AdvaMed
Advanced Medical Technology Association

July 14, 2025

By Electronic Submission to www.regulations.gov

Mr. Robert F. Kennedy, Jr.
Secretary
U.S. Department of Health and Human Services
Attention: AHRQ-2025-0001
200 Independence Avenue, SW
Washington, DC 20201

Re: Request for Information: Ensuring Lawful Regulation and Unleashing Innovation To Make America Healthy Again (Docket No. AHRQ-2025-0001)

Dear Mr. Kennedy, Jr.:

The Advanced Medical Technology Association ("AdvaMed") appreciates this opportunity to submit the below comments in response to the U.S. Department of Health and Human Services ("HHS") Request for Information: Ensuring Lawful Regulation and Unleashing Innovation To Make American Healthy Again ("Deregulation RFI"), published at 90 Fed. Reg. 20,478 (May 14, 2025).

AdvaMed supports HHS's efforts to rescind or replace regulations that are unnecessary, inconsistent with the law, overly burdensome, outdated, or otherwise unsound, with no clear health benefit, as doing so ensures medical technology ("medtech") companies can continue to successfully invent, develop, distribute, and manufacture innovative and lifesaving/life-enhancing technologies that improve patient care and outcomes, provide better access to healthcare to underserved patient populations, and help manage and improve the lives of patients with chronic diseases. We welcome the opportunity to assist HHS in its deregulation efforts and remain available to discuss further the recommendations included in these comments.

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 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.[1] Yet, this medtech innovation ecosystem is fragile and extremely sensitive to changes in the cost of innovation, which is substantial.[2]

The fragility of the medtech innovation ecosystem results from several factors, including the extremely expensive development process from concept to product launch.[3] Numerous additional obstacles can stifle ideas and cost-saving improvements in healthcare from successfully reaching the market to help patients. In particular, the complexity arising from the over-regulation of the industry and certain regulations that are unnecessary, 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.

II. Regulations to Be Rescinded or Replaced

We recommend and request that the following regulations[4] be rescinded or replaced as they fail to serve patient care and innovation, often impairing these efforts, and otherwise stifle American businesses and American ingenuity, including by imposing significant costs and undue burdens on private parties, such as medtech companies, which are not outweighed by any potential public benefits. These regulations are also unnecessary, inconsistent with the law, overly burdensome, outdated, or otherwise unsound, as further discussed herein.

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

[2] See National Library of Medicine, National Center for Biotechnology Information, Public Health Effectiveness of the FDA 510(k) Clearance Process: Balancing Patient Safety and Innovation: Workshop Report at 21, 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).

[3] Id.

[4] For purposes of these comments, we interpret "regulation" broadly to mean, without limitation, regulations, rules, memoranda, administrative orders, guidance documents, policy statements, and interagency agreements, regardless of whether the same were enacted through the processes in the Administrative Procedure Act, which is consistent with the definition of this term in Executive Order 14192 of January 31, 2025 ("Unleashing Prosperity Through Deregulation").

Our comments herein are in response to the questions listed in the Deregulation RFI ("Deregulation RFI Questions") and we include throughout reference to the relevant Deregulation RFI Questions to which we are responding.

A. Anti-Kickback Statute Safe Harbors

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. The changes we recommend are also consistent with various criteria and considerations identified in the Deregulation RFI. The current AKS regulations discussed herein significantly and unjustifiably impede technological innovation, access to or delivery of care or services, efforts to innovate, and otherwise interfere with medtech companies' ability to address chronic health conditions or otherwise promote the health and wellbeing of patients and should therefore be adjusted as proposed.

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

[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.

judgment, patient freedom of choice, or clinical decision-making in any way."

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

Response to Deregulation RFI Question 1 (harm national interest by impeding technology innovation), Question 3 (confusing/unnecessarily complicated; impede access to/delivery of care; impede innovation; obsolete; interfere with ability to address chronic disease or promote health), and Question 4 (alternative approach can achieve same goal with lesser burden)

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, 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.[6]

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 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

[6] *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 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.).

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.[7] 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.[8]

(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 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."

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[7] 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.)"*

[8] 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).

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].

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

Response to Deregulation RFI Question 1 (harm national interest by impeding technology innovation), Question 3 (impede access to/delivery of care; impede innovation; obsolete; excessive penalties), and Question 4 (alternative approach can achieve same goal with lesser burden)

We recommend that the warranties safe harbor regulation at 42 CFR § 1001.952(g) and all related HHS-OIG Advisory Opinions[9] be rescinded and replaced with the value-based warranty safe harbor regulation proposed in Exhibit A.[10] 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 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."

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[9] 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).

[10] 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).

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.

1. 42 CFR § 1001.952(d)(2) – Outcomes-Based Payments Safe Harbor

Response to Deregulation RFI Question 1 (harm national interest by impeding technology innovation) and Question 3 (impede access to/delivery of care; impede innovation; interfere with ability to address chronic disease or promote health)

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.[11] 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.

2. 42 CFR § 1001.952(ff) – Substantial Downside Risk Safe Harbor and 42 CFR § 1001.952(gg) – Full Financial Risk Safe Harbor

Response to Deregulation RFI Question 1 (harm national interest by impeding technology innovation), Question 2 (recommendation will permit focus on reversing chronic disease), and Question 3 (impede access to/delivery of care; impede innovation; interfere with ability to address chronic disease or promote health)

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

[11] 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.[12] 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[13] 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 harbors.[14] Both beliefs are misguided.

Regarding care coordination, medtech companies don't just produce medical devices and diagnostics that

[12] 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)

[13] 42 CFR § 1001.952(d)(2), (ee), (ff), (gg).

[14] *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.").

save and improve patients' lives, they provide a range of solutions that include products and services to improve patient outcomes. CMS recently has recognized this, specifically "seeking public input on how best to advance a seamless, secure, and patient-centered digital health infrastructure."[15] 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 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.

[15] 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.

- **42 CFR § 1001.952(d)(1) – Personal services and management contracts**

Response to Deregulation RFI Question 1 (impose undue burdens on small business/impede private enterprise) and Question 3 (excessive penalties; obsolete)

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."[16] 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.[17]

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.[18] We believe it also aligns with the position that DOJ has taken in enforcing a similar provision contained in the Eliminating Kickbacks in Recovery Act ("EKRA").[19]

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.[20] 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 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

[16] 42 CFR 1001.952(d)(1)(iv).

[17] 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.").

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

[19] 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."

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

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 reply 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.

Commission based payments to independent contractors are not *per se* illegal under the AKS,[21] 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.[22] But even if medtech companies do so, they have no guarantee of how an arrangement will be analyzed by OIG or DOJ, but for if 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 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

[21] See 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.").

[22] See Advisory Opinion 98-10, *available at* https://oig.hhs.gov/documents/advisory-opinions/385/AO-98-10.html (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).

concerns with independent contractor relationships, and protect industry standard commissions-based arrangements thereby promoting appropriate competition. Further, our proposal includes safe guards 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. [23]

- **Group Purchasing Entities**

Response to Deregulation RFI Question 1 (significant costs upon private parties not outweighed by public benefits), Question 3 (obsolete), and Question 4 (alternative approach can achieve same goal with lesser burden)

We recommend all advisory opinions that grant protection to certain arrangements whereby GPO-like entities (GPEs) receive fees paid by vendors based upon purchases by entities either wholly-owned by the GPE or subsidiaries of a parent corporation that wholly owns the GPE be rescinded, and that OIG develop a Special Fraud Alert regarding GPEs, clarifying the applicability of the GPO safe harbor[24] to GPEs and identifying appropriate practices of GPEs. Doing so will restore the integrity of the ownership requirements under the GPO safe harbor and ensure that the practices of GPEs do not inappropriately increase the cost to federal health care programs and others, nor lead to fraud, waste, and abuse, as discussed further below.

We have found that GPEs often have administrative fees above 3% (many over 8%) on purchases by their affiliates and refuse to consider arrangements where the excess administrative fee is substituted with a specified rebate to the purchasing entity compliant with the discount safe harbor.

This is contrary to the OIG's stated rationale when establishing the GPO safe harbor in 1991, where it reasoned that a single entity requesting an administrative fee on its own behalf would appear to represent an illegal inducement. Importantly, in promulgating the safe harbor, OIG noted that "wholly owned subsidiaries of a single corporate entity for all practical purposes constitutes a single entity and not a "group" of entities" and do not qualify as a GPO under the safe harbor. In explaining this position, the OIG could see no reason how a solicitation for administrative fees on behalf of such a single entity "sanitizes the illegality" if such a solicitation came directly from the health care provider.[25]

We believe the bold behavior by GPEs with respect to fees may be due, at least in part, to a run of OIG advisory opinions[26] in which OIG concluded that it would not impose sanctions in connection with the particular arrangements at issue, notwithstanding that such arrangements did not satisfy the GPO safe

[23] See TN 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).

[24] 42 CFR § 1001.952(j).

[25] See 56 Fed. Reg. 35952, 35982.

[26] *See* OIG Advisory Opinion Nos. 12-01, 16-06, and 18-07.

harbor's ownership requirements, which state that a GPO's members must not be "wholly-owned by the GPO nor subsidiaries of a parent corporation that wholly owns the GPO (either directly or through another wholly-owned entity)."[27]

Left unchecked, these trends with respect to common ownership arrangements increases the risk for higher hospital costs and federal spending. We believe that even at the historical levels of 3% or less, the administrative fees collected often exceed actual GPO expenses to fund their operations and the services provided to its members. Yet, knowing that their members are often not free to seek out a competing GPO, GPEs have tended to demand higher administrative fees than GPOs for the award of vendor business, sometimes in a pay-to-play manner, directly implicating the illegal inducement concerns surrounding common ownership identified by the OIG when promulgating the safe harbor. Additionally, the way the fees are shared with hospitals and ultimately reported may be less transparent.

More broadly, as GPE administrative fees rise over time, they will become an additional cost to the system. Rather than serving its agent function to provide services to its members, the GPE may sacrifice optimal discounting for higher administrative fees while leaving its captive members little choice but to use the higher-cost products. Additionally, with the higher administrative fees being collected and without the competitive threat of members leaving for other GPOs, there is little incentive for a GPE to operate in an efficient manner. Such a structure could lead to waste as well as the inappropriate enrichment of GPE leadership. Providers beyond the GPE may also be negatively affected if manufacturers raise prices generally in the market to cover the costs of higher administrative fees.

