the value-based warranty relates), reasonably necessary or appropriate for one or more of the following purposes:
  - (i) Determining the terms of such value-based warranty before such terms are fixed and disclosed in writing (including, without limitation, determining one or more of the metrics to be used in the value-based warranty);
  - (ii) Measuring, collecting, calculating and/or reporting the metric(s) upon which the value-based warranty is based and/or the resulting value-based warranty remedy (if any) which is to be provided thereunder;

- (iii) Optimizing the effectiveness and clinical utility of the warranted items being provided or supplied by the seller under the value-based warranty (*e.g.*, training and/or process improvements); and/or
- (iv) Otherwise achieving the clinical and/or cost outcomes which, if not achieved, would trigger a value-based warranty remedy under the value-based warranty, including through provision of analysis, software, equipment, information and/or services to patients to facilitate such outcomes;

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

- (D) The term value-based warranty means an agreement or other arrangement under which a seller makes available one or more value-based warranty remedies to a buyer, conditioned upon and/or calculated based upon one or more clinical and/or cost outcomes (determined using one or more measurable metrics) which are associated with the value of the seller's warranted item purchased or used by such buyer when appropriately used, and which does not knowingly induce the buyer to reduce or limit medically necessary items or services to the buyer's patients;
- (E) The term value-based warranty remedy means a warranty price adjustment and/or warranty replacement items and/or services provided by a seller to a buyer under a value-based warranty, in accordance with the terms and conditions of such value-based warranty;
- (F) The term warranted items means items for which payment may be made, in whole or in part, under a Federal health care program, which are manufactured, supplied and/or provided by a seller, and for which such seller makes available any value-based warranty remedy under a value-based warranty;
- (G) The term warranty price adjustment means a payment made by a seller to a buyer (other than a Federal health care program beneficiary) as a reduction to such buyer's price or net cost for one or more warranted items under a value-based warranty. A warranty price adjustment under this paragraph (\*) (5)(G) may include, without limitation, the seller's payment to a buyer of all or a portion of amounts which the buyer owes or fails to receive under a payment arrangement to which the buyer is subject with respect to warranted items, or of costs otherwise borne by the buyer, as a result (directly or indirectly, wholly or in part) of the intended clinical and/or cost outcome not having been achieved (or only partially achieved); and



- (H) The term warranty replacement items and/or services means (i) one or more items supplied or provided to a buyer (including, but not limited to, a Federal health care program beneficiary) by a seller (or by a third party at a seller's expense) to replace or supplement a warranted item, and/or (ii) medical, surgical, hospital or other services and related items provided to a buyer by a seller (or by a third party at a seller's expense) in connection with the replacement or supplementation of a warranted item or as an alternative or supplemental treatment to the use of the warranted item, provided the following requirements are met: (x) such items and/or services are supplied, provided and/or paid for in accordance with the terms and conditions of the value-based warranty; (y) such items and/or services are not billed by any person to any Federal health care program; and (z) such items and/or services are medically appropriate.

## **II. Hypothetical Example—Value Based Warranty Arrangement**

### **SCENARIO**

General Hospital (Hospital) is experiencing high post-operative surgical site infection (SSI) rates for patients undergoing procedures in 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 materially improve clinical outcomes and reduce costs.

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.

Company wants to offer Hospital the Solution through a value-based health care (VBHC) program, that includes offering 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.

### ANALYSIS

This innovative arrangement would satisfy the requirements under our proposed new safe harbor for value-based warranty arrangements.

Like the value-based pricing arrangement hypothetical in Attachment A, any value-based services provided in connection with determining the Baseline Infection Rate (and therefore the terms of the value-based warranty) would be set forth in writing and disclosed by the Company to the Hospital prior to the time any such services are provided, consistent with paragraphs (\*) (2) and (\*) (5) (C) (i).

The Solution consists of a bundle of reimbursable items and/or services (the suture device) and several types of value-based services. Notably, these include patient educational resources, consistent with paragraph (\*) (5) (C) (iv), which allows for provision of information to patients to achieve the targeted clinical outcome (here, the 5% reduction in SSI rates).

