AdvaMed
Advanced Medical Technology Association

May 27, 2025

By Electronic Submission to www.regulations.gov

Abigail Slater
Assistant Attorney General – Antitrust Division
U.S. Department of Justice
950 Pennsylvania Avenue NW
Washington, D.C. 20530

Re: Anticompetitive Regulations Task Force Request for Comments: (Docket No. ATR-2025-0001)

Dear Assistant Attorney General Slater:

The Advanced Medical Technology Association ("AdvaMed") appreciates this opportunity to submit the below comments in response to the U.S. Department of Justice Anticompetitive Regulations Task Force Request for Comments ("Anticompetitive Regulations RFC") published March 27, 2025.

AdvaMed supports DOJ's efforts to rescind or replace regulations that are anticompetitive, impose undue burdens on small businesses, and impede private enterprise and entrepreneurship, as doing so ensures medical technology ("medtech") companies can continue to successfully invent, develop, distribute, and manufacture innovative and lifesaving/life-enhancing technologies that improve patient care and outcomes and provide better access to healthcare to underserved patient populations. We welcome the opportunity to assist DOJ in its efforts.

I. AdvaMed and the Medical Technology Industry's Role in Patient Health and Innovation

AdvaMed is a trade association that represents more than 600 medical technology companies bringing innovative medical devices, diagnostic products, digital health technologies, and health information systems to health care settings across the country. Together, our members invent, develop, manufacture, and distribute much of the lifesaving and life-enhancing healthcare technology transforming healthcare through earlier disease detection, less invasive procedures, and more effective treatments.

Our members, which range from the largest to the smallest medtech companies, help patients stay healthier longer, recover more quickly after treatment, and improve clinicians' ability to detect disease earlier and treat more patients more effectively and efficiently. At the same time, the innovation and advancements in medtech driven by our members result in dramatically reduced healthcare costs.

The role of medtech in improving patient health is well-known. In the U.S. there exists an innovation

ecosystem for medtech that improves both patient health and access to care. Indeed, the U.S. medtech industry is responsible for a highly disproportionate share of medical advances globally.[1] Yet, this medtech innovation ecosystem is fragile and extremely sensitive to changes in the cost of innovation, which is substantial.[2]

The fragility of the medtech innovation ecosystem results from several factors, including the extremely expensive development process from concept to product launch.[3] Numerous additional obstacles can stifle ideas and cost-saving improvements in healthcare from successfully reaching the market to help patients. In particular, the complexity arising from the over-regulation of the industry and certain regulations that are unnecessary, unlawful, unduly burdensome, or unsound inhibit patient care and innovation and otherwise stifle American businesses and American ingenuity. The continued ability of medtech companies to make rapid, significant, and sometimes transformational advances in medtech depends upon a fair and reasonable regulatory system.

Today, our health care system is rapidly evolving towards a value-based approach—focusing on access for underserved patient populations, quality, outcomes, and cost-effectiveness, rather than just volume of care provided. Medtech companies are uniquely positioned to advance solutions that improve patient care and control costs, including in the context of value-based arrangements. First, medtech companies are deeply knowledgeable about their technologies' clinical effects, developed through extensive collaboration with medical experts and rigorous clinical research. Leveraging this expertise enables the design of interventions that significantly enhance patient outcomes. Second, medtech companies often employ dedicated clinical, quality, and reimbursement specialists, as well as health care economists and data analysts. These teams can support providers in identifying effective, cost-efficient care solutions. Third, medtech companies excel at collecting, aggregating, and analyzing health care data. Their analytical insights contribute directly to improved patient outcomes, lower overall health system costs, and enhanced patient experiences. All of this means that medtech companies are capable not just of participating in value-based arrangements but designing, implementing, and leading those arrangements.

II. Proposed Regulations to Be Rescinded or Replaced

The focus of these comments is revisions to the federal Anti-Kickback Statute ("AKS") regulatory safe harbors. The medtech industry wants to provide more comprehensive solutions to detect, treat, and

[1] The United States is ranked first in various measures of healthcare innovation. *See, e.g.,* 2020 FREOPP World Index of Healthcare Innovation, ranking the United States first in Science & Technology Healthcare Innovation with a score of 75.14, well above second-place ranked Netherlands (49.97), https://freopp.org/wihi2020-505b1b60bce6.

