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# U.S. HOUSE OF REPRESENTATIVES COMMITTEE ON ENERGY AND COMMERCE
# SUBCOMMITTEE ON HEALTH
# HEARING ON "EXAMINING BARRIERS TO EXPANDING INNOVATIVE, VALUE-BASED CARE IN MEDICARE"

**SEPTEMBER 13, 2018**

## STATEMENT FOR THE RECORD OF
## THE ADVANCED MEDICAL TECHNOLOGY ASSOCIATION (AdvaMed)
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The Advanced Medical Technology Association (AdvaMed) appreciates this opportunity to submit comments to the Subcommittee for the hearing on "Examining Barriers to Expanding Innovative, Value-Based Care in Medicare." We welcome the Subcommittee's attention to this important topic and look forward to continuing to work with you and the members of the Energy and Commerce Committee as you consider legislative efforts to lower or remove barriers to value-based arrangements.

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 for providers and patients to realize the potential of technology to improve outcomes and reduce costs.

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[1] (also known as the "AdvaMed Code") to distinguish beneficial interactions from those that may inappropriately influence medical decision-making.

*Background on the Anti-Kickback Statute*

From the medtech industry's perspective, the primary barrier to broader engagement in patient-centered, Value-Based Arrangements (VBAs) is the deterring effect of the Federal Anti-Kickback Statute along with the narrow scope and outdated design of the existing regulatory safe harbors, which were designed for a fee-for-service/product (volume-based) framework. Our use of the term "Value-Based Arrangement" is limited to outcomes-based or results-based contracts, which are built around shared accountability for clinical outcomes and cost.

The Federal Anti-Kickback Statute (AKS) proscribes the knowing and willful offer, payment, solicitation, or receipt of any remuneration (directly or indirectly, overtly or covertly, in cash or in kind) in return for or to induce a referral of services or goods payable in whole or in part by a Federal health care program.[2] Congress enacted the AKS in 1972, in the context of Medicare's

[1] 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

[2] 42 U.S.C. § 1320a-7b(b)

then-retrospective reimbursement system. In a fee-for-service/product environment, the AKS was intended to discourage overutilization of Medicare-reimbursed items and services by prescribers motivated by their own financial interest.[3] Congress was further concerned with: (1) possible harm to beneficiaries; (2) increased Medicare and Medicaid costs; and (3) the potential of kickbacks to freeze competing suppliers from the system, mask the possibility of government price reductions, and misdirect program funds.[4] The Anti-Kickback Statute originally prohibited only "bribes and kickbacks,"[5] but Congress extended its reach in 1977 by substituting "any remuneration" for the "bribes and kickbacks" language[6] and increasing the severity of the penalties from a misdemeanor to a felony.[7]

Aspects of VBAs at tension with the AKS 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) and outcomes-based warranties (e.g., rebates and providing complimentary or alternative services when a warranted outcome is not achieved).

Each of these aspects of VBAs can be considered to have value that encourages or rewards the use of a medtech product.

*Challenges posed by current OIG safe harbors*

Even in the fee-for-service/product (volume-based) context, Congress recognized that the expansive reach of the AKS created uncertainty as to which routine commercial arrangements are permitted,[8] and it excluded certain types of payments from consideration by the statute, including

[3] 59 Washington & Lee Law Review 3/1/02 (The Medicare Anti-Kickback Statute: In Need of Reconstructive Surgery for the Digital Age), citing Jost & Davies "The Law of Medicare and Medicaid Fraud and Abuse" 100 (2001-02 ed. 2000) (listing concerns that "patients will suffer, program funds will be unnecessarily depleted, and taxpayer dollars will be wasted" if kickbacks are permitted).

[4] See 56 Fed. Reg., 35952 (July 29, 1991) (original safe harbors, citing United States v. Ruttenberq, 625 F.2d 173, 177, n.9 (7th Cir. 1980)).

[5] Social Security Amendments of 1972, Pub. L. No. 92-603, § 242(b), 86 Stat. 1329,1419 (1972) (codified as amended at 42 U.S.C. § 1320a-7b (1994))

[6] Medicare and Medicaid Anti-Fraud and Abuse Amendments of 1977, Pub. L. No. 95-142, 91 Stat. 1175 (1977)

[7] See Pub. L. 95-142, 91 Stat. 1175 (1977).

[8] See S. REP. 100-109, 27, 1987 U.S.C.C.A.N. 682, 707-08 ("It is the understanding of the Committee that the breadth of this statutory language has created uncertainty among health care providers as to which commercial arrangements are legitimate, and which are proscribed. The Committee bill therefore directs the Secretary, **708 in consultation with the Attorney General, to promulgate regulations specifying payment practices that will not be subject to criminal prosecution under the new section 1128B(b) and that will not provide a basis for exclusion from participation in Medicare or the State health care programs under the new section 1128(b)(7).")

discounts.[9] However, when the Office of Inspector General (OIG) promulgated final implementing regulations, the "safe harbor" for discounts/rebates was very narrowly drawn.

