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**U.S. HOUSE OF REPRESENTATIVES COMMITTEE ON WAYS AND MEANS  
SUBCOMMITTEE ON HEALTH HEARING ON  
“MODERNIZING STARK LAW TO ENSURE THE SUCCESSFUL TRANSITION  
FROM VOLUME TO VALUE IN THE MEDICARE PROGRAM”**

**JULY 17, 2018**

**STATEMENT FOR THE RECORD OF THE  
ADVANCED MEDICAL TECHNOLOGY ASSOCIATION (AdvaMed)  
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The Advanced Medical Technology Association (AdvaMed) appreciates the opportunity to provide a statement for the record regarding the July 17, 2018 hearing of the U.S. House of Representatives Committee on Ways and Means Subcommittee on Health on “Modernizing Stark Law to Ensure the Successful Transition from Volume to Value in the Medicare Program.” We commend the Health Subcommittee for holding this hearing and highlighting the importance and need for modernization of the fraud and abuse laws to promote value-based health care.

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. Some of our members provide Designated Health Services (DHS) as defined under 42 U.S.C. 1395nn (h)(6) and 42 CFR 411.351.

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. To maximize the potential of value-based health care, we need to integrate all of the contributors to health care, including medtech manufacturers, and provide similar protection for these contributors to engage in value-based arrangements.

AdvaMed supports a legal framework that protects patients and the federal health care reimbursement programs from fraud and abuse. Our member companies further recognize the importance of ensuring ethical interactions between medtech companies and providers so that medical decisions are centered on the best interests of the patient. That is why AdvaMed developed a [Code of Ethics](#)<sup>1</sup> (also known as the “AdvaMed Code”) to distinguish beneficial interactions from those that may inappropriately influence medical decision-making.

The current fraud and abuse laws contemplate a volume-based payment system (fee-for-service or

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<sup>1</sup> AdvaMed Code of Ethics on Interactions with Health Care Professionals,  
[https://www.advamed.org/sites/default/files/resource/112\\_112\\_code\\_of\\_ethics\\_0.pdf](https://www.advamed.org/sites/default/files/resource/112_112_code_of_ethics_0.pdf)

fee-for-product) and are ill-suited for innovative value-based arrangements. The existing fraud and abuse laws seek to prevent inappropriate medical decision-making and overutilization by ensuring that the financial interests of parties involved in the provision of care are not structured in a manner that creates inappropriate incentives to provide unnecessary services, leading to increased costs. Our use of the term “Value-Based Arrangement” is synonymous with “Outcomes-Based Arrangement” or “Results-Based Contracting,” which are built around shared accountability for clinical outcomes and cost. Value-Based Arrangements (VBAs) generally lack overutilization concerns since payments are not directly tied to the volume of services provided. Instead frameworks such as risk-sharing, shared savings, and / or capitated payments are inherently designed to limit overall costs to the system with strong measurable quality goals to safeguard against underutilizing or withholding medically necessary services and limiting patient choice. VBAs align the financial interests of providers, industry, and payers to achieve clinical outcome goals and manage costs. However, this alignment creates tension under the current fraud and abuse legal framework. Aspects of VBAs at tension with the Stark Law include: (1) the services that must be bundled in to develop and operationalize the VBA (e.g., data collection, tracking, analysis, reporting); (2) the services and technologies that are a part of the solution to achieve the targeted outcome (e.g., care coordination, monitoring, optimizing care pathways, and technology integration to help clinicians make needed interventions); and (3) elements of the outcomes-based pricing (e.g., front end discounts, rebates, performance payments, and penalty payments). Each of the above could be considered to have value that renders its exchange a compensation arrangement as defined under 42 U.S.C. 1395nn(h)(1).

**AdvaMed endorses modernizing the Stark Law and the Anti-Kickback Statute to promote value-based arrangements that integrate all contributors to health care.** The Stark Law should be updated to broadly permit financial relationships resulting from value-based arrangements. For example, the remuneration exclusions specified in 42 U.S.C. 1395nn(h)(1)(C) could be expanded to include those elements described above that serve the purpose of developing and operationalizing VBAs. Additionally, the definition of “remuneration” at 42 C.F.R. 411.351 could be modified to expand the existing exclusions in that regulation to include value-based reimbursement or price adjustments provided to or by a physician, and value-based services provided to or for the benefit of the physician or the physician’s patients, so long as required criteria are satisfied. These could include documentation and, as appropriate, disclosure of the arrangement, in advance of payments being made or services being provided. Relevant definitions could limit the characteristics of the price adjustments and services which would qualify for the applicable exception. For example, the permitted price adjustments could exclude those which knowingly induce the physician to reduce or limit the provision of medically necessary items or services to the physician’s patients. The permitted services could be subject to requirements that they promote value-based care in defined ways, such as analysis for developing and software for

operationalizing the value-based arrangement, or equipment and services for optimizing clinical outcomes through care coordination or otherwise.

We believe this type of approach would cut through the clutter of the current Stark Law regulations to clearly delineate criteria for value-based arrangements which, once satisfied, would ensure that any Stark Law concerns have been addressed. These criteria should parallel those for a new safe harbor under the Anti-Kickback Statute, given the overlap between these two major fraud and abuse laws. AdvaMed submitted proposals for new value-based safe harbors to the Anti-Kickback Statute in response to the Department of Health and Human Services Office of Inspector General (OIG) annual solicitation for new safe harbors.<sup>2</sup> Attached for your consideration please find a proposed parallel Stark Exception that would support value-based pricing arrangements, tying payments to outcomes, by permitting price adjustments based on whether or not specified clinical or cost outcome targets were achieved (e.g., performance or penalty payments) when certain conditions are met.