[2] *See* National Library of Medicine, National Center for Biotechnology Information, Public Health Effectiveness of the FDA 510(k) Clearance Process: Balancing Patient Safety and Innovation: Workshop Report at 21, https://nap.nationalacademies.org/download/12960 ("The medical device innovation ecosystem is fragile and extremely sensitive to changes in the cost of innovation, which is substantial. . . The system is already under immense economic pressure).

[3] *Id.*

manage disease and wants to share accountability for achieving better outcomes, managing costs, and providing better access to care for underserved patient populations. But the AKS's incredibly broad sweep deters broader participation in these types of value-based arrangements. The AKS prohibits providing or offering anything of value to induce or reward the use of any service or item covered in part by a federal healthcare program. Under the AKS, "induce" has been interpreted by courts to mean any intent, even in part, to influence another party's decision to order, refer, or even recommend items or services reimbursable by a federal healthcare program. Value-based arrangements are necessarily designed to influence decisions to achieve targeted clinical outcomes while controlling costs, naturally placing them in tension with the AKS because they can be considered to offer value for encouraging or rewarding the use of a particular medtech item. Consequently, the AKS prevents many beneficial value-based arrangements from ever reaching patients.

One critical deterrent to implementing meaningful value-based arrangements is the sharp rise in financially motivated whistleblower litigation under the False Claims Act ("FCA"). Because value-based arrangements intentionally align financial incentives with improved patient outcomes and cost reduction, these practices can trigger unwarranted risk under the AKS and, by extension, the FCA. The lawsuits that result are sometimes brought by certain individuals and entities that have developed profitable business models of filing whistleblower lawsuits. These lawsuits often mischaracterize legitimate, beneficial healthcare practices as fraudulent, exploiting the broad language in the AKS and FCA. Compounding matters, courts frequently resist dismissing even weak cases early, subjecting healthcare organizations to costly and ultimately unnecessary discovery costs.

While the U.S. Department of Health and Human Services Office of Inspector General ("HHS-OIG") has implemented regulatory safe harbors that protect certain value-based arrangements, these safe harbors are narrow, burdensome to comply with, and exclude protection for medtech companies. Under the existing system, it is easier for large firms with lots of resources to create complex, value-based contracts that do not necessarily fit plainly within a safe harbor but are nevertheless still legally permissible.[4] Small firms often lack resources to develop such arrangements or to defend them when faulted. For example, just developing a value-based arrangement can cost several hundred thousand dollars in legal fees and take months to finalize. That type of resource outlay would be entirely unworkable for a smaller medtech company absent a willingness to risk the entire company on the arrangement's success. Accordingly, reform is needed to level the playing field. Value-based arrangements would facilitate expanded competition among medtech companies of all sizes, based on the clinical outcomes of using their products and services, since value-based contracts reward good product performance and punish bad outcomes.

In light of the foregoing, we recommend that DOJ work with HHS to rescind and replace or revise the AKS

[4] *See* Medicare and State Health Care Programs; Fraud and Abuse; OIG Anti-Kickback Provisions, 56 Fed. Reg. 35952, 35954 (July 29, 1991) (noting that failure to comply with a regulatory safe harbor does not mean that an arrangement necessarily violates the AKS).

regulations[5] applicable to value-based arrangements to make it easier for medtech companies top engage more expansively in value-based arrangements than currently envisioned under the existing safe harbors. These changes, each of which we discuss in further detail below, are necessary to modernize the safe harbor regulations, encourage innovation, and to fully realize the promise of value-based healthcare in delivering better patient care at a lower cost for patients, providers, and payers and expanding access to underserved patient populations. Importantly, these changes would not constrain physician medical judgment, patient freedom of choice, or clinical decision-making in any way. Indeed, where we have proposed new safe harbor regulations, each safe harbor explicitly provides that the value-based arrangement protected "should not constrain physician medical judgment, patient freedom of choice, or clinical decision-making in any way." *See* Exhibits A, B, and C.

