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January 8, 2021

By Electronic Mail to InnovationCaucus@mail.house.gov

The Honorable Ami Bera, M.D.
United States House of Representatives
1431 Longworth House Office Building
Washington, DC 20515

The Honorable Tony Cárdenas
United States House of Representatives
2438 Rayburn House Office Building
Washington, DC 20515

The Honorable Mike Kelly
United States House of Representatives
1707 Longworth House Office Building
Washington, DC 20515

The Honorable Ron Kind
United States House of Representatives
1502 Longworth House Office Building
Washington, DC 20515

The Honorable Markwayne Mullin
United States House of Representatives
1113 Longworth House Office Building
Washington, DC 20515

The Honorable Raul Ruiz, M.D.
United States House of Representatives
2342 Rayburn House Office Building
Washington, DC 20515

The Honorable Brad Wenstrup
United States House of Representatives
2419 Rayburn House Office Building
Washington, DC 20515

Re: Feedback on finalized OIG rulemaking on the federal Anti-Kickback Statute and suggested legislative text to modernize the Anti-Kickback Statute

Dear Health Care Innovation Caucus:

The Advanced Medical Technology Association (AdvaMed) appreciates this opportunity to submit feedback in response to the Health Care Innovation Caucus (HCIC) Request for Information (RFI) regarding the revisions to the safe harbors under the federal Anti-Kickback Statute (AKS), published by the Office of the Inspector General of the Department of Health and Human Services (OIG) at 85 Fed. Reg. 77684 (December 2, 2020) (RIN 0936–AA10, the AKS Final Rule) and suggested legislative text to modernize the AKS.

I. INTRODUCTION

AdvaMed is a trade association that represents the world's leading innovators and manufacturers of medical devices, diagnostic products, digital health technologies, and health information systems. Together, our members manufacture much of the life-enhancing and life-saving health care technology purchased annually in the United States and globally. Our members are committed to the development

of new technologies and services that allow patients to lead longer, healthier, and more productive lives.

Health care providers and payors want partners who will share accountability for achieving targeted health outcomes for patients, while also managing costs. They are increasingly looking to medtech companies for help in tackling complex problems through strategic partnerships as opposed to simple sales arrangements. AdvaMed members are uniquely positioned to engage with providers, payors, and others in beneficial value-based arrangements to improve care and reduce costs and are at the forefront of the development of collaborations intended to advance the objectives of value-based care.

Our members support efforts to transform the health care system into one that pays for value and to remove unnecessary governmental obstacles to value-based care and care coordination. We greatly appreciate HCIC's efforts to encourage and protect legitimate, good-faith arrangements necessary to coordinate care, control costs, and improve patient outcomes. As you have recognized, all health care contributors need to be integrated to maximize the potential of value-based health care. Thank you for your expressions of support for including device manufacturers and DMEPOS suppliers among those entities that should be protected by the new and revised AKS safe harbors.

Below we respond to the RFI's solicitation for (1) feedback on the AKS Final Rule and (2) suggested legislative text to further modernize the AKS.

II. FEEDBACK ON THE AKS FINAL RULE

We appreciate OIG's efforts to establish new and modernized safe harbors under the AKS to encourage and protect arrangements that promote care coordination and advance the delivery of value-based care, while also protecting against the harms caused by fraud and abuse. While we do agree with aspects of the AKS Final Rule, there are certain aspects of the AKS Final Rule with which we do not agree. We appreciate HCIC considering both our positive and constructive feedback regarding the AKS Final Rule, shared below.

A. Positive Feedback

There are several aspects of the AKS Final Rule that we agree with and support, including the following:

- ***Definition of "VBE Participant"*** – In finalizing the definition of "VBE participant," OIG did not categorically exclude from the definition of "VBE participant" any entities, such that all medical technology companies, including manufacturers of devices and medical supplies as well as manufacturers, distributors, or suppliers of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS), may participate in value based enterprises (VBEs). This is particularly important as patients, providers, and payors want and need medical technology companies to participate in value-based arrangements and to share in the accountability for outcomes, and medical technology companies are uniquely qualified to advance value-based health care.
- ***Definition of "Coordination and Management of Care"*** – The AKS Final Rule finalizes a broad definition for the term "coordination and management of care," which is a key term applicable to the value-based safe harbors and in particular for the new care coordination arrangements safe harbor. OIG also confirmed in the preamble discussion that such term is intended to cover a broad range of activities, including patient monitoring, patient diagnostic

activities, patient treatment, communication related to such patient activities, and predictive analytics. The final definition and OIG's confirmation of its broad scope will permit and encourage innovative and beneficial arrangements.