Furthermore, because a GPE may share common ownership with many, but not all of its members, there may be less incentive to pass through excess administrative fees to all members. This could be at the detriment of any unaffiliated members, and ultimately, the federal health care system because those non-affiliated members would not be enjoying the excess fees passed through as discounts and would not be reporting the same in cost reports. When GPEs that are owned or controlled by provider entities negotiate to receive value from sellers in the form of administrative fees, rather than as discounts that are reflected in cost reports and claims to federal healthcare programs, federal healthcare programs may not receive the benefit of this value, resulting in higher costs for public programs. It is also important for OIG to recognize that sellers do not have transparency or control over whether such a GPE organization internally classifies and treats administrative fees as discounts in a manner that benefits public programs, or instead classifies and retains the full amount as an administrative fee that does not benefit public programs.[28]

For the foregoing reasons, we recommend that OIG develop a Special Fraud Alert regarding GPEs and refrain from issuing any further advisory opinions granting protection to such arrangements until further

[27] 42 CFR § 1001.952(j)(2).

[28] An analogy can be drawn to the classification of administrative fees paid by pharmaceutical manufacturers to GPOs for the purpose of calculating Average Manufacturer Prices of covered outpatient drugs for the Medicaid program, where CMS noted the need, in that context, to properly classify administrative fees paid to GPOs as either bona fide service fees (which do not benefit the Medicaid program) or as price concessions (which do benefit the Medicaid program), and also recognized the limited visibility of manufacturer-sellers into how GPOs make this classification. *See Medicaid Program; Covered Outpatient Drugs; Final Rule*, 81 Fed. Reg. 5169, 5180-5181 (Feb. 1, 2016).

data and information can be gathered regarding the practices of GPEs and potential fraud, waste, and abuse implications. For example, audits of hospitals' cost reports could be initiated to ensure that GPO revenue distributions are fully reported, and/or a timely, focused Government Accountability Office (GAO) study—or similar study—could be conducted to determine whether GPEs with common ownership among a substantial portion of their members continue to contribute to lower spending for federal health care programs commensurate with GPOs that fit within the safe harbor requirements.

- **Physician-Owned Distributors**

Response to Deregulation RFI Question 1 (harm national interest by impeding technology innovation; impose undue burdens on small business/impede private enterprise) and Question 3 (interfere with ability to address chronic disease or promote health)

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 extent to 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.

C. Open Payments

- **42 CFR 403.904(c)(8)(ii) and 42 CFR 403.904(f)(1)(iv) - Device Identifier Reporting Requirement**

Response to Deregulation RFI Question 1 (significant costs upon private parties not outweighed by public benefits), Question 3 (confusing/unnecessarily complicated; require excessive reports or unreasonable record keeping; information not needed/effective; impede innovation; interfere with ability to address chronic disease or promote health), and Question 4 (alternative approach can achieve same goal with lesser burden)

We recommend revising the Open Payments regulations at 42 CFR 403.904(c)(8)(ii) and 42 CFR 403.904(f)(1)(iv) to remove the requirement to report device identifiers ("DIs")[29] for general and research payments and transfers of value, respectively. This information does not provide meaningful information to the public and can create an inaccurate or misleading picture regarding the payments and transfers of value that are reported by manufacturers to CMS under the Physician Payment Sunshine Act. It also requires manufacturers to commit time, effort, and cost to maintaining systems and processes to collect and report this data, as opposed to focusing on medical technology innovation to improve patient care.

For additional context, many device manufacturers have tens of thousands, and some over one-hundred thousand DIs as individual products may be associated with multiple DIs because a different DI is required for each variation and version. For example, spinal fixation pedicle screws for degenerative disc disease could have a different DI for each variation in diameter, length, composition, coating, screw head and body connection (monoaxial, polyaxial, and uniplanar), thread depth, thread pitch, and version/model. Further, the pedicle screw is only one part of a spinal fixation system. Other components of a spinal fixation system include rods, rod connecters, plates, laminar hooks, and other types of connectors, where each component has different variations, and some variations have multiple versions, each of which requires a distinct DI. Interactions that involve a transfer of value related to a device frequently occur in the context of a product line or system, comprised of numerous individual devices that are components and options within that product line or system. Reporting a multitude of DIs per product or system for a single payment record is onerous, may distort or confuse the circumstances of the interaction and associated transfer of value, and does not provide useful information to the public, as is the intent of the Open Payments Program. As such, we recommend rescinding 42 CFR 403.904(c)(8)(ii) and 42 CFR 403.904(f)(1)(iv).

[29] The Device Identifier is the mandatory, fixed portion of a Unique Device Identifier that identifies the specific version or model of a device and the labeler of that device. 21 C.F.R. 801.3 24.

- **42 CFR 403.904(c)(8) – Reporting Marketed/Brand Name or Therapeutics Area/Product Category**

Response to Deregulation RFI Question 1 (significant costs upon private parties not outweighed by public benefits), Question 3 (confusing/unnecessarily complicated; require excessive reports or unreasonable record keeping; information not needed/effective), and Question 4 (alternative approach can achieve same goal with lesser burden)

We recommend revising the Open Payments regulations at 42 CFR 403.904(c)(8) to permit applicable manufacturers to report either (1) the marketed or brand name or (2) therapeutics area or product category for related covered devices [and medical supplies]. For related covered devices [and medical supplies], applicable manufacturers should be able to report the product category or therapeutic area in lieu of the marketed or brand name(s) of a covered device, in order to ensure meaningful consumer understanding. Unlike pharmaceuticals and biologics, covered devices typically are not marketed to patients by familiar product names. Also, and again unlike pharmaceuticals and biologics, many separate devices may be combined to compose an item that a consumer would be likely to view as a single device, such as a pacemaker or a heart-lung machine. Thus, reporting a marketed or brand name may not promote clarity for consumer understanding, but rather will actually create confusion with regard to covered devices.

- **42 C.F.R. § 403.904(h)(2) – De Minimis Payments and Transfer of Value**

Response to Deregulation RFI Question 1 (significant costs upon private parties not outweighed by public benefits), Question 3 (require excessive reports or unreasonable record keeping; information not needed/effective), and Question 4 (alternative approach can achieve same goal with lesser burden)

We recommend revising the Open Payments regulation at 42 C.F.R. § 403.904(h)(2) to remove the requirement to report payments or other transfers of value less than $10 when the aggregate for such payments or transfers of value exceeds $100 in a calendar year (both such dollar amounts as increased annually).

The current requirement that *de minimis* payments and transfers of value ($13.46 for 2025) must be reported when the annual aggregate of such payments and transfers of value exceeds the annual aggregate threshold ($134.54 for 2025) has no real value to the public and is extremely burdensome to applicable manufacturers that are required to go through the operational burden of tracking all de minimis payments and transfers of value, compiling and reviewing them, and then reporting them if such *de minimis* payments and transfers of value actually exceed the annual threshold.

As an example, for one AdvaMed member, of the items it reported for Open Payments for the 2024 program year, those that were *de minimis* payments and transfers of value accounted for over 16% of the reports, but the value of these de *minimis* payments and transfers of value represented only 0.2% of all of those reported by the member.

As revised, 42 C.F.R. § 403.904(h)(2) could read, "For CY 2013, payments or other transfers of value less than $10. For CY 2014 and subsequent calendar years, to determine if transfers of value are excluded under this section, the dollar amount specified in paragraph (h)(2)(i) of this section must be increased by the same percentage as the percentage increase in the consumer price index for all urban consumers (all items; U.S. city average) for the 12-month period ending with June of the previous year. CMS will publish the value for the next reporting year 90 days before the beginning of the reporting year."

D. Laboratory Requirements

1. 42 CFR 493 - Laboratory Personnel Qualifications

Response to Deregulation RFI Question 3 (impede access to/delivery of care; interfere with ability to address chronic disease or promote health)

We recommend rescinding the following changes to laboratory personnel qualifications as a result of the final rule issued by the Centers for Medicare & Medicaid Services ("CMS") and the Centers for Disease Control and Prevention (CDC) titled, "Clinical Laboratory Improvement Amendments of 1988 ("CLIA") Fees; Histocompatibility, Personnel, and Alternative Sanctions for Certificate of Waiver Laboratories" ("2023 CLIA Final Rule").[30]

(a) *42 CFR 493.1405(b) – Standard; Laboratory Director Qualifications.*

We recommend rescinding the changes to 42 CFR 493.1405(b) related to laboratory director educational requirements as a result of the 2023 CLIA Final Rule. Point-of-care ("POC") testing has become a standard of practice in many healthcare systems, allowing laboratory results to be delivered to the treating healthcare provider as rapidly as possible. The 2023 CLIA Final Rule significantly increased laboratory director educational requirements, without evidence of an issue.

Specifically, the modifications to the medical residency provision emphasizing the requirement for "clinical laboratory training" and requiring two years of experience supervising high complexity testing to qualify for the position of laboratory director will reduce the number of medical doctors who qualify to function as laboratory directors for laboratories associated with their practice. This increase to educational requirements, combined with the existing decline in laboratory professionals, will lead to laboratory closures and impacts to patient diagnosis and care, especially in rural areas, and other areas experiencing health care deserts where physician office laboratories or laboratories in sites of emergency and critical care are owned and operated by the medical practice owner.

(b) *42 CFR 493.1411(b)(4)(i)(A) - Standard; Technical Consultant Qualifications.*

We recommend rescinding the changes to 42 CFR 493.1411(b)(4)(i)(A) related to laboratory technical

[30] 88 FR 89976 (Dec. 28, 2023), https://www.federalregister.gov/documents/2023/12/28/2023-28170/clinical-laboratory-improvement-amendments-of-1988-clia-fees-histocompatibility-personnel-and.

consultant qualifications as a result of the 2023 CLIA Final Rule, which removed the nursing degree as a qualifying degree to operate as a technical consultant capable of documenting competency to run POC tests in moderately complex laboratories essential to critical care and emergency departments.

Medical doctor degree holders and bachelors of science in nursing should qualify similarly to bachelor's degree holders of chemical, biological, or clinical laboratory science, as was the case under the regulation before the 2023 CLIA Final Rule went into effect. No issues were identified with individuals holding a nursing degree to prompt the change in the regulation under the 2023 CLIA Final Rule and this change ultimately reduces the ability of nurses to perform this procedural role in testing. With an existing decline in laboratory professionals, reducing individuals with a bachelor of science in nursing from operating as a technical consultant reduces available professionals, which will lead to overburdened laboratories, which impacts the ability to deliver timely lab results and ultimately patient care.