A. 42 CFR § 1001.952(h) – Discount Safe Harbor

We recommend that two aspects of the discount regulatory safe harbor—(1) the "single fiscal year" limitation and (2) the "same methodology" limitation—be revised. First, the regulatory discount safe harbor currently requires that the discount be earned by the buyer based on purchases "within a single fiscal year of the buyer." *See* 42 CFR § 1001.952(h)(1)(ii)(A).[6] To accommodate value-based arrangements that (1) measure value over episodes of care that may extend beyond the same fiscal year and (2) measure outcomes over periods that reflect the long-term value of a device, that period should be permissibly set based on a clinically appropriate time frame that the value-based arrangement is designed to demonstrate results. In other words, the measurement period for the discount should be consistent with the clinical and/or cost savings goals of the value-based arrangement. For example, if a five-year survival rate is a clinically important measure for a disease, the period that the buyer can earn the discount for a bundle designed to achieve five-year survival is appropriately five years. For all other discounts, we recommend extending the "single fiscal year" period to three years since a hospital can generally revise its cost report within 3 years of the date it was originally filed. Accordingly, we recommend revising the "single fiscal year" limitation to state that "[t]he discount must be earned on purchases of that same good or service bought within three years or, for a value-based enterprise as defined in 42 CFR § 1001.952(ee)(14)(viii), within the

[5] For purposes of these comments, we interpret "regulation" broadly to mean, without limitation, regulations, rules, memoranda, administrative orders, guidance documents, policy statements, and interagency agreements, regardless of whether the same were enacted through the processes in the Administrative Procedure Act, which is consistent with the definition of this term in Executive Order No. 14192 of January 31, 2025 ("Unleashing Prosperity Through Deregulation"). Because these comments propose some new regulations, and the Executive Order requires that at least 10 prior regulations be identified for elimination with each new regulation issued, we refer you to our response to the Executive Office of the President, Office of Management and Budget's Request for Information: Deregulation for a list of regulations that we propose be rescinded. *See* Letter to Director Russell T. Vought re: Request for Information: Deregulation; OMB-2025-0003-0001 (May 12, 2025), https://www.advamed.org/wp-content/uploads/2025/05/2025.05.12_AdvaMed-Comments-to-OMB-Deregulation-RFI.pdf.

[6] 42 CFR § 1001.952(h)(1)(ii): "If the buyer is an entity which reports its costs on a cost report required by the Department or a State health care program, it must comply with all of the following four standards—

(A) The discount must be earned based on purchases of that same good or service bought within a single fiscal year of the buyer."

time period documented for achieving the value-based purpose(s) or within three years, whichever period is longer."

Second, we propose striking the requirement in 42 CFR § 1001.952(h)(5)(ii)[7] that items and services included in a bundled discounting arrangement be "reimbursed by the same Federal health care program using the same mthodology" (often referred to as the "same methodology" requirement). Accordingly, 42 CFR § 1001.952(h)(5)(ii) would protect the supplying of one good or service without charge to induce the purchase of a different good or service without regard to whether the items and services are reimbursed under the same methodology.[8] There is no definition of "same methodology" in the regulatory discount safe harbor. Historically, HHS-OIG has interpreted the phrase to indicate that bundling items and services paid under the same payment system (e.g., the inpatient prospective payment system ("IPPS"), the outpatient prospective payment system ("OPPS"), etc.) meets the same methodology requirement.[9] For value-based arrangements, however, that interpretation is not sufficient. For example, a value-based arrangement aimed at reducing hospital readmissions may appropriately need to bundle items and services for the patient's inpatient stay reimbursed under the IPPS, with other items and services for post-operative, outpatient care that are reimbursed under a different payment methodology (e.g., OPPS).