- ***Patient Engagement and Support Safe Harbor*** – We appreciate that as finalized, the new safe harbor for patient engagement tools and supports includes multiple features that will offer flexibilities not permitted under certain alternative proposals OIG was considering with respect to this safe harbor. For example, as finalized, OIG has extended the universe of eligible recipients to whom a VBE participant may furnish a protected tool or support to not only include a patient in the target patient population but also a caregiver, family member, or other individual acting on the patient's behalf. In addition, OIG did not finalize a requirement that an offeror must make a reasonable effort to retrieve a furnished tool or support when the recipient is no longer in the target patient population or the offeror is no longer a VBE participant, a requirement that would have been difficult to operationalize. Finally, we appreciate that with respect to the annual monetary cap condition applicable to this safe harbor, OIG included an inflation adjuster; confirmed its interpretation of "retail value" to mean "the commercial cost the patient would have incurred at the time the VBE participant provides the tool or support if the patient had procured the tool or support on the open market on their own"; and confirmed that the annual monetary cap applied per VBE participant and per patient, rather than the VBE level or the value-based arrangement level.
- ***Personal Services and Management Contracts Safe Harbor*** – The Final Rule modifies the existing safe harbor for personal services and management contracts to add additional flexibilities related to part-time arrangements, by replacing the requirement that aggregate *compensation* be set in advance with the requirement that the *compensation methodology* be set in advance, and by removing the requirement that the contract must specify exactly the schedule, length, and charge for part-time services. These are welcome revisions to the personal services and management contracts safe harbor and reflect the reality of how many otherwise low-risk personal services arrangements have been and are currently structured.
- ***Warranties Safe Harbor*** – We appreciate that as finalized, the new warranties safe harbor extends protection to not only warranties covering a product but also warranties covering an item or bundle of items, or services in combination with one or more related items. In addition, OIG confirmed that the finalized definition of the term "warranty" applies to warranty arrangements conditioned on clinical outcomes guarantees, provided other safe harbor requirements are met. Finally, we appreciate that with respect to the reporting obligations applicable to this safe harbor, OIG did not prescribe a specific allocation methodology for purposes of reporting a warranty remedy across multiple items or a combination of items or services, and did not prescribe a timeline for buyers and sellers to fulfill their reporting obligations.

B. Constructive Feedback

Notwithstanding the foregoing, there are several aspects of the AKS Final Rule with which we do not agree. We welcome HCIC's assistance in addressing these aspects of the AKS Final Rule in order to ensure ***all*** legitimate, good-faith value-based arrangements are protected.

- ***Entities Ineligible for Safe Harbor Protection*** – All manufacturers of devices and medical supplies and DMEPOS companies, except physician owned distributors (PODs), should be permitted to rely on the new safe harbor for value-based arrangements with substantial

downside financial risk, the new safe harbor for value-based arrangements with full financial risk, the new care coordination arrangements safe harbor (even outside the separate pathway for digital health technologies), the new patient engagement and support safe harbor (even outside the separate pathway for digital health technologies), and the new protection for outcomes-based payments under the modified personal services and management contracts safe harbor.

  - The active participation of medical technology manufacturers in value-based and outcomes-based payment arrangements is essential to improve outcomes, control costs, and encourage innovation within our health care system, but such active participation is at-risk of being stifled if medical technology manufacturers are unable to enter into such arrangements with the assurance that such arrangements are in fact protected under applicable law. OIG's exclusion of device manufacturers and DMEPOS companies from safe harbor protection discourages beneficial and appropriate value-based arrangements.
  - OIG's assumption that device manufacturers and DMEPOS companies are less likely to be on the front line of care coordination and treatment decisions is not correct.
  - If permitted to use these safe harbors, medical technology manufacturers will be subject not only to the appropriate safeguards the OIG has finalized under the safe harbors, but also to the AdvaMed Code of Ethics.

