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By Electronic Submission via www.regulations.gov

Ms. Patrice Drew
Office of Inspector General, Regulatory Affairs
Department of Health and Human Services
Attention: OIG-127-N
Room 5541C, Cohen Building
330 Independence Avenue SW
Washington, D.C. 20201

Re: OIG-127-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, 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 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.

AdvaMed's medical technology manufacturer members are well-positioned to support the ongoing transformation of the healthcare industry to value-based care. Manufacturers are experts in how their technologies may affect clinical outcomes, and have the specialized knowledge to design solutions to optimize care in a cost-effective manner—often using data generated from devices themselves. Medical technology manufacturers understand the importance of training, support services, data analytics, care coordination and other support in order for providers and patients to realize the potential of technology to improve outcomes and reduce costs.

Modernizing Regulations to Promote Value-Based Care Solutions

OIG recognized in its December 2016 safe harbor rulemaking that “[t]he transition from volume to value-based and patient-centered care requires new and changing business relationships

among health care providers,” and assured that “we will use our authorities, as appropriate, to promote arrangements that fulfill the goals of better care and smarter spending.”¹ Both the Inspector General and the Chief Counsel to the Inspector General have also indicated that OIG is interested in exploring ways to permit greater flexibility for value-based arrangements, while still guarding against the problems that the fraud and abuse laws were designed to prevent.

Accordingly, in response to last year’s OIG annual solicitation for new or revised safe harbors, AdvaMed and several other commenters submitted comments identifying various appropriate and beneficial arrangements to provide value-based care that require greater clarity and certainty than what current fraud and abuse laws provide.² In AdvaMed’s case, we proposed text for two new safe harbors for value-based arrangements: one relating to value-based pricing arrangements, and the other to value-based warranty arrangements.³ Our submission of proposed text for these new safe harbors was intended to provide concrete criteria that, if satisfied, would allow interested parties to engage in such arrangements, subject to appropriate fraud and abuse safeguards. Notably, while the safe harbors we proposed would be available to manufacturers, they would also be open to other buyers and sellers of items and services reimbursable under Federal health care programs, including payors such as Medicare Advantage and Part D plans.

AdvaMed appreciates the interest that OIG expressed in our proposals, and its willingness to discuss them further. In its fall Semiannual Report to Congress, OIG declined to propose new safe harbors for value-based arrangements in response to the comments that we and others submitted last year, stating that they required more study and that questions about the application of the anti-kickback statute to such arrangements should be addressed on a case-by-case basis, such as under the advisory opinion process.⁴

We understand OIG’s desire to consider these issues carefully before proposing new or revised safe harbors. However, we continue to believe that OIG’s adoption of new or revised safe harbors to promote value-based arrangements is imperative, and that the advisory opinion process is not an adequate substitute. While advisory opinions can be an appropriate avenue for addressing some issues, it would not be practicable for manufacturers, providers and payors to submit every value-based arrangement (or even most) to OIG for an advisory opinion, or for OIG to analyze and respond to such arrangements. The time and expense required by the advisory opinion process (in many cases involving over a year of interaction between OIG and fraud and abuse counsel) in large measure precludes its use in designing and executing value-based arrangements in a fast-moving, competitive marketplace, particularly with respect to smaller

¹ “Medicare and State Health Care Programs: Fraud and Abuse; Revisions to the Safe Harbors Under the Anti-Kickback Statute and Civil Monetary Penalty Rules Regarding Beneficiary Inducements,” 81 Fed. Reg. 88368, 88370 (Dec. 7, 2017).

² See, e.g., AdvaMed letter dated Feb. 27, 2017, submitted via Regulations.gov, *available at* <https://www.regulations.gov/document?D=HHSIG-2017-0001-0006>.

³ We also noted that we were also open to modifying existing safe harbors as an alternative way to clarify the regulatory status of beneficial value-based arrangements and reduce current barriers inhibiting the adoption of such arrangements. We remain open to either approach.

⁴ OIG Semiannual Report to Congress—April 1, 2017, through September 30, 2017, Appendix G, *available at* <https://oig.hhs.gov/reports-and-publications/archives/semiannual/2017/sar-fall-2017.pdf>.

manufacturers and start-ups, for whom the cost may be prohibitive. Other limitations, such as OIG's policy of not granting favorable advisory opinions on proposed arrangements implicating issues for which there is an active investigation, further narrow the situations in which the advisory opinion process provides a practical solution.

