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AdvaMed
Advanced Medical Technology Association

February 27, 2017

By Electronic Submission via www.regulations.gov

Ms. Patrice Drew
Office of Inspector General, Regulatory Affairs
Department of Health and Human Services
Attention: OIG–125–N
Room 5541C, Cohen Building
330 Independence Avenue SW
Washington, D.C. 20201

Re: OIG–125–N: Solicitation of New Safe Harbors and Special Fraud Alerts

Dear Ms. Drew:

The Advanced Medical Technology Association (AdvaMed) appreciates this opportunity to submit proposals for new or, in the alternative, modified, safe harbor provisions under the Federal anti-kickback statute at section 1128B(b) of the Social Security Act.

AdvaMed

AdvaMed is a trade association that represents the world's leading innovators and manufacturers of medical devices, diagnostic products, 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 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, allow earlier detection of disease, and treat patients as effectively and efficiently as possible.

Medical Technology Manufacturers Are Uniquely Poised to Drive Value-Based Care Solutions

In addition, medical device manufacturers are working hard to develop new services and strategies that can support the health care industry's transformation from volume to value-based health care delivery, and its efforts to improve outcomes while reducing costs. The device industry, for several reasons, is uniquely positioned to play a pivotal role in supporting payors' and providers' efforts to optimize patient care. First, manufacturers are experts in how their technologies may affect clinical outcomes. This expertise gives them the specialized knowledge necessary to design solutions that can reduce adverse events and the associated costs of treating those events. Second, value-based health care is largely driven by data. Many medical devices either generate data on their own or work in an ecosystem to contribute to data collection and aggregation. Manufacturers thus are capable of contributing to the critical data function driving much of health care delivery today. Finally, manufacturers long ago evolved from "widget

producers" into complex organizations that understand the need for strategic partnerships with providers, payors and others to move global health care in a direction that is sustainable from a quality and cost perspective for the long term. They often have a dedicated health care economics function, reimbursement specialists, data analysts, and others who can help support the health care delivery network's ability to effect positive change.

Existing Safe Harbors Retain Beneficial Value-Based Solutions But Changes Are Needed

As the OIG recently recognized in its December final rule modifying the safe harbors, "[t]he transition from volume to value-based and patient-centered care requires new and changing business relationships among health care providers." OIG further stated that "[w]e intend to continue to monitor changes in the industry, technology, and clinical care and consider whether additional rulemaking is needed to foster high-quality, efficient, patient-centered care. We will continue to seek stakeholder input as appropriate, and we will use our authorities, as appropriate, to promote arrangements that fulfill the goals of better care and smarter spending."

AdvaMed appreciates OIG's attention to these issues, on which our proposals are focused. Unfortunately, the breadth of the anti-kickback statute has inappropriately deterred manufacturers, providers, payors and others from engaging in beneficial value-based arrangements to improve care and reduce costs. This is in large part because the statute and its safe harbors were targeting behaviors that inappropriately drove utilization, cost, and other problems in a fee-for-service reimbursement environment. Many of the historical assumptions, however, are different today and the existing anti-kickback principles are simply outdated. Because that environment is quickly changing, AdvaMed strongly believes that new safe harbors are necessary to give parties additional opportunities to engage in value-based arrangements, subject to appropriate protections to ensure that Federal health care programs are protected against waste, fraud, and abuse. In an effort to help facilitate OIG's consideration of potential changes, we have proposed specific language for OIG's consideration. Alternatively, the existing discount and warranty safe harbors could be updated to achieve these goals.

At the outset, we think it would be helpful to note some of the types of problems that manufacturers and others currently face in seeking to engage in value-based arrangements. We highlight the following hypothetical examples of arrangements that are beneficial from a cost and quality perspective, but that require greater clarity and certainty than current fraud and abuse laws provide:

- *Bundled Items and Services With Rebate Based on Clinical Outcome*—A medtech company offering a hospital a bundle of items and services (e.g., technology, consulting, training, and ongoing patient monitoring) for a fixed price to achieve a specific clinical outcome (e.g., improvement in detection of early-stage cancer in Medicare beneficiaries or a reduction of costly adverse events such as preventable infections or readmissions), and, if the clinical outcome is not achieved, paying the hospital a rebate, thereby reducing the hospital's net cost for the bundle.