- ***Care Coordination Arrangements Safe Harbor*** – Consistent with our feedback above related to Entities Ineligible for Safe Harbor Protection, device manufacturers and DMEPOS companies should be permitted to rely on this new safe harbor, even outside of the separate pathway for digital health technologies finalized for such parties. Further, the contribution requirement under the new care coordination arrangements safe harbor should be removed. We believe this requirement may prevent or discourage parties from entering into beneficial and important arrangements that would otherwise be protected by this safe harbor, either because recipient VBE participants may not have the funds available for the contribution or may question whether they will receive sufficient financial return from the use of care coordination remuneration to merit such contributions. Finally, whether or not the separate pathway related to digital health technologies remains under the care coordination arrangements safe harbor, the condition prohibiting limited technology participants from imposing an exclusive use or minimum-purchasing requirement on any item or service manufactured, distributed, or sold by them should be removed. The establishment of legitimate outcome or process measures, required by the safe harbor, may necessarily require some minimum level of product use (or any related services) or exclusivity arrangement so as to make the outcomes measure statistically meaningful. The safe harbor as finalized otherwise prohibits any limit to the ability to make decisions in the best interests of patients and to provide medically necessary items and services. We believe that, in practice, providers only agree to an exclusivity or minimum use criteria when they believe that doing so does not limit their ability to make medically necessary decisions in the best interests of their patients.
- ***Value-Based Arrangements with Substantial Downside Financial Risk and Value-Based Arrangements with Full Financial Risk*** – Consistent with our feedback above related to Entities Ineligible for Safe Harbor Protection, remuneration exchanged by device manufacturers and DMEPOS companies should not be excluded from protection under these

new value-based safe harbors. Further, protection under these safe harbors should extend to all legitimate pre-arrangement activities, not just those undertaken once a contractual obligation is in place. Additionally, the safe harbor restrictions against ownership or investment interests should be removed from both safe harbors in order to allow VBE participants to dictate the corporate structure of VBEs they create and for which they assume financial risk.

- ***Patient Engagement and Support Safe Harbor*** – Consistent with our feedback above related to Entities Ineligible for Safe Harbor Protection, device manufacturers and DMEPOS companies should be permitted to rely on this new safe harbor, even outside of the separate pathway for digital health technologies finalized for manufacturers of devices or medical supplies. Further, this safe harbor should be broadened to protect any furnished tool or support that is directly connected to any of the four value-based purposes. Finally, OIG should revise the annual monetary cap requirement to allow for a value higher than $500 when the VBE's accountable body or responsible person determines the circumstances support a higher amount.
- ***Outcomes-Based Payments Arrangements*** – Consistent with our feedback above related to Entities Ineligible for Safe Harbor Protection, payments made directly or indirectly by device manufacturers and DMEPOS companies should not be excluded from protection under the modified safe harbor for outcomes-based payment arrangements. Additionally, the finalized safe harbor requirement regarding outcome measure benchmarks used to quantify "a *material* reduction in costs to or growth in expenditures *to payors* while maintaining or improving quality of care for patients" should be revised to remove the "material" and "payor" qualifiers in order to broaden the safe harbor protection and protect outcomes-based payments for arrangements that reduce internal costs to providers.
- ***Warranties Safe Harbor*** – The requirement that all reimbursable items and services in a bundle warranty arrangement be reimbursed under the "same program, same payment" methodology should be removed as a condition of this modified safe harbor. In addition, there should be no cap on the amount of warranty remedies available to the buyer, such that sellers are permitted to provide or pay for medical, surgical, hospital or other services and related items in connection with the replacement or supplementation of a warranted item, even if such remuneration exceeds the cost of the items and services subject to the warranty. We also recommend that this safe harbor be revised to remove the prohibition on a seller conditioning the warranty on a buyer's exclusive use, or minimum purchase, of any of the seller's items or services. The OIG confirmed in the AKS Final Rule that the modified warranties safe harbor can be used to protect warranty arrangements conditioned on clinical outcomes guarantees. Many outcomes-based warranties relate to the performance of warranted items (and, where included, related services) across a patient population. These typically require that there be some minimum level of use of the product (and any related services) so as to make the outcomes measure statistically meaningful. Similarly, an exclusive purchasing requirement is often necessary for the contemplated warranty to make sense since target outcomes may only be achieved if the buyer standardizes their use of bundled warranted items and services.

III. SUGGESTED LEGISLATIVE TEXT TO FURTHER MODERNIZE THE AKS

In addition to our constructive feedback and recommendations above related to the safe harbor regulations finalized by the AKS Final Rule, we also offer at Attachment A proposed legislative text for your consideration. Specifically, we propose the addition of three value-based AKS statutory

exceptions related to value-based pricing arrangements, value-based warranty arrangements, and value-based risk-sharing arrangements. These statutory exceptions are intended to modernize the AKS and protect legitimate, good-faith value-based arrangements involving medical technology companies.

* * *

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

Sincerely,

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

ATTACHMENT A

117TH CONGRESS
1ST SESSION

[Discussion Draft]

H.R. _____

To modernize the safe harbors under the federal Anti-Kickback Statute and the Civil Monetary Penalty Rules Regarding Beneficiary Inducements to promote value-based arrangements.