(c) *42 CFR 493.1423(b)(7) – Blood Gas Analysis Testing Personnel Qualifications.*

We recommend rescinding the changes to 42 CFR 493.1423(b)(7) related to blood gas analysis testing personnel qualifications as a result of the 2023 CLIA Final Rule. The change of qualifications for blood gas testing under the 2023 CLIA Final Rule ignores standard test qualifications and implements higher education requirements in direct conflict with the preamble to the Final Rule and the qualifications of emergency medical technicians (EMTs) who perform these POC tests.

In the preamble to the 2023 CLIA Final Rule, CMS stated, "CLIA allows moderate complexity testing personnel to qualify with a high school diploma or equivalent and documented training of the testing performed prior to reporting patient test results. Individuals who meet the regulatory qualifications for moderate complexity can perform any test categorized by the U.S. Food and Drug Administration ("FDA") as moderate complexity, including blood gases."[31] Yet the regulations revised as a result of the Final Rule reflect a different, higher educational standard for blood gas testing. This requirement has a direct impact on the ability to deliver necessary and life-saving critical care enabled by blood gas testing. EMTs need to run blood gases during critical patient transport and many are no longer qualified under 42 CFR 493.1423(b)(7), as revised. Generally, to become an EMT, one needs a high school diploma or equivalent, CPR certification, completion of an EMT training program, and to pass the National Registry EMT exam and a state-specific practical exam. A trained, competent, and experienced EMT, whose highest level of completed education is high school, should be allowed to run a blood gas test on a POC device. To not allow this will result in a negative impact on patient care.

2. 42 CFR 493.1804(c)(1) - Imposition of Alternative Sanctions

Response to Deregulation RFI Question 1 (significant costs upon private parties not outweighed by public benefits; impose undue burdens on small business/impede private enterprise) and Question 3 (excessive penalties)

We recommend rescinding the changes under the 2023 CLIA Final Rule that allow alternative sanctions

[31] Id.at 90013.

to be levied against certificate of waiver ("CoW") bearing laboratories as unnecessary, unfair, impractical, and a detriment to access to care. The alternative sanctions are financial sanctions for CoW laboratories for improper proficiency testing referral. According to CMS, this change could decrease the burden for sanctions imposed, "[a]lthough we have no data indicating that principal sanctions have been imposed on CoW laboratories for this reason in the past."[32] In fact, proficiency testing is not a required process for laboratories only performing waived testing. This change creates new incentives for accrediting organizations to focus regulatory resources on monitoring compliance in waived laboratories, increasing their cost and burden of compliance for processes that are not currently being monitored today, without evidence of the need to do so. The increase in cost and burden for CoW laboratories will ultimately result in a reduction in their ability to provide necessary patient care. Furthermore, there are about 200,000 waived certificates, making effective oversight of this number of laboratories impractical.

3. 42 CFR 493, Subpart F – General Administration.

Response to Deregulation RFI Question 1 (significant costs upon private parties not outweighed by public benefits; impose undue burdens on small business/impede private enterprise; harm national interest by impeding technology innovation) and Question 3 (impede access to/delivery of care; impede innovation)

We recommend rescinding the changes to Subpart F of Title 42 related to CLIA fees under the 2023 CLIA Final Rule.

In December 2018, CMS increased fees to cover the cost of administering the CLIA program by 20 percent.[33] According to CMS, "The 2018 increase was intended to give CMS time to propose a process through rulemaking to allow for ongoing changes to the CLIA fees. Despite that increase, the level of carryover funding available to cover program expenses is projected to decline continuously. As such, the CLIA program will not be self supporting by the end of FY 2023 without an additional fee increase."[34] As a result, the 2023 CLIA Final Rule imposes an across-the-board fee update of 18%, and a change to allocate directly from CoW laboratories the cost for FDA to categorize clinical laboratory tests as waived, and modifies the CLIA fee provisions at Subpart F of Title 42. 89977. CMS claimed these changes would "stabilize the CLIA program."[35]

In fact, these changes will significantly increase the cost to operate laboratories, reducing laboratory viability, specifically in CoW laboratories. Furthermore, there is no evidence that these updates will "stabilize" the program financially, as the repeated increases in fees have not done so previously and only serve to exacerbate the existing consolidation of laboratories and shortages of laboratory professionals and services that impact access to care. Further increasing the cost of oversight with additional fee

[32] Id. at 89980.

[33] 83 FR 67723 (Dec. 31, 2018), available at https://www.federalregister.gov/documents/2018/12/31/2018-28359/medicare-program-clinical-laboratory-improvement-amendments-of-1988-clia-fees.

[34] 88 FR 89976.

[35] Id.

increases is not to the benefit innovation and access to care.

- **42 CFR 414.510 Laboratory Date of Service (14-Day Rule)**

Response to Deregulation RFI Question 3 (impede access to/delivery of care; interfere with ability to address chronic disease or promote health) and Question 4 (alternative approach can achieve same goal with lesser burden)

We recommend 42 CFR 414.510(b)(5) be amended such that the date of service of the applicable tests is always the date of performance, as long as the results of the test do not guide treatment provided during a hospital encounter. Such an amendment will reduce administrative burdens without compromising patient safety or the integrity of the Medicare program.

Generally, Medicare considers the date of service for a clinical diagnostic laboratory test to be the date the specimen is obtained. If the date of services is during a hospital inpatient stay, payment is bundled into the IPPS payment and not paid separately. If the date of service is during a hospital outpatient encounter, the test must be billed by the hospital and is either bundled into the OPPS payment or paid separately. In 2017, CMS established regulations at 42 CFR § 414.510(b)(5) to revise its date of service policy for clinical laboratory tests to allow a laboratory, rather the hospital, to bill Medicare directly for molecular pathology tests and certain Advanced Diagnostic Laboratory Tests ("ADLTs") (as defined under Section 1834A(d)(5)(A) of the Social Security Act) performed on specimens collected from hospital outpatients. In subsequent years, CMS also included certain Multianalyte Assays with Algorithmic Assays ("MAAAs") in the exception to the OPPS packaging policy. Revising the date of service for these tests from date of collection to date of performance eliminated access delays for Medicare beneficiaries that resulted from the previous requirement that the hospital at which the specimen was collected bill Medicare for these relatively uncommon molecular pathology tests. This change led to significant improvement in beneficiary access to precision diagnostic testing. This exception, however, does not apply when these same laboratory tests are performed on a hospital inpatient. In these cases, the date of service is still date of collection and a clinical laboratory may only bill for a molecular pathology test, MAAA, or ADLT when the specimen is obtained from a hospital if the test is ordered more than 14 days from discharge. The net result is for hospitals to hold samples and order the tests for 14 days or more after the patient is discharged from the inpatient facility. This results in a delay of care for advanced cancer patients for tests that do not affect how the patient is treated as part of the hospital inpatient stay. The same logic that led CMS to revise its date of service policy in 2017 for certain molecular pathology services ordered for hospital outpatients applies to hospital inpatients. CMS should remain consistent across the inpatient and outpatient settings. Specifically, 42 CFR 414.510(b)(5) should be modified such that for the tests listed at 42 CFR 414.510(b)(5), the date of service is always the date of performance as long as the results of the test do not guide treatment provided during a hospital encounter. This change would reduce administrative burden for providers by simplifying regulatory requirements and eliminating the confusing discrepancy between these hospital payment policies that creates unnecessary administrative complexity and limits patients' access to advanced cancer diagnostics.

- **42 CFR 419.2(b)(17) and 42 CFR 419.22(l) – Laboratory Test Packaging**

Response to Deregulation RFI Question 1 (significant costs upon private parties not outweighed by public benefits; impose undue burdens on small business/impede private enterprise)
We recommend that the changes pursuant to the 2013 OPPS Final Rule,[36] effective January 1, 2014, related to laboratory test packaging be rescinded such that laboratory tests are not packaged in the OPPS. Specifically, we recommend 42 CFR 419.2(b)(17) be rescinded and 42 CFR 419.22(l) be revised to remove the phrase "Except as provided in in § 419.2(b)(17)." The approach of packaging laboratory tests in the OPPS creates significant burdens for providers and should be eliminated.

- **Medicare Advantage and Test Requisition Forms**

Response to Deregulation RFI Question 1 (significant costs upon private parties not outweighed by public benefits; impose undue burdens on small business/impede private enterprise), Question 3 (impede access to/delivery of care; interfere with ability to address chronic disease or promote health; require excessive reports or unreasonable record keeping; information not needed/effective), and Question 4 (alternative approach can achieve same goal with lesser burden)
Laboratories often experience situations in which Medicare Advantage ("MA") plans make burdensome demands for additional documents to process claims for services clearly covered under National Coverage Determinations ("NCDs") or Local Coverage Determinations ("LCDs"). For laboratory testing, complete information is often provided in the Test Requisition Form ("TRF"); still, MA organizations fail to recognize the TRF as part of the medical record. Obtaining additional duplicative documentation is incredibly burdensome for both laboratories and the ordering providers. Laboratories may also be limited in their ability to acquire the requested medical documentation when it is outside of the specific coverage requirements for the service. These situations further contribute to delays and/or denials of medically necessary claims, which is particularly problematic for advanced cancer patients that face time-sensitive treatment decisions. We recommend CMS clarifying that the TRF is a valid form of medical documentation and additional documentation should not be requested from the provider when complete medical necessity information is already provided in the TRF. This will accomplish the same goal but with less burden on laboratories. It will also streamline the administrative process, reducing paperwork burden for providers and aligning medical documentation policy pertaining to MA plans with what is already in place for Medicare fee for service ("FFS").[37]

[36] 78 Fed. Reg. 74826 (Dec. 10, 2013).

[37] See Article A59741, *MolDx: Clarification of Order Requirements for Laboratory and Molecular Diagnostic Services*, https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=5974. This Article has been adopted by multiple Medicare Administrative Contractors ("MACs").