- *Payment for Corrective Services if Targeted Clinical Outcome Not Achieved* —A medtech company warranting that its product will achieve a

specific clinical outcome in a less invasive manner; and, if the clinical outcome is not achieved, offering to pay for a corrective surgery to accomplish the desired clinical outcome in the traditional manner.

- *Provision of Ancillary Items and Services at No Additional Cost*—A medtech company offering to buyers of its products at no additional cost ancillary services (e.g., data analytics, follow-up lab testing, patient coaching, and mobile device applications to facilitate patient follow-up care) intended to measure and/or optimize the agreed-upon patient outcomes.

- *Provision of Services Under Risk-Based Compensation Model*—A medtech company offering to providers and/or patients services in addition to or separately from medical devices (e.g., technical consulting services on surgical procedures, post-operative patient care management services), for a specific clinico-economic, value-based purpose, such as improving clinical outcomes, reducing readmissions, or preventing adverse events, where compensation for such services is risk-based.

Various components of the above scenarios may bring them outside of the existing safe harbor framework. For example, the provision of items and services that are not reimbursed under the same payment methodology may not qualify for protection under the discount safe harbor. Additionally, the warranty safe harbor does not expressly allow a seller to provide anything as part of a warranty in excess of the "cost of the item itself." As such, the warranty safe harbor was intended to address defective products, rather than a warranted outcome not being achieved. Finally, the personal services safe harbor does not address whether services can appropriately be provided under a risk-based compensation model for a value-based purpose. Specifically, the aggregate amount of such compensation cannot be determined in advance because the service compensation is tied to the achievement of an outcome not known at the time of entering the arrangement.[1] The resulting potential for regulatory risk has a chilling effect over the development of beneficial value-based arrangements, and presents a significant barrier to arrangements that the OIG has acknowledged should be encouraged.[2]

The OIG's fraud and abuse waivers to date, issued in connection with the Center for Medicare & Medicaid Innovation's (CMMI's) payment and service delivery models, do not extend protection to manufacturers of medical devices. AdvaMed's members have an important role to play in advancing new and innovative care delivery models, and should be permitted to participate in the risk-sharing associated with new payment models. In these proposals, AdvaMed highlights certain key industry considerations that merit greater regulatory flexibility necessary to advance high-quality, efficient, patient-centered care.

[1] Further, the personal services safe harbor does not acknowledge that risk-based compensation as between a medtech company and a health care provider for a value-based purpose can be "consistent with fair market value in arms-length transactions." 42 C.F.R. § 1001.952(d)(5).

[2] 81 Fed.Reg. at 88370 (Dec. 7, 2016).

1. Proposals for New Safe Harbors for Value-Based Arrangements

AdvaMed proposes two new safe harbors for value-based arrangements. The first would protect "value-based pricing arrangements" and the second would protect "value-based warranties." In each proposal, the arrangement would meet certain requirements, as discussed further below, to qualify for protection.

- The proposed value-based pricing arrangements safe harbor would allow for price adjustments, and for services to be bundled with the product being sold or leased, subject to appropriate safeguards, where the arrangement is dependent upon the achievement of a measurable clinical and/or cost outcome.

- The proposed value-based warranty safe harbor would allow manufacturers of products to make certain clinical and/or cost outcome assurances, and provide an appropriate remedy where such outcomes are not achieved.

The proposed safe harbors include/feature concepts from the existing discount and warranty safe harbors, including transparency and disclosure elements, and expand the types of buyers and sellers that may be parties to value-based arrangements to reflect current industry complexities.

Consistent with the OIG's criteria for establishing new safe harbors, AdvaMed believes that these proposed safe harbors would promote "access, quality, patient choice, appropriate utilization and competition, while protecting against increased costs, inappropriate steering of patients, and harms associated with inappropriate incentives tied to referrals."[3]

(a) *Value-Based Pricing Arrangements*

AdvaMed proposes that the value-based pricing arrangements safe harbor be drafted 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.

[3] 81 Fed.Reg. at 88369 (Dec. 7, 2016).

(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 this requirement does not apply to those value-based services provided or made available for one of the purposes described in paragraph (*)(5)(D) of this section.