The terms and conditions for the value-based warranty remedy are set forth in writing as required under paragraph (\*) (1). As required by paragraph (\*) (D), the remedy is conditioned upon a clinical outcome (determined using a measurable metric) associated with the value of the Company's reimbursable item and/or service (the suture device) when appropriately used, and does not knowingly induced the Hospital to reduce or limit medically necessary items or services to its patients. The value-based warranty remedy falls within paragraph (\*) (5) (H), as medical, surgical, hospital or other services and related items provided to a buyer by a seller (or by a third party at a seller's expense) in connection with the replacement or supplementation of a warranted item or as an alternative or supplemental treatment to the use of such warranted item....” The arrangement specifically requires that items and services be provided and paid for in accordance with the terms



and conditions of the warranty, that they not be billed by any person to any Federal health care program, and that they be medically necessary. Notably, Company could compensate Hospital for: (a) an amount that would exceed the cost of the Solution itself if the targeted clinical outcome of 5% reduction in SSI is not met; and (b) a Solution that is not actually deemed “defective,” but rather the Solution just did not meet the negotiated, targeted outcome.

## ATTACHMENT C

### **I. New AKS Safe Harbor for Value-Based Risk-Sharing Arrangements**

(\*) **Value-based, risk sharing arrangements.** As used in section 1128B of the Act, “remuneration” does not include any transfer of value provided under a Value-Based Risk Sharing Arrangement, as defined herein, as long as the following standards (as applicable) are met —

- (1) A Value-based Risk-Sharing Arrangement is a written agreement under which participants agree to:
  - (i) contribute to the achievement of pre-identified and measurable clinical and/or economic target endpoints that are specifically designed to promote improved patient outcomes and/or reduction of the costs of health care delivery, while avoiding negatively affecting patient outcomes;
  - (ii) implement associated processes and procedures that seek to optimize the delivery, efficiency, and/or quality of patient-centered care; and
  - (iii) assume an allocation of the financial risk in achieving the targeted endpoints and/or outcomes, with consideration of the participants’ respective contributions thereto.

Under this section, remuneration shall also not include participant activities reasonably necessary or appropriate to (i) determine the terms of such Value-Based Risk-Sharing Arrangement before such terms are set forth in a written agreement (including, without limitation, determining one or more of the metrics to be used in the Value-Based Risk-Sharing Arrangement) or (ii) measure, collect, calculate and/or report the metric(s) upon which the Value-Based Risk-Sharing Arrangement is based and/or the resulting economic benefit and/or exposure. The activities to determine the terms of a Value-based Risk-Sharing Arrangement shall be identified in writing and disclosed between the participants at or prior to the time such activities take place.

For purposes of this subparagraph, financial risk is defined as the economic benefit and/or exposure that each participant agrees to assume with regard to the other participant(s) and the amount of which is subsequently calculated with reference to a specified methodology, which benefits or exposures may include shared savings payments, underachievement payments, withholds, bonuses, and/or the like. The methodology to determine financial risk must be set forth in writing and in advance of the performance of the specific Risk-Sharing Arrangement and shall not be dependent upon the volume or value of any referrals or the purchase of any participant’s goods or services which do not contribute to the achievement of pre-identified clinical and/or economic target metrics.

- (2) A transfer of value may be exchanged between or among one or more participants under a Value-Based Risk Sharing Arrangement that is intended to:
  - (i) drive or promote accountability for quality, cost, coordination, and overall care of patient populations, including patient populations that receive services that are reimbursed by different methodologies and/or by different payors; or

- (ii) manage and coordinate care for patients through arrangements approved by the entities in the arrangement and administered, furnished, or arranged by such entities; or
- (iii) encourage efficient deployment and utilization of infrastructure and/or facilitate redesign or care process workflow to achieve higher quality and/or more efficient service delivery for patients, where efficient service delivery includes, among other things, redeployment of and training on the use of goods and services, appropriate reduction of costs or more optimal utilization of goods and services provided to patients, and/or expanded access to healthcare choices to patient populations (including previously underserved populations), in each case consistent with quality of care, physician medical judgment, and patient freedom of choice.

## **II. Hypothetical Example—Value Based Risk-Sharing Arrangement**

### **SCENARIO**

A multi-site hospital system (System) enters into a ten-year, master value-based risk sharing agreement with a medical device vendor (Vendor) for the acquisition and maintenance of devices and technology and provision of consulting services. The System's goal is to jointly evaluate with the Vendor the System's operations across departments to identify opportunities to improve patient care and/or operational efficiencies in multiple clinical applications. The Vendor's evaluation includes a review of the System's number and type of currently installed devices, operational workflows, and relative efficiencies of the installed systems (including various installed instrument protocols, staffing levels and types), its use of available data analytics, and other available software technology solutions. This evaluation activity was memorialized in a contemporaneous writing and disclosed to the System.