- **Part C/Medicare Advantage Laboratory Redetermination Timelines**

Response to Deregulation RFI Question 1 (significant costs upon private parties not outweighed by public benefits; impose undue burdens on small business/impede private enterprise), Question 3 (impede access to/delivery of care; interfere with ability to address chronic disease or promote health), and Question 4 (alternative approach can achieve same goal with lesser burden)

We recommend CMS harmonize redetermination timelines across Medicare and extend the Part C deadline for filing a redetermination request to at least 120 days in line with Part B. Medicare administrative processes related to complying with documentation requests are burdensome for providers. This burden is further compounded by the significant volume of denials that laboratories experience from MA plans. When gathering additional documentation to appeal these decisions, laboratory providers often reach out to the ordering provider, and it can take up to 90 days to receive a response. As a result, this process is causing laboratory providers to miss the 65-day timely filing requirement for first-level redetermination, enabling MA organizations to deny all further appeals and preventing an impacted beneficiary from having affordable access to vitally important care. This timeline is simply not feasible for providers delivering ancillary services, such as cancer diagnostics, who appeal claims on behalf of hundreds of beneficiaries at any given time. It is important to note that under Part B, a provider has 120 days for a redetermination request.[38] Thus, the Part C redetermination request filing deadline is not sufficient nor consistent across Medicare. Given the disparate administrative burden on ancillary service providers, CMS should harmonize redetermination timelines within the Medicare Program and extend the Part C deadline for filing a redetermination request to at least 120 days in line with Part B.

- **42 CFR Part 414: Subpart G - Protecting Access to Medicare Act (PAMA)**

Response to Deregulation RFI Question 1 (significant costs upon private parties not outweighed by public benefits) and Question 4 (alternative approach can achieve same goal with lesser burden)

(a) *Insufficient Reporting Data to Support CLFS Rate-Setting*

We recommend CMS maintain current Clinical Laboratory Fee Schedule ("CLFS") rates in 2026, given the insufficient data reporting to date. In its Final Rule implementing the requirements of section 216 of the Protecting Access to Medicare Act of 2014 ("PAMA"), which required revisions to the payment methodology for clinical diagnostic laboratory tests paid under the Clinical Laboratory Fee Schedule ("CLFS"),[39] CMS established regulations related to reporting of private payor rates for laboratory tests to serve as the basis for Medicare payment rates for most laboratory tests on the CLFS. Unfortunately, CMS's implementation of the law in 2016 resulted in CLFS rates that do not reflect rates paid in the commercial market. Whereas the majority of clinical laboratories should have reported data to CMS for CLFS rate-

[38] 42 CFR § 405.942. See also *CMS: First Level of Appeal: Redetermination by a Medicare Contractor*, https://www.cms.gov/medicare/appeals-grievances/fee-for-service/first-level-appeal-redetermination-medicare-contractor

[39] 81 Fed. Reg. 41036 (June 23, 2016).

setting, fewer than one percent of all laboratories reported data, and the data reported was not representative of the full laboratory market. Ninety percent of the data was reported by independent laboratories (which submit only about half of all claims paid under the CLFS), and only 21 hospitals nationwide reported any data to CMS, despite thousands of hospitals receiving payments under the Medicare CLFS each year. CMS should maintain current CLFS rates in 2026, using flexibility in the statue to hold off on further reductions of up to 15% on 800 tests scheduled to begin in January 1, 2026. Sec. 1834A(b)(3) states that payment amounts "shall not result in a reduction in payments for a clinical diagnostic laboratory test for the year of greater than" the applicable percent. Congress limited CMS' authority to impose a rate reduction that exceeds 15 percent, but Congress did not restrict the agency's ability to impose a rate reduction that is less than that amount, and it did not tell CMS exactly the amount that it must reduce a CLFS rate.

(b) *PAMA Commercial Payor Rates and Volume Data Collection Date*

We recommend CMS not use 2019 private payor rates to update the CLFS effective January 1, 2027. Currently, commercial payor rates and volumes from the first half of 2019 (January 1, 2019 through June 30, 2019) are to be reported to CMS beginning January 1, 2026, for rates that would take effect on January 1, 2027. Originally, this data was supposed to have been reported in 2020, but Congress has delayed further implementation of the law for many years, owing to its concerns about how it was implemented, so the intended triennial data collection and reporting cycle has become illusory. Using 2019 to set rates for 2017 is not the intent of the law and will not result in accurate or fair rates under the CLFS.

4. MLN Matters related to QW Modifier for CLIA-Waived Tests

Response to Deregulation RFI Question 3 (require excessive reports or unreasonable record keeping; information not needed/effective) and Question 4 (alternative approach can achieve same goal with lesser burden)

We recommend removing the QW modifier for CLIA-waived tests. Specifically, the following Medicare Learning Network ("MLN") guidance documents related to CLIA-waived tests approved by the FDA should be rescinded:

- MLN Matters Number: MM13858, "New Waived Tests"[40]
- MLN Matters Number: MM13253, "New Waived Tests"[41]

These MLN Matters state that tests must have a QW modifier to be recognized as a waived test. This additional bureaucracy would be avoided in reporting QW modifiers for CLIA waived tests to MACs on MLN Matters and other materials. To our knowledge, Medicare is the only payer that blank- requires the QW modifier. This requirement causes delays in reporting usage (and reimbursement) of CLIA waived-tests on

[40] https://www.cms.gov/files/document/mm13858-new-waived-tests.pdf.

[41] https://www.cms.gov/files/document/mm13253-new-waived-tests.pdf.

claim forms for laboratory tests that are already FDA-approved/cleared.

E. Medicare Reimbursement, Coverage, and Coding

1. 42 CFR sections 412.87 and 412.88 - New Technology Add-On Payments

Response to Deregulation RFI Question 1 (harm national interest by impeding technology innovation; significant costs upon private parties not outweighed by public benefits; impose undue burdens on small business/impede private enterprise), Question 3 (impede access to/delivery of care; impede innovation; interfere with ability to address chronic disease or promote health; require excessive reports or unreasonable record keeping; information not needed/effective), and Question 4 (alternative approach can achieve same goal with lesser burden)

We recommend rescinding 42 CFR sections 412.87 and 412.88, or portions of the same, regarding additional payment for new medical services and technologies used in the inpatient setting as they relate to CMS' determinations of new medical services or technologies that are eligible for the NTAP, and replacing the process detailed under these regulations with a quarterly review cycle of NTAP in alignment with the review cycle for TPT status under the OPPS.

In order for a new medical service or technology to be eligible to receive the additional payment, known as NTAP, the medical service or technology must be the subject of a complete and active FDA marketing authorization request and documentation of FDA acceptance or filing of the request must be provided to CMS. The documentation type required is unnecessarily restrictive; the timing of these documentations is one-year before the effective date of NTAP, and up to 5.5 months ahead of the FDA market authorization data necessary to gain NTAP, meaning significant burdens for the applicants to manage great variables that are not directly related to the CMS's review. Since CMS proposed this policy, industry and other public stakeholders have voiced numerous concerns regarding CMS's lack of understanding of the FDA process and therefore the stringent nature of the documentation required way ahead of the estimated FDA approval date. While CMS dismissed these public concerns in its decision to implement the policy, CMS has since then had to revise through sub-regulatory language twice due to recognition of its flaws. Meanwhile, there have been at least six NTAP applications since 2023 that have been deemed by CMS NTAP policy intent, "ineligible" due to this flawed and arbitrary policy, resulting in at least a one-year delay of their NTAP approval. As implemented, this process is overly complex and out of sync with FDA. This results in limited or delayed adoption by facilities that are unable to cover the incremental costs associated with new life-saving innovations; limited access for patients who would benefit from these therapeutic options; delayed uptake of critical life-saving technologies in the US, which have long been available in other parts of the world, impacting US health care innovative competitiveness.

The current NTAP process is also inconsistent with other analogous CMS programs and creates unnecessary burdens in the inpatient setting. We recommend CMS align the NTAP review cycle with the quarterly cycle used for applications for TPT status under OPPS. The TPT process allows transparent, public review, but requires less administrative burden in rulemaking for CMS compared to the NTAP process. In contrast to the IPPS NTAP application and approval process, the OPPS TPT application and approval process facilitates more timely review of applications and allows for timelines that maximize TPT

eligibility. We therefore recommend CMS establish a quarterly review cycle of NTAP in alignment with the review cycle of TPT.

2. 42 CFR § 419.66(b)(3) - Transitional Pass-Through Payments for Medical Devices

Response to Deregulation RFI Question 1 (harm national interest by impeding technology innovation; significant costs upon private parties not outweighed by public benefits; impose undue burdens on small business/impede private enterprise), Question 2 (recommendation will permit focus on reversing chronic disease), Question 3 (impede access to/delivery of care; impede innovation; interfere with ability to address chronic disease or promote health; require excessive reports or unreasonable record keeping; information not needed/effective), and Question 4 (alternative approach can achieve same goal with lesser burden)

We recommend rescinding 42 CFR §419.66(b)(3) related to TPT payments for medical devices. The TPT program provides additional payments for new medical devices, drugs, and biologicals used in hospital outpatient settings under the OPPS. This program aims to facilitate access to these innovative technologies. The program incentivizes hospitals to adopt these innovations by covering the initial costs while CMS gathers data to determine appropriate future payment rates. This increases access to new technologies that might otherwise be too expensive for hospitals to adopt. The regulation at 42 CFR § 419.66(b)(3) restricts medical devices, such as clinical laboratory tests, from qualifying for pass-through status. Rescinding this regulation will reduce burden, simplify TPT for a variety of medical technologies, and promote patient access to innovative therapies and tests to improve the detection and treatment of chronic disease.

Alternatively, we recommend amending 42 CFR §419.66(b)(3) to clarify that to be eligible a device need not be surgically implanted or inserted either permanently or temporarily. Notwithstanding the important role of the TPT program as it relates to innovation and access to new technologies, the current TPT eligibility criteria at 42 CFR §419.66(b)(3) significantly limit this program to a minute subset of medical technologies. Specifically, 42 CFR §419.66(b)(3) currently requires “The device is an integral part of the service furnished, is used for one patient only, comes in contact with human tissue, and is surgically implanted or inserted (either permanently or temporarily) or applied in or on a wound or other skin lesion.” By limiting the TPT program to inserted or implanted devices, other technologies (such as clinical diagnostic tests) face adoption challenges. In order to help better incorporate these technologies into vital patient care scenarios, we recommend amending 42 CFR §419.66(b)(3) by deleting the phrase “and is surgically implanted or inserted either permanently or temporarily."