(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 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 arrangement relates, taking into account (i) any such value-based price adjustment paid to or by the buyer as part of such value-based arrangement, less (ii) the value reasonably attributed by the seller to the value-based services provided or made available by the seller as part of such value-based arrangement, as provided by the seller under paragraph (*)(4) below; and

(B) The buyer does not submit a claim for any value-based services provided or made available by the seller under the value-based pricing arrangement separate and apart from the buyer's claim for 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 the value-based services 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 value-based services which it provides or makes available as part of the value-based arrangement; and

(C) Such seller refrains from doing anything that would impede the buyer from meetings 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 payable by the seller to the buyer, and/or is the recipient of a value-based price adjustment made available by the buyer to the seller (in each case, subject to the terms and conditions of the value-based pricing arrangement), and may also make available one or more value-based services to or for the benefit of such buyer;

(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 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, 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;

(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, or a buyer provides a value-based price adjustment to a seller,

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; and

(F) The term value-based price adjustment means a payment made by a seller to a buyer, or by a buyer to a seller, as a reduction to or increase in such buyer's price or net cost for one or more reimbursable items and/or services under a value-based pricing arrangement. 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).

(b) ***Value-Based Warranties***

AdvaMed proposes that the value-based warranties safe harbor be drafted 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 this requirement does not apply to those value-based services provided or made available for one of the purposes described in paragraph (*)(5)(C) of this section.

(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) less (ii) the value reasonably attributed by the seller to the value-based services 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 any value-based services provided or made available by the seller under the value-based warranty separate and apart from the buyer's claim for 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 the value-based services 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;

(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 arrangement for no charge apart from the buyer's price or net cost for the warranted items to which the value-based warranty relates, for one or more of the following purposes:

(i) Determining the terms of such value-based 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 arrangement);

(ii) Measuring, collecting, calculating and/or reporting the metric(s) upon which the value-based arrangement is based and/or the resulting value-based payment (if any) which is payable;

(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;

(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)(H) 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 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.

2. <u>Proposals for Modifying Existing Safe Harbors</u>

As an alternative to establishing new safe harbors for value-based pricing arrangements and value-based warranties, modifications to the existing discount and warranties safe harbors could clarify the regulatory status of beneficial value-based arrangements and reduce current barriers inhibiting the adoption of such arrangements, while, at the same time, safeguarding against

inappropriate arrangements that may "increase costs to programs and patients or compromise quality of care."[4]

AdvaMed cautions however that any modifications the OIG makes to the existing discount and/or warranty safe harbor should not be construed to preclude the many existing arrangements that have been structured to comply with the discount and warranties safe harbors to date. As such, any modifications should expand the types of arrangements that qualify for protection under the existing safe harbors to include value-based arrangements, but should not disturb the existing framework of these safe harbors.

(a) *Discounts—42 C.F.R. § 1001.952(h)*

Under the existing safe harbor, discounts provided in connection with a bundled sale may not qualify for protection unless all components of the bundle are "reimbursed by the same Federal health care program using the same methodology."[5] This limitation needlessly narrows the types of discounts that may qualify for protection under the safe harbor, and may discourage value-based discount arrangements involving a bundle of items and services that are tied to quality and outcome measures. Further, the existing safe harbor's definition of discount excludes both services provided in accordance with a personal or management services contract[6] and warranties,[7] creating ambiguity around protection of discounts linked to or premised on the performance of personal services and outcomes.

To address these issues, AdvaMed would propose including exceptions for value-based arrangements to certain exclusions within the existing definition of discount and would propose to protect discounts offered in connection with value-based arrangements, provided the discounts meet certain criteria. Finally, AdvaMed would propose a definition of value-based arrangement that captures appropriate and beneficial arrangements while excluding arrangements that are abusive or create inappropriate financial incentives.

(b) *Warranties—42 C.F.R. § 1001.952(g)*

Under the existing warranties safe harbor, manufacturers and suppliers may not qualify for protection if they pay "any remuneration to any individual (other than a beneficiary) or entity for any medical, surgical, or hospital expense incurred by a beneficiary other than for the cost of the item itself."[8] This limitation unnecessarily discourages the formation of value-based arrangements that would include warranty remuneration to cover services and items that are related to the item that is the subject of the warranty; for example, follow-up treatment where the warranted product did not achieve the desired clinical outcome. To address this, AdvaMed would propose an exception to this limitation for value-based arrangements, provided the warranty remuneration meets certain requirements to ensure that abusive or inappropriate financial incentives are not protected.

[4] 79 Fed. Reg. at 59719-20 (Oct. 3, 2014).

