AdvaMed
Advanced Medical Technology Association

February 9, 2026

By Electronic Submission via www.regulations.gov

Mr. Thomas March Bell
Office of Inspector General, Regulatory Affairs
Department of Health and Human Services
Attention: OIG-1125-N
Room 5628, Cohen Building
330 Independence Avenue SW
Washington, D.C. 20201

Re: OIG-1125-N: Solicitation of Proposals for New and Modified Safe Harbors and Special Fraud Alerts

Dear Mr. Bell:

The Advanced Medical Technology Association (AdvaMed) appreciates this opportunity to submit proposals for additional or modified safe harbor provisions under the federal Anti-Kickback Statute (AKS)[1] and Special Fraud Alerts in response to the Solicitation of Proposals for New and Modified Safe Harbors and Special Fraud Alerts, published by the Office of the Inspector General of the Department of Health and Human Services (OIG) at 90 Fed. Reg. 57,016 (December 9, 2025).

As further discussed below, we recommend OIG (i) develop additional and modified safe harbors, including related to value-based arrangements; (ii) categorically exclude physician owned distributors from protection under all of the safe harbors for value-based arrangements and maintain its longstanding cautious approach with respect to physician owned distributors; and (iii) continue to investigate and prevent abusive pay-to-play schemes and consider collaborating with CMS and stakeholders to endorse the development of a nonprofit, nationwide credentialing platform for Health Care Industry Representatives. AdvaMed believes that these proposals, if accepted and implemented, will help advance OIG's ongoing efforts to modernize and transform our health care system into one that pays for value rather than volume by reducing inefficiencies, controlling and cutting health care delivery costs, promoting access to medical technology, improving patient outcomes, and championing innovation. We welcome the opportunity to assist OIG in its efforts and remain available to discuss further the recommendations included in these comments.

[1] Section 1128B(b) of the Social Security Act, 42 U.S.C. § 1320a-7b(b).

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

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 invent, develop, distribute, and manufacture 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 medical technology ("medtech") innovators and companies, help patients stay healthier longer, recover more quickly after treatment, and improve clinicians' ability to detect disease (including chronic diseases) 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.[2] Yet, this medtech innovation ecosystem is fragile and extremely sensitive to changes in the cost of innovation, which is substantial.[3]

The fragility of the medtech innovation ecosystem results from several factors, including the extremely expensive development process from concept to product launch.[4] 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, inconsistent with the law, overly burdensome, outdated, 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.

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[2] 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). Available at https://freopp.org/wihi2020-505b1b60bce6.

[3] *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, available at 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).

[4] *Id.*

II. Proposals for New and Modified Safe Harbors and Special Fraud Alerts

A. Proposals for New and Modified Anti-Kickback Safe Harbors, Including to Support Value-Based Arrangements

We recommend that the current AKS regulations, including those applicable to value-based arrangements, be rescinded, replaced, or revised to make it easier for medtech companies to engage more expansively in value-based arrangements[5] 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..

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.

Importantly, our recommended changes would not constrain physician medical judgment, patient freedom of choice, or clinical decision-making in any way, nor tether a provider to a particular product or knowingly induce a provider to select products that may not be clinically appropriate for, or in the best interest of, a patient. 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."

We acknowledge OIG's response in the HHS-OIG Fall 2025 Semiannual Report to Congress in which the agency recognized the possibility of entities misusing potential modifications made to safe harbors for the

[5] Except as otherwise noted herein, our use of the phrase "value-based arrangement" throughout is not limited to those arrangements currently defined at 42 C.F.R. § 1001.952(ee)(14)(vii). We use the phrase "value-based arrangement" throughout to refer to arrangements to advance value-based care (also referred to as results-based, outcomes-based, or performance-based payment arrangements) that are designed to increase shared accountability among stakeholders for quality of, access to, and/or the total cost of care. These arrangements often condition payment or modify pricing for health care items or services based upon clinical, economic, and/or patient-experience outcomes, and may include payor-driven reimbursement arrangements for providers, arrangements between providers, and arrangements between providers and manufacturers or other participants in the health care system.

purpose of supporting value-based arrangements. [6] We understand OIG's concerns and the complexities of this issue, and appreciate the agency's willingness to continue evaluating the ways in which these arrangements may contribute to the coordination of care and overall delivery of high-value care. As OIG continues to evaluate these arrangements, AdvaMed welcomes all opportunities to discuss how to address the agency's concerns as noted in its report.

Specifically, and as further discussed below, we recommend the following changes to the current AKS regulations:

- Revise the discount safe harbor at 42 CFR § 1001.952(h) to reflect the modern reimbursement environment and to protect legitimate and effective value-based arrangements;
- Rescind the current warranties safe harbor at 42 CFR § 1001.952(g) and replace it with the value-based warranty safe harbor proposed in Exhibit A;
- Rescind the current outcomes-based payments safe harbor at 42 CFR § 1001.952(d)(2) and replace it with the value-based pricing arrangements safe harbor proposed in Exhibit B;
- Rescind the substantial downside risk and full financial risk safe harbors at 42 CFR § 1001.952(ff) and 42 CFR § 1001.952(gg), respectively, and replace them with the value-based risk sharing arrangements safe harbor proposed in Exhibit C; and
- Revise the personal services and management contracts safe harbor at 42 CFR § 1001.952(d) to protect certain independent contractor commissions-based compensation arrangements.