3. Prior Authorization

Response to Deregulation RFI Question 1 (significant costs upon private parties not outweighed by public benefits; impose undue burdens on small business/impede private enterprise), Question 3 (confusing/unnecessarily complicated; impede access to/delivery of care; impede innovation; interfere with ability to address chronic disease or promote health), and Question 4 (alternative approach can achieve same goal with lesser burden)

(a) *42 CFR 419, Subpart I - Outpatient Department Services*

We recommend rescinding 42 CFR 419, Subpart I (42 CFR 419.80-419.89) related to prior authorization for outpatient department services. CMS cites section 1833(t)(2)(F) of the Social Security Act, which allows the Secretary to develop "a method for controlling unnecessary increases in the volume of covered OPD services," as the authority for this regulation. However, CMS failed to demonstrate that volume increases under OPPS were unnecessary. For example, Medicare claims data clearly demonstrate that the high growth rate of cervical fusions with disc removal in the hospital outpatient setting, cited in CY 2021 OPPS rulemaking as justification for prior authorization, was the direct result of services migrating from the more expensive hospital inpatient setting of care, and not due to medically unnecessary increases in overall utilization as the result of financial incentives, as CMS asserted. For cervical fusion procedures as well as other procedures listed at 42 CFR 419.83, the regulation is bad policy, unreasoned, unsound, and represents an unjustified and significant burden to providers and patients. The negative impact on innovation/patient care is the needless administrative burden for providers associated with prior authorization requirements. Prior authorizations can also lead to confusion or delays in care for patients. As such, we recommend rescinding 42 CFR 419, Subpart I.

(b) *Laboratory-Initiated Prior Authorization for Medicare Advantage*

We recommend CMS clarify and enforce that MA plans cannot restrict prior authorization to ordering providers or primary care providers; they must allow enrollees, an enrollee's representative, and any eligible provider, including laboratory professionals, to request prior authorization.

Unlike every other area of healthcare in which the provider performing the service submits for prior authorization, many MA plans do not permit laboratories to file prior authorizations for the services they perform and provide for MA-insured beneficiaries. This creates a pathway for insurance plans to deny claims for covered and medically necessary testing. Laboratories are Medicare providers with National Provider Identification numbers and bill their laboratory testing claims to MACs and third-party private payers. Importantly, current regulation, 42 CFR § 422.566(c)(1), supports that other individuals and laboratories should be able to initiate requests as it states that an enrollee, enrollee's representative, or any provider that furnishes, or intends to furnish, services to the enrollee can request a determination. To reduce unnecessary burden on providers, CMS should clarify and enforce that plans cannot restrict prior authorization to ordering providers or primary care providers; they must allow enrollees, an enrollee's representative, and any eligible provider, including laboratory professionals, to request prior authorization. CMS could also consider eliminating prior authorization by MA plans for services explicitly covered under an NCD or LCD, especially if indicated for advanced cancer patients. In such instances, prior authorization

can create unnecessary administrative barriers that delay diagnostic testing results and jeopardize patient outcomes.

4. National Correct Coding Initiative ("NCCI") Manual

Response to Deregulation RFI Question 3 (confusing/unnecessarily complicated; impede access to/delivery of care; interfere with ability to address chronic disease or promote health)

(a) *Chapter 1: General Correct Coding Policies*

We recommend rescinding the following language in the NCCI Manual at Chapter 1, Section I:

> The American Medical Association [AMA] publishes CPT Assistant, which contains coding guidelines. CMS does not review or approve the information in this publication. As a result, CMS may adopt NCCI edits that are not consistent with CPT Assistant. If a physician uses information from CPT Assistant to report services rendered to Medicare patients, it is possible that MACs may use different criteria to process claims.[42]

This language causes confusion for coders and should be deleted. CPT Assistant is used by coders broadly. Any language that contradicts the guidance from the AMA/CPT Assistant makes it difficult for providers to determine appropriate coding. If NCCI edits are not clear and aligned with AMA CPT, it may be difficult for providers to properly order and perform services for patients. Coding errors impact patients and can lead to inaccurate or unnecessary cost-sharing estimates, prior authorizations, and other delays in necessary care.

(b) *Chapter 10: Introduction*

We recommend rescinding the following language in the NCCI Manual at Chapter 10, Section A:

> If a laboratory procedure produces multiple reportable test results, only a single HCPCS/CPT code shall be reported for the procedure. If there is no HCPCS/CPT code that describes the procedure, the laboratory shall report a miscellaneous or unlisted procedure code with a single unit of service.[43]

This language does not curb bureaucracy in that laboratories may be unable to report multiplex tests with existing CPT codes. It also creates confusion. Multiple uses of codes, and how they relate to other codes are already addressed via NCCI edits themselves. Further, it decreases patient access to multiplex covered tests that may not have a single multiplex code.

[42] NCCI Manual, ch. 1, sec. I, available at https://www.cms.gov/medicare/coding-billing/national-correct-coding-initiative-ncci-edits/medicare-ncci-policy-manual.

[43] Id at Ch. 10, sec. A.

(c) *Chapter 10: Medically Unlikely Edits (MUE)*

We recommend rescinding the following language in the NCCI Manual at Chapter 10, Section M.15:

> In the case of tests for infectious agents, methodologies include detection by immunofluorescence, immunoassay, or nucleic acid probe techniques. A single laboratory procedure shall be reported as one unit of service whether it generates one or multiple results. CPT codes that test for a single infectious agent that employ one procedure, one methodology, or one test kit are reported with one unit of service.
>
> CPT codes that test for multiple infectious agents are reported with one unit of service if one procedure, one methodology, or one test kit is used to perform the test (e.g., 87300, 87451, 87800, 87801). When multiple procedures, multiple methodologies, or multiple kits are medically necessary and used to perform a test for multiple infectious agents, the units of service reported for CPT codes that identify multiple infectious agents equals the number of different procedures, methodologies, or kits used to perform the test.
>
> For example, if a provider/supplier tests for 5 different species of an infectious agent using a single multiple-result test kit, only 1 unit of service for that test kit may be reported. However, if a provider/supplier tests for 3 different species of an infectious agent by using 3 different single result test kits, the provider/supplier may report 3 UOS of the appropriate CPT code.[44]

This language contradicts the guidance from the AMA/CPT, which makes it difficult for providers to determine appropriate coding. Coding errors impact patients and can lead to inaccurate or unnecessary cost-sharing estimates, prior authorizations, and other delays in necessary care.

5. National Coverage Determinations ("NCDs")

Response to Deregulation RFI Question 1 (harm national interest by impeding technology innovation), Question 2 (recommendation will permit focus on reversing chronic disease), and Question 3 (impede access to/delivery of care; impede innovation; interfere with ability to address chronic disease or promote health; obsolete)

(a) *42 CFR 405.601-405.607 - Medicare Coverage of Innovative Technologies (MCIT)/Transitional Coverage for Emerging Technologies (TCET)*

We recommend CMS proceed with Transitional Coverage for Emerging Technologies (TCET) for currently participating technologies, and reissue an updated Medicare Coverage of Innovative Technologies (MCIT) rule to establish an expedited coverage pathway for recently authorized breakthrough designated medical devices that improves upon the limitations of TCET and expands coverage pathways for more innovative devices. The regulations at 42 CFR 405.601-405.607 established a Medicare coverage pathway to provide

[44] Id at Ch. 10, sec. M.15.

beneficiaries with faster access to recently market authorized medical devices designated as breakthrough by the FDA. The current NCD processes are costly and the additional evidentiary review can outweigh the benefits of accelerated access to life saving or life enhancing new technologies. We strongly believe that for devices and diagnostics that have been designated as breakthrough technologies, and that have completed rigorous FDA review, a new paradigm should be established that would provide expedited coverage. These devices are, by definition, meeting currently unmet needs for patients with severe illness that have no, or limited, alternatives for treatment.

(b) *NCD 40.2 - Blood Glucose Monitoring*

We recommend CMS rescind NCD 40.2[45] and clarify that the Durable Medical Equipment Medicare Administrative Contractors ("DME MACs") should modify the applicable LCD to permit non-diabetic patients to access continuous glucose monitors ("CGMs"). There is clear evidence that many post-bariatric surgery patients suffer from recurrent, severe hypoglycemic events and that CGMs are a useful tool in monitoring for and responding to those dangerous events. The Standards of Care from the American Diabetes Association and the UK Society for Endocrinology and the European Society of Endocrinology recommend the use of CGM after bariatric surgery. The existing Medicare LCD (LCD L33822) for CGM is based on a much older NCD (NCD 40.2), created before the existence of CGM, that limits the use of CGM to only patients with diabetes. The LCD cannot be modified to allow any non-diabetic populations to access CGM until such time as the NCD is rescinded to allow it. As such, we recommend CMS rescind NCD 40.2 and clearly state that it is now up to the Durable Medical Equipment Medicare Administrative Contractors ("DME MACs") to appropriately modify the CGM LCD to permit non-diabetic patients to access CGM, when relevant clinical evidence and standards of care demonstrate that CGM use is reasonable and necessary for those non-diabetic patients.

(c) *Expedited NCD Process*

We recommend CMS implement a streamlined process for reconsiderations or updates to existing NCDs. CMS's NCD process lacks efficiency and prevents timely review of innovative services for Medicare beneficiaries. The process to develop or reconsider an NCD through CMS is extremely burdensome and has a backlog spanning years, resulting in a delay for Medicare beneficiaries in receiving appropriate services. This backlog is due in part to an internal CMS decision to consider small reconsiderations or updates to previous NCDs as novel NCD requests, which then must go into the queue and require extensive agency resources to process the reconsideration.

As an example, NCD 90.2. Next Generation Sequencing (NGS),[46] last updated in 2020, is no longer reflective of the innovations in molecular diagnostics that are integral to cancer patients' treatment, but the reconsideration process is hampering timely revision. Later this year, FDA approval of a precision therapy and companion diagnostic ("CDx") is expected that will involve monitoring a breast cancer patient over time to identify emergence of a specific biomarker and subsequently switch therapies. NCD 90.2.

[45] NCD 40.2, "Home Blood Glucose Monitors," available at https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=222.