Both of these revisions would help encourage value-based arrangements where the success of the arrangement is measured over years and reimbursement comes from different payment systems. For example, a hospital system could partner with a medtech company to design and implement a new workflow that improves access to care and outcomes for rural residents for stroke care. The solution could include a wide range of products and services from the medtech company including (a) construction of a new imaging center closer to patients, (b) new, cutting-edge medical imaging equipment with enabled artificial intelligence to better detect stroke conditions, (c) software designed to allow remote connections between a central radiology department and a remote facility, (d) scheduling software to more efficiently schedule availability of facility space and personnel, (e) staff augmentation services to help place qualified radiology techs and nurses, and (f) consulting services to help design new workflows and improved efficiencies. A value-based arrangement such as this—where the hospital system and medtech company

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[7] 42 CFR § 1001.952(h)(5): "For purposes of this paragraph, the term discount means a reduction in the amount a buyer (who buys either directly or through a wholesaler or a group purchasing organization) is charged for an item or service based on an arms-length transaction. The term discount does not include—

. . .

(ii) Supplying one good or service without charge or at a reduced charge to induce the purchase of a different good or service, unless the goods and services are reimbursed by the same Federal health care program using the same methodology and the reduced charge is fully disclosed to the Federal health care program and accurately reflected where appropriate, and as appropriate, to the reimbursement methodology."

[8] Alternatively, additional guidance could be issued expanding the definition of "same methodology" to include bundled discount arrangements in which all items and services are reimbursed: (1) under a cost- or charge-based reimbursement methodology; or (2) based on a prospectively determined rate (e.g., OPPS and IPPS) or fee schedules that are unrelated to the provider's costs or charges.

[9] *See* HHS-OIG Adv. Op. No. 21-14 (Oct. 5, 2021).

share risk and reward—could lead to reduced costs (especially upfront costs) for the hospital system and improved outcomes at a lower cost per patient.

B. 42 CFR § 1001.952(g) – Warranties Safe Harbor

We recommend that the warranties safe harbor regulation at 42 CFR § 1001.952(g) and all related HHS-OIG Advisory Opinions[10] be rescinded and replaced with the value-based warranty safe harbor regulation proposed in Exhibit A.[11] The current warranties safe harbor regulation inhibits beneficial value-based arrangements, which are imperative for patient care and innovation, as discussed above. For example, it 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 medtech company's product was not achieved—clearly at odds with the goals of value-based care. Indeed, a medtech company putting such an arrangement into place could face allegations that it has violated the AKS simply because of having stood behind its product through such a warranty. In contrast, our proposed value-based warranty safe harbor regulation 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 medtech company to share risk by providing a payment, item, or service when a targeted clinical or economic outcome is not realized. For example, if an infection occurs from contaminated equipment or if a readmission occurs within a certain number of days of a device implant surgery and a new surgery is needed, the medtech company could cover the cost of care for treating the infection or cover the cost of the replacement surgery.

C. 42 CFR § 1001.952(d)(2) – Outcomes-Based Payments Safe Harbor

We recommend that the outcomes-based payments safe harbor regulation at 42 CFR § 1001.952(d)(2) and all related HHS-OIG Advisory Opinions be rescinded and replaced with the value-based pricing arrangements safe harbor regulation proposed in Exhibit B.[12] The current outcomes-based payments safe harbor regulation excludes from protection payments made directly or indirectly by medtech companies notwithstanding the important role these parties can and do play in value-based arrangements. In addition, the current safe harbor is unnecessarily narrow as a result of the benchmarks used to measure outcomes, including requiring "a material reduction in costs to or growth in expenditures to payors while maintaining

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[10] Including HHS-OIG Adv. Op. No. 01-8 (July 3, 2001), HHS-OIG Adv. Op. No. 02-6 (May 14, 2002), HHS-OIG Adv. Op. No. 17-03 (Aug. 18, 2017), HHS-OIG Adv. Op. No. 18-10 (Sept. 10, 2018), and HHS-OIG Adv. Op. No. 21-12 (Sept. 10, 2021).

[11] This recommendation is similar to a previous AdvaMed recommendation made in 2019. *See* Advanced Medical Technology Association, Letter to Deputy Secretary Eric Hargan re: Safe Harbors for Value-Based Arrangements (May 8, 2019), https://www.advamed.org/member-center/resource-library/may-8-2019-advamed-letter-refining-value-based-safe-harbor-proposals (see Value-Based *Warranty* Safe Harbor Proposal on p. 11 of the PDF).