1. 42 CFR § 1001.952(h) – Discount Safe Harbor

We recommend revising two aspects of the discount regulatory safe harbor—(1) the "same methodology" limitation; and (2) the discount definition exclusion for personal or management services contracts. These proposed revisions, together with the corresponding revisions recommended further below to the warranties safe harbor, remove current regulatory barriers to protect value-based arrangements among collaborating providers, payers and medtech companies, thereby supporting technological innovation, greater access to or delivery of care or services, and the ability to effectively address chronic health conditions and promote health and wellbeing.

a. Same Methodology

First, we recommend striking the requirement in 42 CFR § 1001.952(h)(5)(ii) that items and services included in a bundled discounting arrangement be "reimbursed by the same Federal health care program using the same methodology" (often referred to as the "same methodology" requirement). Accordingly,

[6] *See* HHS OIG FALL 2025 SEMIANN. REP. TO CONG. 29–30 (Jan. 21, 2026).

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. There is no definition of "same methodology" in the regulatory discount safe harbor. The regulatory history of the bundled discount provision suggests 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.[7]

The concern animating the "same methodology" requirement relates to situations where connecting the price of items or services reimbursed by Medicare under different payment methodologies could result in shifting costs among reimbursement systems and distorting the true cost of items and services to federal healthcare programs. 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. However, there is very little remaining cost-based or charged-based reimbursement, as opposed to reimbursement based on a prospectively determined rate (*e.g.*, diagnostic related groups ("DRGs") and ambulatory payment classifications ("APCs")) or fee schedules that are unrelated to the provider's costs or charges. As such, the fraud and abuse risks stemming from incorrect reporting of such costs are much less significant than they once were. The "same methodology" limitation can materially restrict the range of possible devices and services that may be integrated to deliver the best value.

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 what might be considered a different payment methodology (e.g., OPPS). Further, because reimbursement rules are complicated and can vary significantly depending on the site of care (e.g. acute care hospital versus physician clinic or skilled nursing facility) this "same methodology" limitation can materially restrict the range of possible innovative devices and services that may be integrated to deliver the best value because of the uncertainty around what

[7] *See* Medicare and State Health Care Programs: Fraud and Abuse; Revisions and Technical Corrections, 65 Fed. Reg. 63035, 63035 (proposed Oct. 20, 2000) (to be codified at 42 C.F.R. pts. 1001, 1003, 1005 and 1008). OIG proposed a "clarification" to the safe harbor over twenty-five years ago, that would have inserted the following parenthetical after the reference to the "same methodology" in the safe harbor: "(*e.g.*, under the same DRG, prospective payment, or per diem, but not including fee schedules)." The proposed clarification would have narrowed the concept of "same methodology" to mean "same payment," so that, for example, items paid under the same DRG may be bundled, but not items paid under different DRGs. However, the proposed revision to the safe harbor was never enacted, and was eventually withdrawn, in 2002. OIG's decision to withdraw the proposal suggests that it did not ultimately believe that the "same methodology" meant only the "same payment." Stakeholders who submitted comments in response to the 1999 final rule and 2000 proposed rule advocated that all payment methodologies, including fee schedules, be covered by the same methodology concept. 64 Fed. Reg. 63518, 63527 (Nov. 19, 1999); 65 Fed. Reg. 63035, 63035 (proposed Oct. 20, 2000). *See also* OIG Adv. Op. No. 21-14 (Oct. 5, 2021) (OIG's position in Advisory Opinion 21-14 is consistent with interpreting the "same methodology" to be at the payment system level (e.g., IPPS, OPPS, etc.).

products or services would be considered to fall under the "same methodology."

The "same methodology" limitation is also outdated and unworkable in today's complicated reimbursement environment. In order to improve clinical or cost outcomes it is often essential to craft value-based arrangements around a combination of items and/or services. Moreover, in many cases, items or services included in a bundle are not reimbursed specifically but might be deemed reimbursed indirectly as part of a payment for another item or service; in such cases there might be numerous potential payments or reimbursement methodologies that could be viewed as providing such indirect reimbursement. However, it is frequently impossible to determine that the same program/methodology criteria will be satisfied with respect to all the items and services included in a discounted bundle.

As an alternative to striking the requirement in 42 CFR § 1001.952(h)(5)(ii) that items and services included in a bundled discounting arrangement be "reimbursed by the same Federal health care program using the same methodology," 42 CFR § 1001.952(h)(5)(ii) could be revised to clarify that the term discount includes discounted bundle arrangements in which all items/services are reimbursed: (1) under cost- or charged-based reimbursement methodology; or (2) based on a prospectively determined rate (e.g., DRGs or APCs) or fee schedules that are unrelated to the provider's costs or charges.[8] Such a clarification is reasonable and appropriate because while costs reported by hospitals are averaged and theoretically used by CMS to inform future adjustments to DRG and APC payment rates, hospital costs don't impact DRG or APC payments, outside of very specific (and limited) circumstances (e.g., Medicare add-on payments related to devices, i.e., new technology add-on payment ("NTAP") and transitional pass-through ("TPT")). And even with respect to NTAP and TPT add-on payments, bundling items/services eligible for these add-on payments with those that are not so eligible still does not affect Medicare reimbursement. This is because Medicare uses a hospital's cost-to-charge ratio (CCR) to determine NTAP and TPT reimbursement. For at least one hospital we are aware of, CCR is calculated using specific lines in a cost report, but no single line in the cost report used to calculate CCR are attributable to device costs.[9]

b. Personal Services

Third, we recommend rescinding 42 CFR § 1001.952(h)(5)(vi), which currently provides, "The term discount does not include— . . . Services provided in accordance with a personal or management services