[46] https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=372.

currently prohibits reimbursement for an NGS test if the cancer patient has been previously tested. As a result, until the NCD is updated to remove this limitation (at Section B.1.a.ii), the lack of coverage for an FDA-approved CDx may limit Medicare patients' access to an FDA-approved drug that can improve breast cancer patient outcomes.

Additionally, Sections C and D of NCD 90.2. currently prohibit MACs from assessing and providing coverage for innovative diagnostics that fall outside of the original use-cases anticipated by NCD 90.2. The NCD was written to cover a technology but limits this coverage to only a specific use-case in advanced cancer patients at the time of diagnosis or progression, thereby prohibiting coverage of this technology in other circumstances, such as early-stage patients as well as monitoring in advanced cancer patients and minimal residual disease ("MRD"). Removing Sections C and D would simply eliminate this blanket non-coverage limitation and provide flexibility to the MACs to determine coverage policy where appropriate. This would allow for a streamlined less burdensome process for coverage of innovative NGS tests.

CMS should use a streamlined process for reconsiderations or updates to existing NCDs to align coverage to (1) be consistent with an FDA authorized covered service's expanded intended use or to (2) remove coverage limitations that preclude MACs from establishing coverage policies for new and innovative technologies. This would reduce the backlog of NCD requests, decrease CMS agency resources needed to review and process these requests, and improve Medicare beneficiary access to new and innovative services more quickly.

(d) *Outdated Coverage*

Medicare coverage policies, including NCDs and LCDs, become outdated over time, with current studies and guidelines not always taken into account. Medicare's coverage of services can and should change, based on factors like medical advancements, patient needs, and policy changes. Keeping NCDs and LCDs updated is a complex process that requires ongoing monitoring and adjusting of coverage policies to ensure they remain effective and meet the needs of beneficiaries. One way to streamline this process and ensure policies remain current and reflect the latest medical evidence and best practices is for CMS and MACs to prioritize NCDs and LCDs that have a high volume of claims and those in rapidly evolving fields. Relatedly, CMS should use this streamlined process to hold MA plans accountable when they do not adhere to coverage updates and thereby add unnecessary burden and complexity for patients and providers by requiring prior authorization, utilization management, or appeals processes for claims that are indeed covered by an NCD or LCD.

F. 42 CFR 414.202 – Definition of Durable Medical Equipment

Response to Deregulation RFI Question 1 (not based on best reading of the underlying statutory authority; harm national interest by impeding technology innovation) and Question 3 (impede innovation; obsolete)

We recommend revising the definition of Durable Medical Equipment at 42 CFR 414.202 to remove the following two conditions:

- Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years; and

- Generally is not useful to an individual in the absence of an illness or injury.

The regulation as it currently exists is inconsistent with the underlying statute and no longer reflects the current state of technology. The first condition noted above unnecessarily restricts new and innovative technology like digital and artificial intelligence ("AI") based technology from the definition of DME. In addition, the 3-year useful lifetime limit is not required by statute and sets arbitrary limits on what type of technology can be considered DME. The second condition noted above also unnecessarily restricts new and innovative technology from the definition of DME and restricting the definition of DME to items that are both primarily used for a medical purpose and are not useful in the absence of illness or injury is overly restrictive. As such, we recommend eliminating from the definition of DME the 2 conditions noted above.

G. Electronic Clinical Quality Measures - Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults

Response to Deregulation RFI Question 3 (require excessive reports or unreasonable record keeping; information not needed/effective; impede access to/delivery of care)

We recommend CMS rescind from quality reporting programs the Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults Electronic Clinical Quality Measure (the "eCQM"), including for the Hospital Inpatient Quality Reporting ("HIQR") Program, Hospital Outpatient Quality Reporting ("HOQR") Program, and the Merit-based Incentive Payment System ("MIPS").[47] The Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) eCQM was finalized for adoption in the FY 2024 IPPS final rule for HIQR and the CY 2024 OPPS final rule for HOQR as a facility-based measure. The measure was also finalized for the MIPS Program in the CY 2024 PFS/QPP final rule. The eCQM requires facilities to utilize a third-party vendor software product to successfully report the measure data. Typically, eCQMs can be extracted from or directly reported within the electronic health record ("EHR") regardless of the EHR vendor. However, eCQMs were not designed for radiology and cannot currently access and consume elements from Digital Imaging and Communications in Medicine ("DICOM") objects, so an additional resource is necessary for reporting the measure data. This has created operational challenges for facilities and clinicians and significantly increases the burden of reporting, which eCQMs are intended to reduce. Furthermore, the eCQM's technical specifications and limits for noise and dose compromise image quality and restrict clinicians from making appropriate and necessary adjustments to radiation doses, potentially resulting in inaccurate dosage or misdiagnosis. Therefore, we recommend CMS remove the eCQM from quality reporting programs.

[47] The eCQM was finalized for the HIQR Program, the HOQR Program, and MIPS at 88 FR 59154, 88 FR 81986, and 88 FR 79329, respectively.

H. FDA Regulations

1. FDA should utilize the authority provided in Section 3054 of the 21st Century Cures Act (amending Sections 510(l) and 510(m) of the FD&C Act)[48] to exempt from the 510(k) requirement, using a streamlined mechanism, additional Class I and Class II devices that no longer warrant a 510(k).

Section 3054 of the 21st Century Cures Act requires FDA to identify within certain timeframes and on a regular systematic cadence Class I and II devices currently subject to the 510(k) requirement that no longer warrant a 510(k), for instance the device is now well established and/or is better understood over time. These provisions provide for an efficient mechanism to exempt these lower risk devices from the 510(k) requirement. We encourage use of these exemption provisions, which provide for a risk-based, effective use of government regulatory resources and supports innovation for patients. We would be happy to assist with possible recommendations of devices for consideration.

2. FDA should utilize the authority provided in Section 707 of the FDA Reauthorization Act (FDARA) (FDARA)((adding section 513(f)(6) of the FD&C Act)) to distinctly classify accessories into class I.

The FDA has accessory classification authority under section 513(f)(6) of the FD&C Act, as amended by FDARA Section 707. In accordance with section 513(f)(6)(D)(i), the FDA finalized a list of accessories that the FDA found to be suitable for distinct classification in class I in 2019. In accordance with section 513(f)(6)(D)(i), the FDA is required to publish a list of accessories to be classified as class I at least once every 5 years. We encourage the FDA to meet its statutory requirements to publish a new class I accessories list.

- **Title 21, Chapter I – Point-of-Care (POC) Tests**

Response to Deregulation RFI Question 1 (significant costs upon private parties not outweighed by public benefits; harm national interest by impeding technology innovation; impose undue burdens on small business/impede private enterprise), Question 3 (require excessive reports or unreasonable record keeping; information not needed/effective; impede innovation; obsolete), and Question 4 (alternative approach can achieve same goal with lesser burden)

We recommend FDA rescind the portion of those regulations that require manufacturers to submit a premarket notification to FDA for devices that are in vitro devices intended for POC testing, including 21 CFR § 878.9; 21 CFR § 882.9; 21 CFR § 862.9; 21 CFR § 864.9; 21 CFR § 874.9; 21 CFR § 866.9; 21 CFR §880.9; 21 CFR § 884.9; 21 CFR § 868.9; 21 CFR § 872.9; 21 CFR § 888.9; 21 CFR § 870.9; 21 CFR § 876.9;21 CFR § 886.9; 21 CFR § 890.9; 21 CFR § 892.9.25.

The value of POC *in vitro* diagnostic testing, including those tests intended for use in a doctor's office, school, workplace or even the home, was demonstrated during the COVID-19 pandemic and continues to grow today. For instance, POC testing empowers patients by providing information needed to make

[48] See 21 U.S.C 360(l) and (m).

decisions about their care. Significant regulatory hurdles make it extremely difficult for developers of POC tests to succeed. Throughout Title 21, identical limiting language appears requiring a test that would otherwise be low-risk—and could therefore be launched without FDA review— to go through FDA review for the sole reason that the test is intended for the POC setting. Identical limiting language appears repeatedly (e.g., 21 C.F.R. § 862.9(c)(9)). Over two decades have passed since the promulgation of these outdated regulations, and modernizing the treatment of near patient testing in a risk-based manner would benefit all patients. Categorically limiting a device simply because it is POC no longer makes sense, particularly as POC tests are proven powerful tools to empower patients with information for their health. It does not support the public health in today's health care environment and it creates unnecessary regulatory hurdles that stifle innovation.

3. 21 CFR Part 11 - Electronic Records; Electronic Signatures

Response to Deregulation RFI Question 3 (obsolete)

We recommend rescinding 21 CFR Part 11, related to the requirements for validation, audit trails, record retention, and electronic record copying. These requirements are currently subject to enforcement discretion per FDA guidance. This dates back to August 2003 when FDA announced that it was reevaluating Part 11 and exercising enforcement discretion for a narrower application of Part 11 while retaining the regulation in its entirety. The significant resource expenditures associated with Part 11 were identified as the reason for enforcement discretion. However, nearly twenty-two years later, Part 11 remains in the Code of Federal Regulations, even though they are outdated and unnecessary. These regulations set forth the criteria under which FDA considers electronic records to "be trustworthy, reliable, and generally equivalent to paper records and handwritten signatures executed on paper."[49] Since the regulations were promulgated, the common use of electronic systems (and away from paper recordkeeping) has greatly expanded. We therefore recommend 21 CFR Part 11 be rescinded in its entirety (along with associated Part 11 guidance) in order to ensure a modern and efficient regulatory framework.

4. FDA Guidance Documents

We recommend rescinding the following FDA guidance documents for the reasons discussed below with respect to each FDA guidance document.

Response to Deregulation RFI Question 1 (not based on best reading of the underlying statutory authority; harm national interest by impeding technology innovation; harm national interest by impeding research and development) and Question 3 (obsolete; confusing/unnecessarily complicated; require excessive reports or unreasonable record keeping; information not needed/effective; impede access to/delivery of care; impede innovation; interfere with ability to address chronic disease or promote health)

(a) *510(k) Premarket Notification Draft Guidance Documents (2023)*

[49] 21 CFR § 11.1(a).

We recommend rescinding the following 510(k) draft guidance documents issued by the FDA in 2023 as they each include recommendations that are inconsistent with longstanding regulatory practice, and they are not supported by existing statutes and regulations. We include illustrative examples below from each of these draft guidance documents to support our recommendations.