IN THE HOUSE OF REPRESENTATIVES OF THE UNITED STATES

_____ introduced the following bill; which was referred to the Committee on _____

A BILL

To modernize the safe harbors under the federal Anti-Kickback Statute and the Civil Monetary Penalty Rules Regarding Beneficiary Inducements to promote value-based arrangements.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ["_____ _____ Act of 2021".

SEC. 2. [TBD].

(a) IN GENERAL.—Section 1128B(b)(3) of the Social Security Act (42 U.S.C. 1320a–7b(b)(3)) is amended—

(1) in subsection (b)(3)(J) by striking "and" after the semicolon at the end;

(2) in subsection (b)(3)(K) by striking the period at the end and inserting a semicolon; and

(3) by inserting after subsection (b)(3)(K) the following new subparagraphs:

"(L) any value-based price adjustment or value-based services provided in connection with a value-based pricing arrangement pursuant to the following, as applicable—

"(i) 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 subparagraph (L)(v)(III) of this subsection) 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.

"(ii) 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

subparagraph (L)(v)(IV)(aa), 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.

"(iii) In the case of the buyer:

"(I) 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 (aa) any such value-based price adjustment provided to or by the buyer as part of such value-based pricing arrangement, and (bb) 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 subparagraph (L)(iv) below; and

"(II) 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.

"(iv) In the case of a seller:

"(I) If reasonably requested by the buyer in order to satisfy a reporting obligation of the buyer under subparagraph (L)(iii) of this subsection, 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;

"(II) 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

"(III) Such seller refrains from doing anything that would impede the buyer from meeting its obligations under subparagraph (L)(iii) of this subsection.

"(v) For purposes of this subparagraph (L):

"(I) The term buyer means (aa) 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 (bb) 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);

"(II) 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);

"(III) 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;

"(IV) 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:

"(aa) 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);

"(bb) 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;

"(cc) 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

"(dd) 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 items (cc) and (dd) 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.

"(V) 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;

"(VI) 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:

"(aa) 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 subparagraph (L)(i) of this subsection, as part of a value-based pricing arrangement which also includes terms and conditions for a value-based price adjustment provided in accordance with item (bb) of this definition and/or value-based services

provided in accordance with items (cc) or (dd) of the definition of such term; and/or

"(bb) 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 subparagraph (L)(i) of this subsection.

Without limitation of the foregoing, a value-based price adjustment under this subparagraph (L)(v)(VI) may include, without limitation, (AA) 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 (BB) 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).

"(M) 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, pursuant to the following, as applicable—

"(i) 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.

"(ii) 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 subparagraph (M)(v)(III)(aa), 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.

"(iii) In the case of the buyer:

"(I) 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 (aa) any warranty price adjustment (as defined in subparagraph (L)(v)(VII) of this section) and (bb) 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 subparagraph (M)(iv) below;

"(II) The buyer does not report or reflect any cost for any warranty replacement items and/or services (as defined in subparagraph (M)(v)(VIII) 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

"(III) 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.

"(iv) In the case of the seller:

"(I) If reasonably requested by the buyer in order to satisfy a reporting obligation of the buyer under subparagraph (M)(iii) 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;

"(II) 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

"(III) Such seller refrains from doing anything that would impede the buyer from meeting its obligations under subparagraph (M)(iii) of this section.

"(v) For purposes of this subparagraph (M):

"(I) The term buyer means (aa) a Federal health care program beneficiary who receives a warranted item under a Federal health care program, (bb) 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 (cc) 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);

"(II) 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;

"(III) 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:

"(aa) 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);

"(bb) 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;

"(cc) 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

"(dd) 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 items (cc) and (dd) 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;

"(IV) 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;

"(V) 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;

"(VI) 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;

"(VII) 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 subparagraph (M)(v)(VII) 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

"(VIII) The term warranty replacement items and/or services means (aa) 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 (bb) 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: (AA) such items and/or services are supplied, provided and/or paid for in accordance with the terms and conditions of the value-based warranty; (BB) such items and/or

services are not billed by any person to any Federal health care program; and (CC) such items and/or services are medically appropriate.

"(N) any transfer of value provided under a Value-Based Risk Sharing Arrangement pursuant to the following, as applicable—

"(i) 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 subsection, remuneration shall also not include participant activities reasonably necessary or appropriate to 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 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 clause, 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.

"(ii) 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.".

SEC. 3. CONFORMING EDITS.

[TBD]