[8] As revised, 42 CFR § 1001.952(h)(5)(ii) could read, "The term *discount* does not include— . . . 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. *(For purposes of paragraph (h)(5)(ii) of this section, goods and services reimbursed according to a cost- or charged-based methodology, pursuant to prospectively determined rates, and based on fee schedules that are unrelated to the buyer's costs or charges are considered to be reimbursed by the same Federal health care program using the same methodology.)"*

[9] *See United States of America ex rel. Thomas Schroeder v. Medtronic, Inc., and Hutchinson Regional Medical Center*, , No. 17-2060-DDC-BGS at *FN 13 (D. Kan. Sep. 26, 2024) (Declaration of Tony Maida in Support of Medtronic, Inc. and Covidien L.P.'s Partial Motion for Summary Judgment and Opposition to Relator's Motion for Partial Summary Judgment).

contract." This exclusion from the definition of discount is ambiguous and may disincentivize legitimate and effective value-based arrangements that involve discounts linked to and/or premised on the performance of personal services. Alternatively, we recommend revising 42 CFR § 1001.952(h)(5)(vi) to clarify that the exclusion from the definition of discount related to services provided in accordance with a personal or management services contract does not apply if the accompanying services are provided under a value-based arrangement. The revised provision could read, "The term discount does not include— . . . Services provided in accordance with a personal or management services contract, unless such services are provided under an arrangement to advance value-based care."

The foregoing revisions would help encourage value-based arrangements where the success of the arrangement is measured over years, reimbursement comes from different payment systems[, and those involving discounts linked to the performance of personal services].

2. 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.

As an alternative, we recommend revising 42 CFR § 1001.952(g) to (1) clarify that certain restrictions under

[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).

the warranties safe harbor do not apply if the arrangement qualifies for a value-based arrangement; and (2) remove the requirement that all reimbursable items and services in a bundle warranty arrangement be reimbursed under the "same program, same payment" methodology, for similar reasons discussed above with respect to the discount safe harbor. Specifically, 42 CFR § 1001.952(g)(4) could be revised to read, "*Except for arrangements to advance value-based care,* the manufacturer or supplier must not pay any remuneration to any individual (other than a beneficiary) or entity for any medical, surgical, or hospital expense incurred by a beneficiary other than for the cost of the items and services subject to the warranty." And 42 CFR 1001.952(g)(5) (which currently provides, "If a manufacturer or supplier offers a warranty for more than one item or one or more items and related services, the federally reimbursable items and services subject to the warranty must be reimbursed by the same Federal health care program and in the same Federal health care program payment") could be rescinded in its entirety.

3. 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 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. Alternatively, we recommend the recission of 42 CFR § 1001.952(d)(3)(iii)(A)(5), which makes medtech companies ineligible for protection under this safe harbor.

4. 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

[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).

risk sharing arrangements safe harbor regulation proposed in Exhibit C.[13] These risk-based safe harbors exclude from protection remuneration paid under value-based risk sharing arrangements 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. Specifically, if the current safe harbor regulations for substantial downside risk and full financial risk at 42 CFR § 1001.952(ff) and 42 CFR § 1001.952(gg) are not rescinded and replaced with the value-based risk sharing arrangements safe harbor regulation proposed in Exhibit C, we recommend rescission of 42 CFR § 1001.952 (ee)(13)(v), (ff)(1)(v), and (gg)(1)(v), each of which make medtech companies ineligible for protection under the applicable safe harbors for care coordination arrangements to improve quality, health outcomes, and efficiency; value-based arrangements with substantial downside financial risk; and value-based arrangements with full financial risk, respectively, to allow medtech companies to qualify for their protection.

Currently, the value-based safe harbors exclude medtech companies because, at the time of promulgation, OIG believed that: (1) medtech companies are not at the frontline of care coordination; and (2) based on historical enforcement experience, medtech companies are more likely to misuse the safe

[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).

harbors.[15] Both beliefs are misguided.

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 has recognized this, specifically "seeking public input on how best to advance a seamless, secure, and patient-centered digital health infrastructure."[16] 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 enroute 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 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

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[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.").

[16] CMS Press Release, "CMS Seeks Public Input on Improving Technology to Empower Medicare Beneficiaries" (May 13, 2025), *available at* https://www.cms.gov/newsroom/press-releases/cms-seeks-public-input-improving-technology-empower-medicare-beneficiaries.

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 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, if 42 CFR § 1001.952(ff) and 42 CFR § 1001.952(gg) and not rescinded and replaced with the value-based risk sharing arrangements safe harbor regulation proposed in Exhibit C.