(1) Best Practices for Selecting a Predicate Device to Support a Premarket Notification [510(k)] Submission: Draft Guidance for Industry and Food and Drug Administration Staff[50]

This draft guidance document recommends manufacturers select a predicate device that meets certain characteristics to support a 510k premarket notice submission; however, there is no statutory basis to make or enforce such recommendation. The draft guidance document also recommends manufacturers disclose information regarding their predicate device selection process in a public-facing 510(k) summary; however, this information is not a required element per 21 CFR 807.92, it is irrelevant to the determination of a substantial equivalence determination, and may inadvertently result in disclosure of proprietary information.

(2) Evidentiary Expectations for 510(k) Implant Devices: Draft Guidance for Industry and Food and Drug Administration Staff[51]

This draft guidance document appears to change the definition of an implanted medical device as defined in 21 CFR 860.3(d). The draft guidance document also includes blanket recommendations that do not consider the risk of the device, which is inconsistent with FDA's longstanding benefit-risk and "least burdensome" principles.

(3) Use of Clinical Data in Premarket Notification [510(k)] Submissions: Draft Guidance for Industry and Food and Drug Administration Staff[52]

The examples and recommendations included in this draft guidance document related to the use of clinical data in 510(k) submission suggest a deviation from the statutory standard to demonstrate equivalence and a shift towards a premarket approval ("PMA")-like demonstration of safety and effectiveness.

(b) *FDA Draft Guidance: Evaluation of Thermal Effects of Medical Devices that Produce Tissue*

[50] U.S. Food & Drug Admin., Ctr. for Devices & Radiological Health & Ctr. for Biologics Evaluation & Research, Best Practices for Selecting a Predicate Device to Support a Premarket Notification [510(k)] Submission: Draft Guidance for Industry and Food and Drug Administration Staff (Sept. 7, 2023), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/best-practices-selecting-predicate-device-support-premarket-notification-510k-submission.

[51] U.S. Food & Drug Admin., Ctr. for Devices & Radiological Health & Ctr. for Biologics Evaluation & Research, Evidentiary Expectations for 510(k) Implant Devices: Draft Guidance for Industry and Food and Drug Administration Staff (Sept. 7, 2023), https://www.fda.gov/media/171835/download.

[52] U.S. Food & Drug Admin., Ctr. for Devices & Radiological Health & Ctr. for Biologics Evaluation & Research, Recommendations for the Use of Clinical Data in Premarket Notification [510(k)] Submissions: Draft Guidance for Industry and Food and Drug Administration Staff (Sept. 7, 2023), https://www.fda.gov/media/171837/download.

Heating and/or Cooling: Draft Guidance for Industry and Food and Drug Administration Staff[53]

We recommend rescinding this draft FDA guidance. It is overly broad in scope and will impede device discovery and developments. This guidance document widely applies to many device types and is well beyond the guidance it is intended to supersede. It includes within its scope all premarket submissions, including IDE applications—without any delineation across the product lifecycle. In addition, it is both inconsistent with the criteria for IDE applications and contrary to the least burdensome approach, in which Congress has directed the FDA take a least burdensome approach to medical device premarket evaluation in a manner that eliminates unnecessary burdens that may delay the marketing of beneficial new products.[54] Further, the guidance has created much confusion in light of its conflicts with FDA established policies and recognized standards and does not reflect a risk-based approach. As such, we recommend FDA withdraw this draft guidance and instead work with industry and other stakeholders to develop a workable tailored policy. Ideally, this would be done via established consensus standards development processes.

(c) *FDA Guidance: Notifying the Food and Drug Administration of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the Federal Food, Drug, and Cosmetic Act*[55]

We recommend FDA rescind this guidance and revise its approach to notice under Section 506J of the Federal Food, Drug, and Cosmetic ("FD&C") Act ("Section 506J") of discontinuance or interruption of device manufacturing in a public health emergency ("PHE"). This guidance revised previous guidance to expand the criteria and recommendations for reporting, inconsistent with Congress' focus on devices needed "during, or in advance of, a public health emergency." Further, pursuant to this guidance, FDA published an associated 506J Device List on its website[56] that is confusing and unnecessarily wide in scope. As an initial recommendation, FDA should withdraw the guidance and focus solely on Section 506J statutory reporting criteria and not "additional notifications." The expectation for expansive Section 506J reporting—referred to as "additional notifications"— beyond a PHE will further strain the supply chain while diverting already critical resources from vital manufacturing and response activities. While FDA may receive voluntary notifications pertaining to a permanent discontinuation or interruption in the manufacture of a device at any time, this concept should not be included in policy guidance for the

[53] U.S. Food & Drug Admin., Ctr. for Devices & Radiological Health, Evaluation of Thermal Effects of Medical Devices that Produce Tissue Heating and/or Cooling: Draft Guidance for Industry and Food and Drug Administration Staff (Mar. 15, 2024), https://www.fda.gov/media/177004/download.

[54] See The Least Burdensome Provisions: Concept and Principles, Guidance for Industry and Food and Drug Administration Staff, issued February 5, 2019, available at https://www.fda.gov/media/73188/download.

[55] U.S. Food & Drug Admin., Ctr. for Devices & Radiological Health & Ctr. for Biologics Evaluation & Research, Notifying FDA of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the FD&C Act: Guidance for Industry and Food and Drug Administration Staff (Jan. 7, 2025), https://www.fda.gov/media/155245/download.

[56] U.S. Food & Drug Admin., 506J Device List, FDA (Jan. 6, 2025), https://www.fda.gov/medical-devices/medical-device-supply-chain-and-shortages/506j-device-list.

industry.

Furthermore, FDA should revise its 506J Device List to focus on what is truly critical in a given or typical PHE consistent with Section 506J. Without a focus on key devices for which a positive impact on availability can be made in a given PHE, we lose focus on what is truly critical for patients and healthcare providers. The above approach will result in a patient-centric approach tailored to maximize healthcare in a PHE and align with Congress' public health emergency focus and those devices that Congress prioritized in Section 506J.

Finally, before pursuing any expansion of requirements, outstanding challenges with the current system should be addressed. More transparency should be implemented around determinations of product shortages and public listing and delisting. Regulators are still absorbing how to interpret and understand the data it receives. With any additional reports, it is likely that regulators will not be able to keep pace with maintaining accurate, actionable data. It could also detract from efforts of medical technology manufacturers, who are supplying the products needed for PHEs and the routine practice of medicine while facilitating new innovations for U.S. patients.

(d) *FDA Guidance: Infusion Pumps Total Product Life Cycle*[57]

We recommend FDA rescind this guidance. This guidance was introduced in 2014 with an expectation that a safety assurance case ("SAC") would be submitted with all infusion pump 510(k) submissions. The SAC framework was intended to provide an organized case that the infusion pump adequately addresses hazards associated with its intended use within its environment of use. However, the SAC framework does not achieve its intended goal to improve safety, and it slows the submission and review of innovative devices.

(e) *FDA Cybersecurity Guidance Documents*

We recommend FDA rescind the following two guidance documents:

- Cybersecurity for Networked Medical Devices Containing Off-the-Shelf (OTS) Software;[58] and
- Information for Healthcare Organizations about FDA's "Guidance for Industry: Cybersecurity for Networked Medical Devices Containing Off-The-Shelf (OTS) Software."[59]

These guidance documents, issued in 2005, are dated, given the significant evolution of the cybersecurity

[57] U.S. Food & Drug Admin., Ctr. for Devices & Radiological Health, Infusion Pumps Total Product Life Cycle: Guidance for Industry and FDA Staff (Dec. 2, 2014), https://www.fda.gov/media/78369/download.

[58] U.S. Food & Drug Admin., Ctr. for Devices & Radiological Health, Cybersecurity for Networked Medical Devices Containing Off-the-Shelf (OTS) Software (Jan. 2005), https://www.fda.gov/media/72154/download.

[59] U.S. Food & Drug Admin., Ctr. for Devices & Radiological Health, Information for Healthcare Organizations about FDA's "Guidance for Industry: Cybersecurity for Networked Medical Devices Containing Off-The-Shelf (OTS) Software" (Feb. 2005), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/information-healthcare-organizations-about-fdas-guidance-industry-cybersecurity-networked-medical.

landscape in the past two decades. Medical device cybersecurity has matured and evolved substantially, with more robust expectations through Section 524B of the Federal Food, Drug, and Cosmetic Act ("FD&C") Act, guidance, and industry best practices. Notably, FDA's Center for Devices and Radiological Health has already identified these guidance documents for review, revision, or withdrawal as part of its retrospective review process. In addition, there is terminology in these guidance documents that is no longer aligned with FDA's current cybersecurity guidance, potentially leading to confusion among stakeholders. Moreover, content in these guidance documents has largely been supplemented and replaced by FDA's more comprehensive premarket and postmarket cybersecurity guidance documents. Rescinding these guidance documents will help ensure that stakeholders are referencing up-to-date, relevant, and consistent cybersecurity expectations.

(f) *FDA Draft Guidance: Laser-Assisted In Situ Keratomileusis Lasers – Patient Labeling Recommendations*[60]

We recommend FDA rescind this draft guidance and engage in a collaborative effort to develop more appropriate patient labeling recommendations. The draft guidance is problematic in that its approach interferes with the patient-physician relationship, is not balanced, and fails to include both the benefits and risks of LASIK procedures.

(g) *FDA Guidance: Hydrogen Peroxide-Based Contact Lens Care Products: Consumer Labeling Recommendations – Premarket Notification (510(k)) Submissions*[61]

We recommend FDA rescind this guidance as outdated and unnecessary as the information included has been superseded.

(h) *FDA Guidance: User Labeling for Devices that Contain Natural Rubber (21 CFR 801.437); Small Entity Compliance Guide-Guidance for Industry*[62]

We recommend FDA rescind this guidance as outdated and unnecessary as the information included has been superseded.

(i) *FDA Guidance: Content and Format of Premarket Notification [510(k)] Submissions for*

[60] U.S. Food & Drug Admin., Ctr. for Devices & Radiological Health, Laser-Assisted In Situ Keratomileusis (LASIK) Lasers – Patient Labeling Recommendations: Draft Guidance for Industry and Food and Drug Administration Staff (July 28, 2022), https://www.fda.gov/media/160239/download.