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."[10] 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.

AdvaMed and other commenters requested OIG to create new safe harbors or revise existing safe harbors to accommodate value-based arrangements because 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 consider 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."[11] 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

[9] 42 U.S.C. § 1320a-7b(b)(3).

[10] "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).

[11] 42 C.F.R. § 1001.952(h)(1)(ii).

Act, as a consequence of doing so.[12] 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.

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.[13] Similar cases have been noted by other commenters.[14]

*AdvaMed proposals to modernize legal frameworks to support value-based arrangements*

**I. Prioritize the creation of new value-based AKS safe harbors that can integrate all contributors to health care into value-based arrangements.**

To maximize the potential of value-based health care, a goal that is shared among lawmakers, industry, and consumers of health care alike -- we need to integrate all of the contributors to health care, including medtech manufacturers, who can play a pivotal role in delivering solutions to help physicians and hospitals meet the triple aim of achieving better outcomes, lowering costs, and improving the patient experience. The Administration should prioritize the OIG's development of value-based safe harbors in its work plan and allocate additional resources to the OIG if needed to accomplish this.

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

[12] 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.

[13] *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).

[14] 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.

current fraud and abuse laws provide.[15] 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[16] These are revised versions of the two safe harbors that we proposed in 2017.[17] These proposed AKS Safe Harbors would protect arrangements where contributors to health care can share accountability for achieving clinical outcomes and the total cost of care for a patient or population. 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.

The AdvaMed proposed Value-Based Pricing Arrangements Safe Harbor would allow for price adjustment (e.g., front end discount, rebate, performance / incentive payment) based on the achievement of a measurable outcome (clinical, cost or patient experience). Our 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. In other words, the outcome warranty would allow a manufacturer to share risk by providing a payment, item, or service when a targeted clinical or economic outcome is not realized. In other words, the outcome warranty would allow a manufacturer to share risk by providing a payment, item, and/or service when a targeted clinical or economic outcome is not realized. Both proposed safe harbors would allow for the bundling of Value-Based Services, which are limited to software, equipment, analysis, information and services provided for one of the following purposes:

(1) determining the terms of the VBA;
(2) operationalizing the VBA (measuring, collecting, calculating, or reporting metrics and the resulting pricing adjustment or warranty remedy);
(3) optimizing the effectiveness and clinical utility of reimbursable items or services; or
(4) otherwise achieving clinical and/or cost outcomes on which the VBA is based.

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.

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

[15] *See, e.g.*, AdvaMed letter dated Feb. 26, 2018, submitted via Regulations.gov, *available at* https://www.advamed.org/sites/default/files/resource/advamed_2018_aks_safe_harbor_proposals_for_value-based_arrangements_0.pdf.

[16] 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.

[17] AdvaMed letter dated Feb. 27, 2017, submitted via Regulations.gov, *available at* https://www.advamed.org/sites/default/files/resource/advamed_letter_to_oig_re_aks_safe_harbor_proposals_for_value-based_arrangements_20170227.pdf

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 proposed safe harbor is drafted accordingly.

## II. The Center for Medicare & Medicaid Innovation (CMMI) should use its waiver authority to integrate medtech manufacturers as risk-sharing collaborators in current and future demonstrations.

In the interim period before new value-based AKS safe harbors are promulgated, the CMMI should use its waiver authority to integrate medtech manufacturers as risk-sharing collaborators in current and future demonstrations to capitalize on and demonstrate the benefits of medical technology manufacturers sharing in the risk to deliver on clinical and cost outcomes. AdvaMed proposes instituting waivers and guidance across existing and future demonstrations, which include protections for patients and Federal health care programs, while allowing for greater involvement and investment in demonstrations. These waivers could be structured similar to AdvaMed's proposed AKS safe harbors for value-based arrangements.[18]

*Conclusion*

AdvaMed strongly supports value-based health care arrangements centered on collaborations between medtech manufacturers, providers and other key stakeholders such as payers to improve outcomes, enhance patient satisfaction, and reduce costs. We appreciate the increasing level of interest shown by both Congress and the Administration in understanding and addressing barriers to VBAs, including the recent requests for information issued by the U.S. Department of Health and Human Services on Stark Law and AKS reforms, the request for information from the congressional Health Care Innovation Caucus, and the hearing held by this Subcommittee and others. We look forward to additional opportunities to develop legislative and regulatory solutions that allow providers, hospitals, payers, and manufacturers to work together to provide the highest level of care possible, across the care continuum, for patients. Thank you for the opportunity to submit these comments.

[18] *See* AdvaMed letter to CMMI dated Nov. 20, 2017 submitted via email, *available at* https://www.advamed.org/sites/default/files/resource/advamed_comment_letter_-_request_for_information_regarding_innovat.pdf