5. 42 CFR § 1001.952(d)(1) – Personal services and management contracts

We recommend revising the personal services and management contracts safe harbor regulation at 42 CFR § 1001.952(d)(1) to narrowly allow for independent contractor arrangements with compensation that varies based on the volume or value of referrals or business, so long as certain safeguards are met. Specifically, 42 CFR § 1001.952(d)(1) could be amended as follows to protect certain commissions-based compensation:

42 C.F.R. § 1001.952 Exceptions

The following payment practices shall not be treated as a criminal offense under section 1128B of the Act and shall not serve as the basis for an exclusion:

(d) Personal services and management contracts and outcomes-based payment arrangements.

(1) As used in section 1128B of the Act, "remuneration" does not include any payment made by a principal to an agent as compensation for the services of the agent, as long as all of the following standards are met:

(i) The agency agreement is set out in writing and signed by the parties.

(ii) The agency agreement covers all of the services the agent provides to the principal for the term of the agreement and specifies the services to be provided by the agent, and if such services include selling, promoting, or marketing the items or services provided by the principal, the agreement clearly identifies such products and services.

(iii) The term of the agreement is not less than 1 year.

(iv) The methodology for determining the compensation paid to the agent over the term of the agreement is set in advance, is consistent with fair market value in arm's-length transactions, and either is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare, Medicaid, or other Federal health care programs., or if the compensation

is determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare, Medicaid, or other Federal health care programs, then the agency agreement meets all of the following additional standards:

(A) The agent is expressly prohibited from soliciting or engaging with beneficiaries as defined in 42 C.F.R. § 1000.10;

(B) The agent is not employed by and does not have a direct or indirect financial relationship with any buyer purchasing items or services that are covered by the agency agreement;

(C) The agent is expressly prohibited from offering any discounts, rebates, or other sales incentives to any buyer purchasing items or services that are covered by the agency agreement except for the discounts, rebates and sales incentives approved by the principal;

(D) None of the items and services covered by the agency agreement are separately reimbursable by a Federal health care program, whether on the basis of charges or costs;

(E) The agency agreement requires the agent to comply with the principal's policies and lists the specific services to be performed by the agent in support of the sale, promotion or marketing the items or services provided by the principal and covered by the agency agreement, including, as applicable, product support, complaint management, and training and other specific services relating to the items or services covered by the agency agreement;

(F) The compensation payable to the agent:

(1) reasonably reflects the principal's good faith assessment of the fair market value of the services covered by the agency agreement pursuant to paragraph (E);

(2) is determined either (i) on the basis of the number of leads generated (such as per click fees for website visits, per call fees, or other similar measure) so long as the actual sales (or revenue from sales) of items or services covered by the agency agreement arising from those leads are not taken into account, or (ii) on the basis of a fixed percentage of the sales of items or services and the methodology for the determination is disclosed in the agency agreement;

(3) is not determined with respect to sales of or the volume of business that is related to or accounts for any items or services that are not covered by the agency agreement; and

(G) Prior to the commencement of services and at least annually thereafter, the agent, and employees, contractors and staff of the agent involved in the performance of services under the agency agreement, if any, are required to participate, and certify to the principal their participation in, training on compliance with, at a minimum, section 1128B of the Act, with such training to be substantially the same as that provided to the principal's employees and provided or arranged by the principal at its expense and without charge to the agent.

(v) The services performed under the agreement do not involve the counseling or promotion of a business arrangement or other activity that violates any State or Federal law.

(vi) The aggregate services contracted for do not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the services.

(2) As used in section 1128B of the Act, "remuneration" does not include any outcomes-based payment as long as all of the standards in paragraphs (d)(2)(i) through (viii) of this section are met:

(i) To receive an outcomes-based payment, the agent achieves one or more legitimate outcome measures that:

(A) Are selected based on clinical evidence or credible medical support; and

(B) Have benchmarks that are used to quantify:

(*1*) Improvements in, or the maintenance of improvements in, the quality of patient care;

(*2*) A material reduction in costs to or growth in expenditures of payors while maintaining or improving quality of care for patients; or

(*3*) Both.

(ii) The methodology for determining the aggregate compensation (including any outcomes-based payments) paid between or among the parties over the term of the agreement is: Set in advance; commercially reasonable; consistent with fair market value; and not determined in a manner that directly takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part by a Federal health care program.

(iii) The agreement between the parties is set out in writing and signed by the parties in advance of, or contemporaneous with, the commencement of the terms of the outcomes-based payment arrangement. The writing states at a minimum: A general description of the services to be performed by the parties for the term of the agreement; the outcome measure(s) the agent must achieve to receive an

outcomes-based payment; the clinical evidence or credible medical support relied upon by the parties to select the outcome measure(s); and the schedule for the parties to regularly monitor and assess the outcome measure(s).

(iv) The agreement neither limits any party's ability to make decisions in their patients' best interest nor induces any party to reduce or limit medically necessary items or services.

(v) The term of the agreement is not less than 1 year.

(vi) The services performed under the agreement do not involve the counseling or promotion of a business arrangement or other activity that violates any State or Federal law.