As a consequence, in response to this year's annual solicitation, we are proposing below for OIG's consideration revised versions of the two safe harbors for value-based arrangements that we proposed last year. The reasons we and other commenters requested OIG to create new safe harbors or revise existing safe harbors to accommodate value-based arrangements remain: the breadth of the anti-kickback statute is inappropriately deterring manufacturers, providers, payors and others in the health care industry from engaging in beneficial value-based arrangements to help improve care, reduce costs and improve the patient experience.

As we and other commenters have pointed out, many of the barriers faced by parties desiring to enter into value-based arrangements stem from provisions contained in existing safe harbors that have not been updated to accommodate new and innovative technologies or clearly and appropriately take into account the numerous changes in health care payment and reimbursement occurring since they were originally adopted. Thus, the existing safe harbors effectively discourage progressive arrangements and undermine the general trend toward value-based health care.

For example, numerous provisions of the discount safe harbor are focused on making sure that buyers which report their costs on a cost report appropriately reflect the discounted price on such report. While such a requirement may have made sense when the discount safe harbor was originally adopted, the reality of today's reimbursement system is that it is extremely rare for providers to be paid based upon their costs, even where they continue to report such costs on a cost report. As such, the fraud and abuse risks stemming from incorrect reporting of such costs are much less significant than they once were. Even so, the discount safe harbor continues to contain provisions that could be interpreted to exclude from protection discounts under various value-based pricing arrangements to which these criteria are not applicable or for which these criteria cannot be satisfied. For example, a cost-reporting buyer must earn a discount "based on purchases of that same good or service bought within a single fiscal year of the buyer," and the buyer must "claim the benefit of the discount in the fiscal year in which the discount is earned or the following year."⁵ It may not be possible to satisfy these criteria for an outcomes-based rebate that is determined to be payable 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. Due to these and similar limitations on the discounts that qualify for safe harbor protection, parties may decide that the benefits of entering into such arrangements do not outweigh the risks of potentially being accused of violating the anti-kickback statute, with enormous potential liabilities under the False Claims Act, as a consequence of doing so.⁶ Such decisions are particularly unfortunate where patients and/or the health care system as a whole could stand to greatly benefit from the value-based proposal in question.

⁵ 42 C.F.R. § 1001.952(h)(1)(ii).

⁶ Other aspects of the discount safe harbor which inappropriately prevent value-based pricing arrangements are detailed in the letter we submitted last year, as well as in other commenters' letters.

Other existing safe harbors also inhibit beneficial value-based arrangements. For example, the warranty safe harbor precludes a seller from paying providers for “any medical, surgical, or hospital expense incurred by a beneficiary other than for the cost of the item itself.” This requirement could be read to preclude sellers from agreeing to pay for an alternative therapy (e.g., surgery) if a warranted clinical outcome from using the manufacturer’s product were not achieved—clearly at odds with the goals of value-based care. Indeed, a manufacturer putting such an arrangement into place could face allegations that it has violated the anti-kickback statute (and, as a result, the False Claims Act) simply because of having stood behind its product through such a warranty.

In addition to aspects of the existing safe harbors that are out-of-date, we note that many courts’ treatment of certain safe harbor requirements has further confused the issues, compounding the risk for our member companies. 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.⁷ Similar cases have been noted by other commenters.⁸

Proposed Safe Harbors for Value-Based Pricing and Warranty Arrangements

As noted above, AdvaMed proposes that the OIG adopt two new safe harbors, one for “value-based pricing arrangements” and the other for “value-based warranty arrangements.” While these safe harbors generally align with the safe harbors we proposed last year, we have incorporated certain revisions in response to comments received from OIG and others.

- The proposed value-based pricing arrangements safe harbor would allow for value-based price adjustments, and for value-based services to be bundled with the product being sold or leased, subject to appropriate safeguards.
- 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 if such outcomes are not achieved.

The proposed safe harbors include many features of the existing discount and warranty safe harbors, but are cast in terms appropriate for value-based arrangements within today’s health care reimbursement system, using provisions less likely to cause confusion regarding their requirements. 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

⁷ *United States ex rel. Herman et al. v. Coloplast Corp. et al.*, C.A. No. 11-12131-RWZ, Opinion and Order at 3 (D. Mass, Aug. 24, 2016).