Due to the evolution of the healthcare system since the Stark Law was passed and implemented, current restrictions have become an unnecessary deterrent to the adoption of modern value-based care arrangements. It is time to update the Stark Law, in concert with similar changes to the safe harbors under the Anti-Kickback Statute, to clearly permit value-based arrangements, subject to appropriate program integrity protections. These updates should promote the integration of all contributors to health care (including medtech manufacturers) into value-based arrangements to share accountability for clinical outcomes and managing costs.

AdvaMed commends the Health Subcommittee's work to modernize the fraud and abuse laws to promote value-based health care. We would be pleased to discuss these proposals in greater detail at your convenience.

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<sup>2</sup> Comment Letter from AdvaMed to OIG (February 26, 2018), <https://www.advamed.org/resource-center/advamed-2018-aks-safe-harbor-proposals-value-based-arrangements>

## **Proposal to Advance Value-Based Health Care New Stark Exception for Value-Based Arrangements**

Within 42 CFR 411.351, under the definition of Remuneration, add a fourth exception to remuneration for value-based pricing adjustments and value-based services under a value-based pricing arrangement.

§ 411.351 Definitions. As used in this subpart, unless the context indicates otherwise:

...

Remuneration means any payment or other benefit made directly or indirectly, overtly or covertly, in cash or in kind, except that the following are not considered remuneration for purposes of this section:

...

(4) Any value-based price adjustment between a physician and an entity under a value-based pricing arrangement, or any value-based services provided to or for the benefit of a physician or any of such physician's patients under a value-based pricing arrangement, each as defined in paragraph (4)(iii) of this section, as long as the following standards are met—

- (i) The terms and conditions of the value-based price adjustment are set forth in writing and disclosed to the recipient of such value-based price adjustment by the entity or physician making such value-based price adjustment available, at or prior to the time of the first purchase or coverage of the reimbursable items and/or services (as defined in paragraph (4)(iii)(A) of this section) to which such value-based price adjustment relates under the value-based pricing arrangement. For such purposes, terms and conditions shall be deemed set forth in writing 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 as part of such value-based pricing arrangement are set forth in writing and disclosed by the entity to the physician at or prior to the time of the first purchase or coverage of the reimbursable items and/or services to which such value-based services relate under the value-based pricing arrangement.
- (iii) For purposes of this paragraph (4):
  - (A) The term reimbursable items and/or services means health care items and/or services (x) for which payment may be made, in whole or in part, under one or more of a Federal health care program, private health insurance coverage, or any other arrangement through which a third party provides health care coverage or services to patients, or (y) which are provided directly to patients on a private pay or charitable basis by a physician or entity;
  - (B) The term value-based services means analysis, software, equipment, information and/or services, provided or made available by an entity (or by a third party pursuant to an arrangement with the entity) to or for the benefit of a physician or any of the physician's patients, as part of a value-based pricing arrangement between such entity and such physician, for a reduced charge or no charge (apart from the 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 set forth 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 physician to reduce or limit medically necessary items or services to the physician's patients.

- (C) The term value-based pricing arrangement means an agreement or other arrangement under which an entity provides a value-based price adjustment to a physician, a physician provides a value-based price adjustment to an entity, and/or value-based services are made available to or for the benefit of a physician or any patients of such physician, in each case in accordance with the requirements of this section;
- (D) The term value-based price adjustment means a reduction to or increase in an entity's or physician's price or net cost for one or more reimbursable items and/or services to which the value-based pricing arrangement relates, consisting of one or both of the following:
  - (I) a discounted or bundled price or net cost initially payable for one or more such reimbursable items and/or services 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, in each case as set forth in the written document referenced in paragraph (4)(i) of this section; and/or

- (II) a payment made by a physician to an entity, or by an entity to a physician, as a reduction to or increase in the recipient'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 such reimbursable items and/or services purchased under such value-based pricing arrangement when appropriately used, and which does not knowingly induce the physician to reduce or limit medically necessary items or services to the physician's patients, in accordance with terms and conditions set forth in the written document referenced in paragraph (4)(i) of this section.

Without limitation of the foregoing, a value-based price adjustment under this paragraph (4)(iii)(D) may include, without limitation, (x) an entity's payment to a physician of all or a portion of amounts which the entity receives or is not required to pay under a payment arrangement to which the entity is subject with respect to some or all of the reimbursable items and/or services to which the value-based payment arrangement relates, as a result (directly or indirectly, wholly or in part) of an intended clinical and/or cost outcome under such payment arrangement having been achieved (or partially achieved), and (y) a physician's payment to an entity (directly or through credit against amounts otherwise payable) of all or a portion of amounts which the entity owes or fails to receive under a payment arrangement to which the entity is subject with respect to some or all of the reimbursable items and/or services to which the value-based payment arrangement relates, or of costs otherwise borne by such entity, as a result (directly or indirectly, wholly or in part) of an intended clinical and/or cost outcome under such payment arrangement not having been achieved (or only partially achieved).