(vii) For each outcome measure under the agreement, the parties:

(A) Regularly monitor and assess the agent's performance, including the impact of the outcomes-based payment arrangement on patient quality of care; and

(B) Periodically assess, and as necessary revise, benchmarks and remuneration under the arrangement to ensure that the remuneration is consistent with fair market value in an arm's length transaction as required by paragraph (d)(2)(ii) of this section during the term of the agreement.

(viii) The principal has policies and procedures to promptly address and correct identified material performance failures or material deficiencies in quality of care resulting from the outcomes-based payment arrangement.

(3) For purposes of this paragraph (d):

(i) An agent of a principal is any person other than a *bona fide* employee of the principal who has an agreement to perform services for or on behalf of the principal.

(ii) Outcomes-based payments are limited to payments between or among a principal and an agent that:

(A) Reward the agent for successfully achieving an outcome measure described in paragraph (d)(2)(i) of this section; or

(B) Recoup from or reduce payment to an agent for failure to achieve an outcome measure described in paragraph (d)(2)(i) of this section.

(iii) Outcomes-based payments exclude any payments:

(A) Made directly or indirectly by the following entities:

(*1*) A pharmaceutical manufacturer, distributor, or wholesaler;

(*2*) A pharmacy benefit manager;

(*3*) A laboratory company;

(*4*) A pharmacy that primarily compounds drugs or primarily dispenses compounded drugs;

~~(*5*) A manufacturer of a device or medical supply as defined in paragraph (ee)(14)(iv) of this section;~~

(*6*) A medical device distributor or wholesaler that is not otherwise a manufacturer of a device or medical supply, as defined in paragraph (ee)(14)(iv) of this section; or

(*7*) An entity or individual that sells or rents durable medical equipment, prosthetics, orthotics, or supplies covered by a Federal health care program (other than a pharmacy or a physician, provider, or other entity that primarily furnishes services); or

(B) Related solely to the achievement of internal cost savings for the principal; or

(C) Based solely on patient satisfaction or patient convenience measures.

(iv) Financial relationship means any relationship or arrangement described in 42 C.F.R. § 411.354(a), but without regard to whether the buyer purchasing items or services that are covered by the agency agreement is a provider or supplier of designated health services.

To qualify for the protection of the personal services safe harbor regulation as it currently exists, compensation paid to independent contractors must not be "determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs."[17] In contrast, compensation paid to employees can take into the account the volume or value of referrals or business because such compensation is statutorily excluded from the reach of the AKS.[18]

Our proposed amendment to 42 CFR § 1001.952(d)(iv) is intended to address OIG's concerns of the potential for abusive practices by salespersons who are independent contractors, as opposed to employees, by requiring appropriate supervision and control of independent contractors by principals similar to that of the supervision and control of employees by employers.[19] We believe it also aligns with the position that DOJ has taken in enforcing a similar provision contained in the Eliminating Kickbacks in

[17] 42 CFR 1001.952(d)(1)(iv).

[18] 42 USC 1320a-7b(b)(3)(b); *see also* 54 Fed. Reg. 3088 (Jan. 23, 1989) ("This statutory exemption permits an employer to pay an employee in whatever manner he or she chooses for having that employee assist in the solicitation of Medicare or State health care program business.").

[19] *See* 56 Fed. Reg. 35952 (July 29, 1991).

Recovery Act ("EKRA").[20]

The reason that employees are allowed to be compensated based on the volume or value of referrals or business under the employee safe harbor is that OIG expects that employees will receive adequate training and supervision from their employers regarding compliance with the AKS.[21] Yet independent contractors can, and often are, subjected to the same or similar training and supervision as employees, by virtue of a company's policies. Accordingly, allowing one to be compensated based on the volume or value of referrals or business but subjecting the other to potential AKS liability if compensated in that manner makes little sense. Under our proposal, protection would only be available for independent contractors paid on a commission basis if the agent is required to comply with the principal's policies, including with respect to training and supervision.

Revising the personal services safe harbor to protect properly structured commissions-based compensation arrangements would also alleviate the anti-competitive and unduly burdensome nature of the current personal services safe harbor regulation. As an example, consider that under the current regulations companies that sell technology that is utilized with medical devices but is not be categorized as a medical device or reimbursable by Federal health care programs (e.g., connectivity platforms/remote radiology solutions/ software informatics) may compensate independent contractors on a commission basis, yet a medical device company that has similar offerings could not do so. Similarly, the decision to employ sales representatives versus engage independent contractors to perform the same functions is a company-specific determination that is based on a variety of factors and considerations. Protecting those companies that choose to, or can, employ sales representatives, but not those companies that choose to, or must, engage independent sales representatives may create an unequal playing fields amongst competitors. In particular, a company with in-house (employed) sales representatives is at an advantage over smaller, start-up, or newer companies that may have to rely on independent contractors/distributors for market reach. Large manufacturers have broad product portfolios and sufficient revenues to support full time sales employees compensated on a commission basis, while smaller companies with limited product offerings may not be able to effectively reach the market without using independent sales agents who typically receive, and in fact expect, compensation paid on a commission basis. Innovation in medtech is often driven by smaller companies that are at a competitive disadvantage by the limitations in the personal services and management agreement safe harbor.