⁸ See, e.g., letter of the Pharmaceutical Research and Manufacturers of America, dated Feb. 27, 2017, submitted to OIG via Regulations.gov in response to last year’s annual solicitation, at 5-6, *available at* <https://www.regulations.gov/document?D=HHSIG-2017-0001-0007>.

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 noteworthy refinements to our proposal from last year relate to value-based services provided as part of a value-based pricing arrangement. In particular, the safe harbor would clearly protect a seller's provision of a product together with related software, equipment, analysis and services (including those provided to patients), all designed to achieve a targeted clinical and/or cost outcome for patients with a given condition that the product diagnoses or treats.⁹ We believe that sellers' provision of such value-based services for no additional charge 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.¹⁰ These services do not constitute a "discount" to the buyer with respect to the cost of the product purchased, but instead are part of a combined product-and-services offering to diagnose or treat the disease at issue. As such, their value generally should not need to be taken into account by the buyer in its cost-reporting calculations, inasmuch as the buyer's cost for the set of reimbursable items and associated value-based services has not changed—its cost is still only the price of the reimbursable items and/or services.¹¹ Apart from being the correct treatment of such services analytically, this will avoid the need for buyers and sellers to have to try to assign values to services that do not have a fair market value in the conventional sense, and whose value will often be dependent upon whether the targeted outcome was achieved.

In the common scenario of a hospital purchasing a medical device, a manufacturer's provision of value-based services to help the hospital's patients who use the device achieve clinical goals is plainly a benefit to the patient, and potentially a benefit to the hospital and the health care system as a whole. Importantly, however, this is not the problematic type of benefit to a purchasing health care provider, that is unrelated to the purchased product, and that the anti-kickback statute was designed to preclude as improper "remuneration." Accordingly, safe harbor protection should be available to facilitate such offerings. Moreover, while such value-based services frequently are provided in connection with a value-based pricing adjustment (an increase or a decrease), we do not believe that safe harbor protection for such value-based services should be limited only to those arrangements in which such a pricing adjustment is contemplated, and the

⁹ Please note that we have included a new proviso in the value-based services definition of each proposed new safe harbor which sets forth certain additional requirements for these types of services to qualify for safe harbor protection. In particular, the services must "relate to achieving clinical and/or cost outcomes in connection with conditions diagnosed or treated by one or more reimbursable items and/or services to which the value-based pricing arrangement relates or to the use of one or more such reimbursable items and/or services (including, but not limited to, avoiding potential adverse outcomes related to such condition, diagnosis, treatment or use), in each case when such reimbursable items and/or services are appropriately used, and which do not knowingly induce the buyer to reduce or limit medically necessary items or services to the buyer's patients." This provision ensures that there will be an appropriate connection between the services being provided and the reimbursable product—i.e., that the product and the services all relate to achieving the same targeted outcome.

¹⁰ See, e.g., OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731, 23735 (May 5, 2003).

¹¹ We have made revisions to section (*) (3)(A) of the proposed safe harbor for value-based pricing arrangements to reflect these points. We note that where there is a bundled pricing arrangement involving two or more reimbursable items and/or services (including any value-based services which constitute reimbursable items and/or services), the seller would be required to allocate value to the different items in the bundle upon the request of the buyer.

proposed safe harbor is drafted accordingly.¹²

Safe Harbor for Value-Based Pricing Arrangements

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

¹² Please note that we have also made technical edits to the proposed safe harbor for value-based pricing arrangements to reflect that any up-front discounts or bundled prices provided as part of such arrangement would constitute a value-based pricing adjustment subject to the requirements and protections of the safe harbor.

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), 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 relate to achieving clinical and/or cost outcomes in connection with conditions diagnosed or treated by one or more reimbursable items and/or services to which the value-based pricing arrangement relates, or to the use of one or more such reimbursable items and/or services (including, but not limited to, avoiding potential adverse outcomes related to such condition, diagnosis, treatment or use), in each case when such reimbursable items and/or services are appropriately used, and which do not knowingly induce the 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).

Safe Harbor for Value-Based Warranty Arrangements

AdvaMed further 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 this requirement does not apply to those value-based services provided or made available for one of the purposes described in paragraph (*) (5) (C) (i) 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) 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), 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 relate to achieving clinical and/or cost outcomes in connection with conditions diagnosed or treated by one or more reimbursable items and/or services to which the value-based warranty 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.