[12] This recommendation is similar to a previous AdvaMed recommendation made in 2019. *Id.* (*see* Value-Based *Pricing* Arrangements Safe Harbor Proposal on p. 5 of the PDF).

or improving quality of care for patients." With these limitations, the outcomes-based payments safe harbor regulation does not protect outcomes-based payments for arrangements that reduce internal costs to providers and/or lead to more efficient delivery of care to underserved patient populations.

The proposed value-based pricing arrangements safe harbor regulation would allow for price adjustments based on the achievement of a measurable outcome. For example, if a device does not improve a customer's quality metric for detecting a certain symptom by a certain amount (e.g., 25%), the company could provide a 30% rebate. Conversely if the device improved that quality metric by the required amount, entitling the customer to increased reimbursement under the Merit-Based Incentive Payment System program, the company could receive a share of the increased reimbursement.

D. 42 CFR § 1001.952(ff) – Substantial Downside Risk Safe Harbor and 42 CFR § 1001.952(gg) – Full Financial Risk Safe Harbor

We recommend that the substantial downside risk and full financial risk safe harbor regulations at 42 CFR § 1001.952(ff) and 42 CFR § 1001.952(gg), respectively, be rescinded and replaced with the value-based risk sharing arrangements safe harbor regulation proposed in Exhibit C.[13] These risk-based safe harbors exclude from protection remuneration value-based risk sharing arraignments between medtech companies and other entities, notwithstanding the important role medtech companies can and do play in value-based arrangements. In addition, these safe harbors are unnecessarily narrow in that they only protect activities undertaken once a contractual obligation is in place, not legitimate pre-arrangement activities, and they include restrictions against ownership or investment interests, which means the participants are unable to dictate the corporate structure of enterprises they create and for which they assume financial risk. These limitations inhibit value-based arrangements that improve patient care and encourage innovation. For example, under the current framework, a medtech company could not enter into a value-based risk sharing arrangement with a hospital system through which the medtech company would provide devices, technology, and consulting services intended to improve patient care or operational efficiencies and be compensated based on whether certain metrics were achieved. Under the proposed value-based risk sharing arrangements safe harbor, a medtech company could enter into such an arrangement, which would lead to reduced costs and/or improved patient outcomes because the parties would be incentivized to work together to achieve those goals.

Alternatively, all of these value-based safe harbors[14] should collectively be revised to allow medtech companies to qualify for their protection. Currently, the value-based safe harbors exclude medtech companies because, at the time of promulgation, HHS-OIG believed that: (1) medtech companies are not at the frontline of care coordination; and (2) based on historical enforcement experience, medtech

[13] This recommendation is similar to a previous AdvaMed recommendation made in 2019. *Id.* (see Value-Based *Risk-Sharing* Arrangements Safe Harbor Proposal on p. 17 of the PDF)

[14] 42 CFR § 1001.952(d)(2), (ee), (ff), (gg).

companies are more likely to misuse the safe harbors.[15] Both are misguided assumptions.

Regarding care coordination, medtech companies don't just produce medical devices and diagnostics that save and improve patients' lives, they provide a range of solutions that include products and services to improve patient outcomes. CMS recently has recognized this, specifically "seeking public input on how best to advance a seamless, secure, and patient-centered digital health infrastructure." Indeed, today's medtech companies are true partners in care, working to diagnose, treat and manage disease, bring in useful data, and share accountability for achieving better outcomes and managing costs. For example:

- Manufacturers of insulin pumps and continuous glucose monitors are entering into value-based arrangements in the commercial market that tie reimbursement for advanced diabetes management technologies to the achievement of clinically meaningful, outcomes-related metrics such as Time in Range or reduced diabetes-related hospitalizations. They are also introducing combinations of devices, patient-engagement tools, and support services designed to both improve diabetes management and coordination of care with their physician.

- Manufacturers of implantable and retrievable medical devices are working with hospitals and EMS providers to offer tools to more quickly diagnose, route and, on the hospital end, prepare for arrival and treatment of patients who need every single minute, such as those suffering from stroke or a cardiac event.

- Medtech companies are also developing data analytics and related services. Working with health systems, these tools can help identify patients for targeted interventions or allow resources to be allocated more efficiently and effectively, ensuring the right treatment gets delivered to the right patient in the right setting at the right time, while also tracking and measuring outcomes.