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[20] During oral argument in *United States of America v. Schena*, 23-2989, (9th Cir.), DOJ distinguished problematic incentive compensation arrangements under EKRA from commonplace arrangements with employees. Specifically, DOJ stated that "it's very fact dependent" whether commission-based payments to marketers are suspect, "[a] percentage-based payment is not per se unlawful," and "the structure of a contract alone would not be by itself sufficient evidence [to establish an EKRA violation]." DOJ confirmed that the government has to show "that the purpose of the … quid pro quo was to induce referrals. It is not to compensate marketing or advertising or hours worked or other legitimate services, that it is in exchange for the referrals."

[21] *See* 56 Fed. Reg. 35952 (July 29, 1991).

Commission based payments to independent contractors are not *per se* illegal under the AKS,[22] but they are not protected under the current regulations. This means that medtech companies may seek to structure arrangements in a manner that they believe are likely to mitigate any potential AKS risk, for example by avoiding suspect characteristics identified by OIG.[23] But even if medtech companies do so, they have no guarantee of how an arrangement will be analyzed by OIG or DOJ, unless the company seeks an advisory opinion from the OIG or is subject to an investigation or litigation brought by or on behalf of the DOJ, both expensive and time-consuming propositions. This approach is unduly burdensome and unfair for medtech companies. It also encourages financially motivated whistleblowers to allege that legitimate and longstanding, industry-standard commissions arrangements with independent contractors violate the AKS and, by extension, the False Claims Act ("FCA"). Compounding matters, courts frequently resist dismissing even weak cases early, subjecting healthcare organizations to costly and ultimately unnecessary discovery costs. These misguided and opportunistic FCA cases also drain government resources, requiring DOJ to expend time and resources that could be better spent elsewhere than investigating legitimate arrangements.

Revising the personal services safe harbor as we propose would shut down improper attempts to drain government and corporate resources through opportunistic FCA actions, safeguard against OIG's primary concerns with independent contractor relationships, and protect industry standard commissions-based arrangements thereby promoting appropriate competition. Further, our proposal includes safeguards OIG has itself accepted in declining enforcement in certain cases of commission-type payments to independent sales agents, would ensure the personal services safe harbor protects proper arrangements that do not implicate any of the purposes underlying the AKS, and would facilitate innovation by creating a level playing field for smaller companies.[24]

B. Proposals Related to Physician-Owned Distributors

1. Exclusion of Physician-Owned Distributors from Safe Harbor Protection

We recommend that OIG categorically exclude physician owned distributors ("PODs") from protection under all of the safe harbors for value-based arrangements, although such exclusion should not extend to

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[22] *See United States v. Sorensen*, 134 F.4th 493, 502 (7th Cir. 2025); 85 Fed. Reg. 77684, 77701 (Dec. 2, 2020) ("We remind readers that failure to comply with a safe harbor provisions (or any attendant, defined term) does not mean that an arrangement is per se illegal.").

[23] *See* HHS OIG, Advisory Opinion No. 98-10 (Sept. 8, 2025), https://oig.hhs.gov/compliance/advisory-opinions/98-10/ (concluding that an arrangement involving payment of a sales commission to an independent manufacturers' representative for the sale and distribution of disposable medical supplies could constitute prohibited remuneration under the AKS if requisite intent were present, but that OIG would not subject the arrangement to AKS sanctions; including characteristics of arrangements among sellers, sales agents, and purchasers that appear to be associated with an increased potential for program abuse).

[24] *See* T. Bulleit, *Right-sizing Inflation in Anti-kickback Law Rhetoric: Avoiding Unnecessary Market Distortion in Commissions on Medical Device Sales,* Indiana Health Law Review, Volume 22, pp. 27-62 (2025).

manufacturers of devices and medical supplies and DMEPOS companies with physician ownership for legitimate business reasons. In general, PODs are entities that derive revenue from selling, or arranging for the sale of, devices ordered by their physician-owners for use in procedures the physician owners perform on their own patients. PODs are created primarily to allow treating physicians to enter the medical device supply chain, and such arrangements permit the physician owners to profit from selling products to hospitals at which the POD's physician owners treat their patients. PODs pose conflicts of interest and ethical concerns that are incompatible not only with the AKS, but also with the Stark Law, and a physician is placed in a conflict situation when personal financial incentives are dependent on the choice of treatment options with no counterweighing incentive to achieve certain clinical outcomes and reduce costs.

There are clear distinctions between legitimate, innovative manufacturers with physician ownership for legitimate business reasons apart from the ability to generate referrals to the manufacturer on the one hand, and PODs on the other hand. Many start-up manufacturers that create innovative, groundbreaking technology have an element of physician ownership (e.g., as a result of a founding investment, a transfer of equity in exchange for bona fide consulting services, or a contribution of novel, significant, or innovative intellectual property). Innovative manufacturers' revenue, however, is not tied to physician owners, their referrals, or the procedures they perform using the manufacturer's products. Physician ownership interests in these innovator manufacturers, in fact, generally form an insignificant portion of the manufacturer's total equity.