Discussion of OIG Criteria for Modifying and Establishing Safe Harbor Provisions

We address below the factors that OIG takes into account in connection with considering the potential adoption of new safe harbors.

Access to Health Care Services / Patient Benefits

AdvaMed believes that access to health care services will be promoted through the adoption of the foregoing safe harbors, inasmuch as inappropriate restrictions on beneficial value-based arrangements will be removed. Further, access to value-based services (e.g., software applications and services to promote successful patient outcomes) will be enhanced by eliminating the current barriers that often inappropriately inhibit manufacturers and other sellers from making such services available, greatly benefiting more patients.

Quality of Health Care Services

These safe harbors will help to improve the quality of health care services provided to Federal health care program beneficiaries by better enabling manufacturers and other sellers to provide solutions tailored to improve clinical outcomes, and which expressly put the seller at economic risk for achievement of defined clinical goals.

Freedom of Choice

Nothing in AdvaMed's proposals should negatively affect patient freedom of choice. To the contrary, the availability of safe harbor protection for value-based pricing or warranty arrangements is likely to enhance patient freedom of choice by making it easier for sellers to compete on the basis of value, rather than simply on the basis of a price that does not reflect adjustments for outcomes. Moreover, sellers' increased flexibility to offer value-based warranties will give patients an important additional basis upon which to base their choices—e.g., selecting products of manufacturers who stand behind their products and will provide a warranty remedy if they fail to achieve warranted results.

Competition

Contrary to concerns expressed by some, value-based pricing and warranty arrangements will promote competition. In particular, smaller manufacturers with innovative products will be able to compete by offering a price tied to their products' performance—creating a win-win for buyers and sellers. Further, buyers and patients will be better able to base competition between competing sellers upon what really matters—achieving successful clinical outcomes on a cost-effective basis—rather than only on whose product is cheapest or most effectively promoted through a sales force.

Cost to Federal Health Care Programs

Value-based pricing and warranty arrangements should reduce costs to Federal health care programs by promoting competition on the right bases—clinical outcomes and cost savings. Importantly, the safe harbors we have proposed prohibit sellers and buyers for submitting claims for separate reimbursement of value-based services, apart from the reimbursement for reimbursable items and/or services to which they relate; as such, there should be no separate Federal costs for such services. Similarly, to the extent value-based warranties result in sellers bearing costs for alternative or replacement treatments that otherwise would have been paid for by Federal health care programs, Federal programs will clearly avoid such costs.

Potential overutilization of health care services

Adoption of the safe harbors we have proposed would not be likely to cause overutilization. There is nothing in value-based pricing or warranty arrangements that would be likely to lead providers to provide, prescribe or order unnecessary services for patients; to the contrary, the existence of these safe harbors is likely to facilitate payors' and providers' agreement to base providers' compensation on clinical and cost outcomes, helping to squeeze out existing overutilization in our health care system.

Relative to underutilization, the safe harbors we have proposed expressly condition safe harbor protection upon the targeted outcomes not knowingly inducing the buyer to reduce or limit medically necessary items or services to the buyer's patients. As such, an arrangement that fails to satisfy that condition so as to result in underutilization would not qualify for safe harbor protection.

Impact on Medically Underserved Areas/Populations

The proposed safe harbors would permit value-based pricing and warranty arrangements to be provided in all areas and for all patient groups, including medically underserved areas and groups. At a minimum, medically underserved areas and patient groups should not be adversely affected, and we believe that the flexibility for sellers and buyers to enter into such arrangements would permit tailoring of services to better meet the unique needs of many underserved areas and groups.

Financial Benefit to Health Care Professionals or Providers

We believe the proposals discussed above may result in potential financial benefit to health care professionals and/or providers who enter into value-based pricing or warranty arrangements, but only for the right reasons—i.e., achievement of targeted clinical and/or cost outcomes established under the arrangement. For example, providers may enter into arrangements with payors which effectively compensate them for reducing unnecessary patient admissions or readmissions. In these cases, financial benefits are appropriately tied to quality and outcomes, not to increased volumes of services ordered or inappropriate referrals to particular practitioners or providers.

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

Sincerely,



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