As for HHS-OIG's concerns regarding the risk of fraud and abuse that could come with allowing medtech companies to gain the protection of the value-based safe harbor regulations, those safe harbors already include numerous requirements that effectively mitigate that risk. Indeed, to gain the protection of those safe harbors, entities must, among other things, include documented processes; establish monitoring and tracking of evidence-based, valid outcomes measures against which arrangements would be evaluated; and prohibit limiting medically necessary items or services provided to patients. We believe these and other guardrails are sufficient to prevent waste, fraud, and abuse in the system and that an entity-agnostic

[15] *See* Medicare and State Health Care Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements, 85 Fed. Reg. 77,684, 77,711 (Dec. 2, 2020) ("[M]anufacturers of devices and medical supplies may play an important role in some value-based arrangements, including by offering digital health technologies that can improve coordination and management of care. However, we continue to believe, as a general matter, that they are not as directly engaged in care coordination as other entities, such as providers and clinicians. We continue to have concerns, as described in the OIG Proposed Rule, based on our historical law enforcement experience, that manufacturers of devices and medical supplies could misuse the flexibilities afforded by the value-based safe harbors to offer kickbacks under the guise of care coordination activities or to tether a clinician to a particular product.").

approach will promote innovative and patient-centered health care solutions.

Accordingly, the provisions of the value-based safe harbors that make medtech companies ineligible for protection—42 CFR § 1001.952(d)(3)(iii)(A)(5), (ee)(13)(v), (ff)(1)(v), (gg)(1)(v))—should be rescinded.

III. Conclusion

In order to ensure medtech companies can continue bringing lifesaving/life-enhancing technologies to patients as quickly and effectively as possible, and to ensure patient health and innovation thrives in the U.S., reasonable regulatory reform consistent with our comments herein is necessary.

Thank you in advance for your consideration of AdvaMed's comments. Please do not hesitate to contact Terry Chang (tchang@advamed.org) with any questions.

Sincerely,

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

EXHIBIT A

New AKS Safe Harbor for Value-Based Warranty Arrangements

AdvaMed recommends rescinding the current warranties safe harbor at 42 CFR § 1001.952(g) and replacing it with the following new safe harbor for value-based warranty arrangements:

(*) **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 with respect to value-based services described in paragraph (*)(5)(C)(i), 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.

(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.; and

(D) Upon the request of the Secretary or a State agency, the buyer provides the Secretary or such State agency (or its designee) the following information, all of which must be retained by the buyer for a period of at least 5 years following the completion of the value-based warranty arrangement:

i. the terms and conditions of any such value-based warranty remedy as fixed and

disclosed in writing pursuant to paragraph (*)(1) above;

ii. the amount of any such value-based warranty price adjustment and an itemization of any such warranty replacement items and/or services provided or paid for by the seller under the value-based warranty, together with a writing setting forth in reasonable detail the manner in which such value-based warranty remedy was determined, including the value(s) of any metric(s) relating to clinical and/or cost outcomes based upon which such value-based warranty remedy was conditioned or determined; and

iii. to the extent such value(s) of metric(s) relating to clinical or cost outcomes were determined by the buyer or based upon information provided by the buyer, information indicating the manner in which such metrics or information were obtained and factored into the determination of the value-based warranty remedy.

(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.

(D) Upon the request of the Secretary or a State agency, the seller provides the Secretary or such State agency (or its designee) the following information, all of which must be retained by the seller for a period of at least 5 years following the completion of the value-based warranty arrangement:

i. the terms and conditions of any such value-based warranty remedy as fixed and disclosed in writing pursuant to paragraph (*)(1) above;

ii. the amount of any such value-based warranty price adjustment and an itemization of any such warranty replacement items and/or services provided or paid for by the seller under the value-based warranty, together with a writing setting forth in reasonable detail the manner in which such value-based warranty remedy was determined, including the value(s) of any metric(s) relating to clinical and/or cost outcomes based upon which such value-based warranty remedy was conditioned or determined; and

iii. to the extent such value(s) of metric(s) relating to clinical or cost outcomes were determined by the seller or based upon information provided by the seller, information indicating the manner in which such metrics or information were obtained and factored into the determination of the value-based warranty remedy.