PODs, on the other hand, simply sell or arrange for the sale of existing implantable devices and are not innovators of new products. PODs tend to sell only to a handful of entities, frequently even just one entity, and a majority of a suspect POD's revenue is derived from its physician owners, their referrals, and/or the procedures they perform using POD-distributed devices. In fact, the primary purpose of the POD itself is to benefit the physician owners. PODs have no incentive to participate in value-based arrangements that seek to encourage cost savings across the continuum of care, and in fact, their model specifically discourages value-based initiatives that may create cost savings at the point-of-sale.

2. Maintain Caution With Respect to Physician-Owned Distributor Arrangements

We further recommend OIG maintain its longstanding cautious approach with respect to PODs, particularly as it pertains to issuing favorable Advisory Opinions for POD arrangements.

In August of 2025, OIG issued Advisory Opinion 25-09, an opinion in response to a POD Requestor that determined the arrangement at issue did not generate prohibited remuneration under the Federal anti-kickback statute because the POD was protected by the small entity investment safe harbor.[25] The favorable opinion was issued, in part, because the Requestor had certified that no more than 40 percent of the value of the investment interests of each class of investment interests were held or had been held in the previous fiscal year or previous 12-month period by investors in a position to make or influence

[25] HHS OIG, Advisory Opinion No. 25-09 (Aug. 12, 2025), https://oig.hhs.gov/compliance/advisory-opinions/25-09/.

referrals to, furnish items or services to, or otherwise generate business for the Requestor. Presumably, if more than 40 percent of gross revenue came from referrals generated by investors in a subsequent 12-month period, the Requestor would no longer be protected by the small entity investment safe harbor. However, there is no direct obligation to track or report this information, and it is currently unclear whether OIG or CMS monitors and audits the associated utilization. Questions therefore remain with respect to whether Advisory Opinion 25-09 will function as a loophole for suspect POD arrangements.

Despite the favorable nature of its opinion, OIG still emphasized its longstanding concerns regarding such entities and highlighted its own previous finding in a 2013 Special Fraud Alert that certain types of physician-owned entities are inherently suspect.[26] We agree and hope this favorable opinion does not signal a shift in how OIG views PODs. We welcome the opportunity to discuss this issue further with OIG.

C. Proposals related to Credentialing Health Care Industry Representatives

We recommend OIG continue to investigate and prevent abusive pay-to-play schemes and collaborate with CMS and stakeholders to endorse the development of a nonprofit, nationwide credentialing platform for Health Care Industry Representatives ("HCIRs"). Additionally, we welcome further engagement with and guidance from OIG regarding this issue.

HCIRs are specialists from medical technology companies who provide training and technical support for medical devices used in hospitals and operating rooms ("ORs"). They are sometimes called "company representatives" or "reps" and function to help clinical teams understand how to safely and effectively use and maintain medical devices. Clinicians request HCIR to be present during surgical procedures to provide real-time technical guidance. They may need to explain how a medical technology's unique settings and technical controls function and may make recommendations. HCIRs may also calibrate devices or input settings according to the physician's specifications. For example, a representative could assist the surgical team in calibrating a laser or programming a pacemaker to the surgeon's specifications. This support helps procedures proceed efficiently and can improve patient outcomes by optimizing device performance.[27]

However, the credentialing requirements to permit HCIRs access to hospitals vary widely across the country. Each hospital may impose its own credentialing requirements (including certain background checks, drug tests, immunization proofs, training modules, and vendor-specific fees for third-party credentialing services). The proliferation of varied credentialing requirements, the lack of reciprocity between facilities, and frequent demands for "primary source" verification of documents (even when a credential had already been verified elsewhere) have resulted in highly inefficient and duplicative

[26] *Id*.

[27] Additional background on the role of HCIRs is available at https://www.advamed.org/health-care-industry-representatives-hcirs/.

credentialing processes. This patchwork imposes heavy costs on the healthcare system – over $1 billion annually by one estimate – and slows the deployment of qualified industry reps who support patient care, in some cases resulting in delays to urgent care. Further, the implementation of "expedited review fees" by credentialing services for routine but necessary approvals force HCIRs to choose between paying additional out-of-pocket expenses or providing support for scheduled patient cases. Small businesses and new market entrants are especially disadvantaged, as they must navigate a maze of credentialing vendors and hospital-specific rules in each state before their experts can enter an operating room or other procedural area.

Beyond direct costs, these fragmented requirements create barriers to interstate commerce. A company operating nationally must ensure each of its representatives meets the idiosyncratic credentialing rules of numerous hospitals in different states, each using different platforms and standards. In practical terms, patients may face delays in care if a needed device expert cannot quickly satisfy a new hospital's unique credentialing steps. Some states have introduced legislation to establish specific HCIR credentialing requirements on a statewide level.

The credentialing systems appear to borrow from the model deployed for clinician privileging, which integrates numerous redundancies to prevent clinicians who have been disciplined or sanctioned by one institution or state board from easily moving to another hospital and repeating the same practices. Redundancies in clinician privileging are also crucial in preventing physician impersonators from participating in patient care. On the other hand, HCIRs never make medical decisions or directly provide patient care, so numerous redundant and varied credentialing requirements do not offer the same value and instead undermine healthcare efficiency on a national scale.