The written agreement establishes a process for jointly evaluating and benchmarking the System's current operations over the term and pursuing specific mutually developed projects intended to improve operations and/or patient outcomes. Each such project under the agreement (Project) is set forth in a written statement of work (Project SOW) that details (1) pre-identified clinical and/or economic target metrics tailored to promote the targeted improved patient outcomes and/or reduction of the costs of health care delivery during a defined time period – e.g., improvement of quality of patient care through efficient utilization of devices and staffing resources, and (2) joint allocation of financial risk based on the relative success of the Project in achieving the targeted metrics and the relative contributions of each party.

Upon conclusion of each Project, the parties measure the outcome(s) against the pre-defined metrics, which are evidence-based and may be benchmarked to publicly available statistics. To the extent that the metrics/targets are met or exceeded, the System would pay the Vendor an amount determined in accordance with the written formula set forth in the agreement based on achieved metrics in the Project. Conversely, to the extent metrics/targets are not met, the Vendor would receive no compensation or transfer an underachievement amount to the System, also as determined based upon the formula and terms and conditions set forth in the agreement.



An example of a Project may target outcome improvements in the System's treatment of cardiac care patients in the various clinical settings. The Project may include the following:

- Using device utilization data to reduce the number of installed devices necessary to deliver at least the same volume and quality of care from 30 to 25;
- Re-deploying the remaining devices and re-training the device operators to achieve a more efficient workflow, resulting in the capacity to treat 15% more patients in the initial twelve-month period;
- Re-designing the patient scheduling system to make the fleet of medical devices more efficient in meeting patient demand and device operator availability and quality of patient care;
- Implementing uniform operational protocols for each type of device across the fleet, enabling technicians to safely and effectively operate the devices in a consistent manner across the System; and
- Incorporating new technology solutions into the System's existing workflows to improve the quality of the patient experience or to foster necessary follow-up care, particularly for vulnerable patient populations (such as the elderly or chronically ill).

### **ANALYSIS**

The hypothetical arrangement described here would satisfy the requirements under our proposed new safe harbor for Value-Based Risk-Sharing Arrangements ("VBRSA").

First, the safe harbor provides that remuneration does not include participant activities that are reasonably necessary or appropriate to determine the terms and/or the metrics to be used in the VBRSA before such terms are set forth in a written agreement. In the hypothetical, the parties engage in a necessary and targeted review of the System's number and type of installed devices, workflows (including staffing and protocols), use of data analytics and software technology. This review is necessary and appropriate to develop the metrics to be included in the written VBRSA that ultimately is entered into by the parties as described in the hypothetical. The review activity was memorialized in a contemporaneous writing and disclosed to the System consistent with the safe harbor writing requirement for activities to determine the terms of a VBRSA.

Second, the safe harbor requires the VBRSA to be set forth in writing. In the hypothetical, the VBRSA is set forth in a written "framework agreement" that describes the process and governance for the parties to jointly evaluate and mutually develop projects intended to improve/operations and/or outcomes and pursuant to which each such project shall be set forth in a written statement of work ("Project SOW"). The framework agreement defines the costs for the products and services the System is acquiring under the framework agreement and describes the means for determining applicable benchmarks, performance metrics, and the methodology for calculating the risk sharing remuneration under each future Project SOW.

Third, under the terms of the VBRSA framework agreement, each Project SOW establishes in writing and in advance of the performance of the Risk-Sharing Arrangement: (i) the specific clinical and/or economic benchmarks and the metrics to measure clinical and/or economic target results designed to promote improved patient outcomes (e.g., recommended follow-up care for at risk patient populations) and/or (ii) the reduction of the costs of health care delivery (e.g., increased efficiency allowing redeployment of unneeded capital or staff or decreased patient wait times). Each Project SOW also specifies the financial risk to be borne by each party based on the parties' respective contributions to the arrangement. Moreover, each Project SOW describes with specificity the respective roles and responsibilities of the System and the Vendor to design and implement improved processes and/or tools in order to achieve the agreed upon target goals.

The transfer of value – from Vendor to System for underachievement or from System to Vendor for overachievement – in the hypothetical is designed to drive reduced costs and/or improve patient outcomes by incentivizing the Vendor and the System to work together to achieve the desired reduced costs and/or improved patient care as described by the parties in the written agreement.