(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), reasonably necessary or appropriate 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 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. Value-based services should not constrain physician medical judgment, patient freedom of choice, or clinical decision-making in any way.

(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 buyer or 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.

EXHIBIT B

New AKS Safe Harbor for Value-Based Pricing Arrangements

AdvaMed recommends rescinding the current outcomes-based payments safe harbor at 42 CFR § 1001.952(d)(2), and replacing it with the following new safe harbor for value-based pricing arrangements:

(*) **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 with respect to value-based services described in paragraph (*)(5)(D)(i), 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.

(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;

(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 apart from the buyer's claim which includes the reimbursable items and/or services included in the value-based pricing arrangement; and

(C) Upon the request of the Secretary or a State agency, the buyer provides the Secretary or such State agency (or its designee) the following information, all of which must be retained by the buyer for a period of at least 5 years following the completion of the value-based pricing

arrangement:

i. the terms and conditions of any such value-based price adjustment as fixed and disclosed in writing pursuant to paragraph (*)(1) above;

ii. the amount of any such value-based price adjustment, together with a writing setting forth in reasonable detail the manner in which such value-based price adjustment was determined, including the value(s) of any metric(s) relating to clinical and/or cost outcomes based upon which such value-based price adjustment was conditioned or determined; and

iii. to the extent such value(s) of metric(s) relating to clinical or cost outcomes were determined by the buyer or based upon information provided by the buyer, information indicating the manner in which such metrics or information were obtained and factored into the determination.

(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.; and

(D) Upon the request of the Secretary or a State agency, the seller provides the Secretary or such State agency (or its designee) the following information, all of which must be retained by the seller for a period of at least 5 years following the completion of the value-based pricing arrangement:

i. the terms and conditions of any such value-based price adjustment as fixed and disclosed in writing pursuant to paragraph (*)(1) above;

ii. the amount of any such value-based price adjustment, together with a writing setting forth in reasonable detail the manner in which such value-based price adjustment was determined, including the value(s) of any metric(s) relating to clinical and/or cost outcomes based upon which such value-based price adjustment was conditioned or determined; and

iii. to the extent such value(s) of metric(s) relating to clinical or cost outcomes were determined by the seller or based upon information provided by the seller, information indicating the manner in which such metrics or information were obtained and factored into the determination.

(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), reasonably necessary or appropriate 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 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. Value-based services should not constrain physician medical judgment, patient freedom of choice, or clinical decision-making in any way.

(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).

EXHIBIT C

New AKS Safe Harbor for Value-Based Risk-Sharing Arrangements

AdvaMed recommends rescinding the current substantial downside risk and full financial risk safe harbors at 42 CFR § 1001.952(ff) and 42 CFR § 1001.952(gg), respectively, and replacing them with the following new safe harbor for value-based risk sharing arrangements:

(*) **Value-based, risk sharing arrangements**. As used in section 1128B of the Act, "remuneration" does not include any transfer of value provided under a Value-Based Risk Sharing Arrangement, as defined herein, as long as the following standards (as applicable) are met —

(1) 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 section, remuneration shall also not include participant activities reasonably necessary or appropriate to (i) 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 (ii) 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 subparagraph, 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.

(2) 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.

A Value-Based Risk Sharing Arrangement should not constrain physician medical judgment, patient freedom of choice, or clinical decision-making in any way.

(3) Upon the request of the Secretary or a State agency, a participant provides the Secretary or such State agency (or its designee) the following information, all of which must be retained by the participant for a period of at least 5 years following the completion of the Value-Based Risk-Sharing Arrangement:

i. the written agreement setting forth such Value-Based Risk-Sharing Arrangement pursuant to paragraph (*)(1) above; and

ii. the amount of each payment or other transfer of value provided or received by such participant under such Value-Based Risk Sharing Arrangement based upon such participant's assumed financial risk thereunder, together with a writing setting forth in reasonable detail the manner in which such payment or other transfer of value was determined in accordance with the methodology set forth in the Value-Based Risk Sharing Arrangement.