The current environment has also given rise to questionable "pay-to-play" arrangements, in which medical technology companies feel pressured to pay fees to third-party credentialing or purchasing vendors in order to conduct business at certain hospitals. OIG examined such practices in 2025. In OIG Advisory Opinion 25-04, a device manufacturer proposed paying an annual fee (~$450,000 in total) on behalf of its hospital customers to a vendor for performing required screening and compliance checks (exclusion list monitoring, etc.).[28] OIG concluded that this arrangement could violate the federal Anti-Kickback Statute, finding that it constituted improper remuneration covering a cost the hospitals would otherwise incur and raised "anti-competitive 'gatekeeper' concerns" by potentially steering business toward manufacturers willing to pay these fees. Likewise, in OIG Advisory Opinion 25-08, OIG issued an unfavorable opinion on a proposal where a medical device company would pay a third-party vendor for access to the vendor's electronic "bill-only" purchasing system used by some hospitals.[29] OIG again warned that paying to

[28] HHS OIG, Advisory Opinion No. 25-04 (June 20, 2025), https://oig.hhs.gov/compliance/advisory-opinions/25-04/.

[29] HHS OIG, Advisory Opinion No. 25-08 (July 7, 2025), https://oig.hhs.gov/compliance/advisory-opinions/25-08/.

access a hospital's preferred billing/credentialing platform poses a kickback risk – effectively a fee to gain or maintain business. These Advisory Opinions underscore that the current patchwork of non-standard credentialing and purchasing systems can lead to duplicative services and pay-to-play fees, which not only burden companies but also raise concerns about fraud and abuse nationwide. We welcome further discussion from OIG related to these Advisory Opinions, which directly affect the medtech community and highlight gatekeeper and inappropriate steering concerns in the types of arrangements that are increasingly being sought from HCIRs, as well as the development of a relevant Special Fraud Alert related to this issue, as appropriate. For example, questions remain with respect to whether HCIR credentialing that is hospital-mandated and directed through a single, third-party vendor credentialing solution would be viewed differently from the arrangements in Advisory Opinions 25-04 and 25-08.

In order to address these issues, AdvaMed previously recommended that the Centers for Medicare & Medicaid Services ("CMS") utilize its authority to establish a national credentialing standard that hospitals must follow as a condition of participating in Medicare, thereby effectively preempting inconsistent state, local, and institution-specific rules; specifically, AdvaMed has urged CMS to recognize the current version of the American National Standard for Supplier Credentialing in Healthcare as satisfying the relevant elements of the CMS Medicare Conditions of Participation for hospitals, 42 C.F.R. Part 482.[30]

In addition, OIG could endorse the development of a nonprofit, nationwide credentialing platform – one that charges only a nominal fee to cover costs – as an alternative means of conducting or verifying the ANSI SC 1-2020 specified credentialing elements. Such a neutral, nonprofit could operationalize the national standard into an interoperable "passport" across hospitals through a voluntary national HCIR credentialing and "bill-only" purchasing portal (potentially under the aegis of a coalition of healthcare providers and suppliers). Such a platform would allow industry reps to upload credentials once to meet the ANSI SC 1-2020 standard, and the platform could facilitate the verification of the uploaded credentials by recognized Credentials Verification Organizations ("CVO") and display when the listed CVO verified X credential, eliminating the need for re-verification by the numerous other hospitals a HCIR must support. Likewise, for "bill-only" transactions (where devices are supplied for a procedure and billed afterward), this platform could serve as a common electronic purchase order and invoicing system accessible to all participating hospitals and suppliers. Importantly, if structured as a low-cost utility, it avoids the profiteering that concerned the OIG. Hospitals and suppliers would share in the efficiencies – fewer administrative overheads for hospitals, and a single point of entry for suppliers (without hefty access fees). The Healthcare Standards Institute ("HSI") is already spearheading a related effort to develop a national "Bill Only" standard for healthcare procurement with anticipated ANSI accreditation. This standard aims

[30] *See* AdvaMed response to U .S. Department of Justice Request for Information on State Laws Having Significant Adverse Effects on the National Economy or Significant Adverse Effects on Interstate Commerce, dated September 15, 2025, *available at* https://downloads.regulations.gov/DOJ-OLP-2025-0169-0208/attachment_1.pdf.

to streamline the documentation and data elements required in bill-only device purchasing, reducing the current complexity and variability in these processes. We support HSI's work and believe a federally endorsed platform leveraging such standards could operationalize the concept. We have previously recommended that CMS, with input from OIG, explore a demonstration or pilot for a unified credentialing and billing clearinghouse.[31] Federal endorsement would send a strong signal and likely draw broad participation, given the much-needed relief from today's costly maze.

III. Conclusion

Thank you in advance for your consideration of the above proposals. We would greatly appreciate the opportunity to meet with OIG to openly discuss in more detail how AdvaMed may partner with and support OIG's ongoing efforts to modernize the health care system to encourage and protect legitimate, good-faith arrangements necessary to coordinate care, control costs, and improve patient outcomes—including but not limited to these proposals. Please do not hesitate to contact me at (202) 783-8700 or cwhite@advamed.org with any questions.

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

[31] *Id*.

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 price charged to or the net cost of the buyer 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 price charged to or the net cost of the buyer 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 price charged to or the net cost of the buyer 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.