[5] 42 C.F.R. § 1001.952(h)(5)(ii).

[6] 42 C.F.R. § 1001.952(h)(5)(vi).

[7] 42 C.F.R. § 1001.952(h)(5)(v).

[8] 42 C.F.R. § 1001.952(g)(4).

3. Discussion of OIG Criteria for Modifying and Establishing Safe Harbor Provisions

AdvaMed understands that the OIG will consider a number of factors[9] in reviewing the above proposals and recommendations, and we address each in turn below:

(a) *Access*

Shared risk among industry, providers, and/or payors will expand access to new and cutting edge technologies and services, thus encouraging patients and their providers to consider and adopt new and clinically effective approaches to treatment and management of medical conditions, that yield more comprehensive, cost-efficient solutions.

(b) *Quality*

Improved quality is a critical component of AdvaMed's proposed definition of "value-based arrangement." Clinical, quality, and economic measures underlying value-based arrangements would be identified in advance, and would form the basis for financial or other remuneration. Many of the arrangements AdvaMed seeks to enable and promote include data analysis, training, follow-up services, and other value-added components to deliver the most optimal quality and cost-efficient care.

(c) *Freedom of Choice*

Because value-based arrangements are directed to achieving beneficial and targeted clinical outcomes for patients, they are by definition not designed to steer patients toward particular products or services or inappropriately skew medical decision-making. By contrast, value-based arrangements promote patient freedom of choice by making items and services available to them when they otherwise might not be; for example, in connection with a hospital or payor's decision to invest in services and solutions (e.g., remote monitoring capabilities) that would allow a patient to go home earlier and return to work and engage in other activities of daily life.

(d) *Competition*

Value-based arrangements promote competition on the basis of the manufacturer's overall ability to offer solutions to customers that demonstrate not only the products' clinical value and ultimate cost savings, but also the manufacturers' willingness to take more responsibility for outcomes and include service offerings that can effectively improve quality and lower costs. As such, they reward innovation, quality, and efficiency in care delivery models.

[9] Specifically, the OIG will consider extent to which the proposals would affect an increase or decrease in: access to health care services; the quality of health care services; patient freedom of choice among health care providers; competition among health care providers; the cost to Federal health care programs; the potential overutilization of health care services; the ability of health care facilities to provide services in medically underserved areas or to medically underserved populations.

(e) ***Cost***

It is important to note that value-based arrangements are not intended to increase costs to Federal health care programs. Claims volume and Federal health care program reimbursement to providers would not be affected. Instead, value-based arrangements would align financial incentives with quality outcomes and would result in costs being based upon the value of the items or services provided. Indeed, we believe that because the innovative solutions being developed by medtech manufacturers better align provider, manufacturer and patient interests, the arrangements overall can be expected to result in better health outcomes and thereby decrease costs over the long term.

(f) ***Overutilization***

A value-based arrangement has built-in safeguards against overutilization. Specifically, remuneration exchanged between parties to a value-based arrangement would not be directly tied to the volume of services provided. Instead, value-based arrangement remuneration would align the financial interest of providers, industry, and payers to achieve clinical quality goals and manage costs.

With respect to underutilization, measurable quality goals, which are a component of AdvaMed's proposed definition of value-based arrangement, would safeguard against underutilizing or withholding medically necessary services.

(g) ***Medically Underserved***

Value-based arrangements are designed to achieve beneficial clinical outcomes for all patients, including those in medically underserved areas.

(h) ***Financial Benefit to Health Care Professionals or Providers***[10]

We believe the proposals discussed above will result in potential financial benefit to health care professionals and/or providers who enter into value-based arrangements. Current arrangements with manufacturers, among other goals, are directed to eliminating unnecessary patient admissions or readmissions, enabling prompt discharges to home through improved surgical procedures, and permitting ongoing follow-up post-acute care via telemonitoring. In these cases, financial benefits are appropriately tied to quality and outcomes, not to volume.

* * *

[10] The OIG will also consider the existence (or nonexistence) of any potential financial benefit to health care professionals or providers that may take into account their decisions whether to (1) order a health care item or service or (2) arrange for a referral of health care items or services to a particular practitioner or provider, among other factors.

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

Sincerely,

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

cc: Scott Whitaker, President and CEO, AdvaMed
Terry Chang, MD, JD, Assoc. General Counsel and Director, Legal & Medical Affairs, AdvaMed