[61] U.S. Food & Drug Admin., Ctr. for Devices & Radiological Health, *Hydrogen Peroxide-Based Contact Lens Care Products: Consumer Labeling Recommendations - Premarket Notification (510(k)) Submissions: Guidance for Industry and Food and Drug Administration Staff* (July 2023), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/hydrogen-peroxide-based-contact-lens-care-products-consumer-labeling-recommendations-premarket

[62] U.S. Food & Drug Admin., Ctr. for Devices & Radiological Health, User Labeling for Devices that Contain Natural Rubber (21 CFR 801.437); Small Entity Compliance Guide; Guidance for Industry (Apr. 1, 2003), https://www.fda.gov/media/71135/download.

Sharps Containers[63]

We recommend FDA rescind this guidance as it contains outdated recommendations. There are recent ISO standards (ISO 23907-1 and-2)—both consensus standards recognized by FDA— that cover many of the same product safety and performance requirements included in the guidance document.

(j) *FDA Guidance: Commercially Distributed Analyte Specific Reagents (ASRs); Frequently Asked Questions*[64]

We recommend FDA rescind this guidance document as it interprets which products qualify as analyte specific reagents ("ASRs") inconsistent with (more narrowly than) the regulatory definition of ASRs at 21 CFR 864.4020(a).

(k) *FDA Guidance: Oncology Drug Products Used with Certain In Vitro Diagnostic Tests: Pilot Program*[65]

We recommend FDA rescind this guidance document. FDA did not provide an opportunity to comment prior to issuing the pilot as a final guidance, and thus it did not capture input on how to structure the pilot for success. To date, no one has enrolled in the pilot, and FDA officials have previously indicated that they are considering whether to continue the pilot. To the extent that FDA does continue the pilot, the guidance is not needed and should be rescinded.

(l) *FDA Guidance: Software as a Medical Device (SAMD): Clinical Evaluation*[66]

We recommend FDA rescind this guidance document. FDA issued an International Medical Device Regulators Forum (IMDRF) Software as a Medical Device (SaMD): Clinical Evaluation document as an FDA guidance, titled "Guidance for Industry and Food Administration Staff: Software as a Medical Device (SAMD): Clinical Evaluation." The document was released as direct to final with no comment period, therefore good guidance practices were not followed. While industry strongly supports international harmonization, this particular document should not have been adopted without consideration of the FD&C Act's approach to classifying devices. While FDA has removed all references to the IMDRF SaMD

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[63] U.S. Food & Drug Admin., Ctr. for Devices & Radiological Health, *Guidance on the Content and Format of Premarket Notification [510(k)] Submissions for Sharps Containers* (October 1993), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-content-and-format-premarket-notification-510k-submissions-sharps-containers.

[64] U.S. Food & Drug Admin., Ctr. for Devices & Radiological Health & Ctr. for Biologics Evaluation & Research, Commercially Distributed Analyte Specific Reagents (ASRs): Frequently Asked Questions: Guidance for Industry and FDA Staff (Sept. 14, 2007), https://www.fda.gov/media/71127/download.

[65] U.S. Food & Drug Admin., Ctr. for Drug Evaluation & Research, Ctr. for Devices & Radiological Health & Oncology Ctr. of Excellence, *Oncology Drug Products Used with Certain In Vitro Diagnostic Tests: Pilot Program: Guidance for Industry, Clinical Laboratories, and Food and Drug Administration Staff* (June 20, 2023), https://www.fda.gov/media/169616/download.

[66] U.S. Food & Drug Admin., Ctr. for Devices & Radiological Health, *Software as a Medical Device (SAMD): Clinical Evaluation: Guidance for Industry and Food and Drug Administration Staff* (Dec. 2017), https://www.fda.gov/media/100714/download.

document from its subsequent Clinical Decision Support Guidance, the document on SaMD Clinical Evaluation guidance remains in effect. Because of the misalignment between the classification approach listed in the document and the regulations, the guidance cannot be implemented; the guidance therefore is not utilized. We recommend FDA withdraw this guidance and potentially reissue it with a classification approach aligned with the FD&C Act and associated regulations.

(m) *FDA Guidance: Recommendations to Reduce the Risk of Transmission of Disease Agents Associated with Sepsis by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)*[67]

We recommend FDA rescind this guidance document. This follows withdrawal of the original guidance for industry issued on January 7, 2025. While we appreciate FDA's efforts to reissue it for public comment, we believe the draft guidance raises serious questions as to its utility and will exacerbate existing shortfalls of critical tissue types already in low supply with estimated reductions of up to 30–35% for patients in need. The proposed guidance introduces a host of ambiguous, scientifically unsupported criteria that could exclude donors unnecessarily and lead to conflicting determinations, even for the same donor, due to inconsistent and unclear provisions.

Importantly, and as noted by multiple stakeholders including the American Association of Tissue Banks, the fundamental medical and scientific foundation of the guidance that sepsis is a relevant communicable disease agent or disease is scientifically and medically invalid. A sepsis diagnosis does not confirm that any infection is present or systemic. Using sepsis alone as a surrogate for disease transmissibility is both under- and over-inclusive in screening for the risk of Mycobacterium tuberculosis ("Mtb") transmission. Additionally, sepsis is not transmissible from human to human and therefore should not result in donor exclusion as the guidance suggests.

We respectfully and strongly urge FDA to indefinitely suspend (or otherwise withdraw) both this draft 2025 guidance and the 2007 Sepsis Guidance (otherwise referred to as "Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps), Guidance for Industry")[68] in their entirety. Absent such action, we remain deeply concerned that such guidance will contribute to severe reductions in tissue supply, create substantial implementation confusion, and ultimately increase the risk of harm to patients.

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[67] U.S. Food & Drug Admin., Ctr. for Biologics Evaluation and Research, *Recommendations to Reduce the Risk of Transmission of Disease Agents Associated with Sepsis by Human Cells, Tissues and Cellular and Tissue-Based Products (HCT/Ps): Draft Guidance for Industry* (May 5, 2025), https://www.fda.gov/media/186261/download.

[68] U.S. Food & Drug Admin., Ctr. for Biologics Evaluation and Research, *Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps): Guidance for Industry* (August 2007), https://www.fda.gov/files/vaccines,%20blood%20&%20biologics/published/Eligibility-Determination-for-Donors-of-Human-Cells--Tissues--and-Cellular-and-Tissue-Based-Products--Guidance-for-Industry.pdf.

(n) *FDA Guidance: Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use*[69]

We recommend FDA rescind this guidance document. The guidance stifles innovation and limits a patient's access to safe biologic treatments that facilitate the body's natural healing process and serve as effective alternatives to pharmacological options. The policy limits patient access to autologous (from patient's own body) biologics and encroaches into the practice of medicine. Specifically, the guidance imposes restrictions on the use of autologous biologics such as platelet rich plasma ("PRP") and bone marrow aspirate concentrate without any formal rulemaking or statutory mandate. This guidance redefined key regulatory terms such as "minimal manipulation" and "homologous use" in ways that restrict physician discretion and limit patient access to low-risk, personalized care. We do not believe this policy is in the best interest of public health. Rescinding the guidance would restore the original intent of Section 361 of the Public Health Service Act ("PHSA"), allow safe biologics to be used under appropriate clinical oversight, and eliminate this barrier to regenerative care using a patient's own blood rather than relying on systemic pharmaceutical interventions. By taking such action, it will correct the misguided and expansive statements in the guidance that PRP and other blood products are not HCT/P under 21 CFR Part 1271 contrary to Section 361 of PHSA and that a patient's own biological material constitutes a "drug" under current FDA regulatory scheme.

I. 37 CFR 201.40(b)(17) - DMCA Exemption

Response to Deregulation RFI Question 1 (not based on best reading of the underlying statutory authority; significant costs upon private parties not outweighed by public benefits; harm national interest by impeding technology innovation) and Question 3 (impede access to/delivery of care; impede innovation

We recommend the Librarian of Congress ("Librarian") rescind 37 CFR 201.40(b)(17), related to an exemption from the prohibition against circumvention under the Digital Millennium Copyright Act ("DMCA")[70] for medical devices or systems to allow the diagnosis, maintenance, or repair of such devices or systems (the Exemption). Rescission of this regulation is critical for public health, patient safety, patient privacy, and protecting intellectual property. The regulation is also inconsistent with law and the DMCA was not properly applied in adopting the Exemption.[71]

Many medical devices are embedded with copyrighted software that enables functionalities of the device. These devices usually contain technological protection measures ("TPMs") to prevent unauthorized

[69] U.S. Food & Drug Admin., Ctr. for Biologics Evaluation and Research & Ctr. For Devices & Radiological Health, *Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)—Minimal Manipulation and Homologous Use: Guidance for Industry and Food and Drug Administration Staff* (July 21, 2020), https://www.fda.gov/media/109176/download.

[70] 17 U.S.C. 1201(a)(1)(A).

[71] See Memorandum of Points and Authorities in Support of Plaintiffs' Motion for Summary Judgment, Advanced Medical Technology Association, et al. vs. Library of Congress, et al., No. 1:22-cv-499 (BAH) (D.D.C.).

access to the copyrighted software, protecting the device from malicious code, among other patient safety-focused concerns. The anti-circumvention provision of the DMCA makes it illegal to circumvent a TPM used to prevent unauthorized access to copyrighted works, so the DMCA prohibits hackers from bypassing TPMs on medical devices enabled by copyrighted software. However, the statute also allows the Librarian to adopt temporary exemptions to this prohibition. The Librarian adopted 37 CFR 201.40(b)(17) to create an exemption to permit circumventing TPMs to access computer programs that are contained in and control the functioning of a medical device or system to repair, maintain, or diagnose problems with the medical device or system.

Of great concern, the Exemption creates serious safety risks for patients and promotes the violation of copyrights. It also negatively impacts medical technology innovation, health care costs, and supply chain integrity. It allows unauthorized, unregulated entities to hack into medical device software for repairs. These unauthorized, unregulated entities, known as independent service organizations ("ISOs"), are not obligated to adhere to FDA quality system regulation ("QSR") requirements. Of note, original equipment manufacturers (OEMs) contract with authorized ISOs to provide repair and maintenance services for OEM devices. In these approved instances, authorized access is provided by the OEM to the ISO, along with training, competency assessments, and validated parts and software to perform servicing that meets QSR requirements. Medical device software is broadly licensed and available to healthcare providers. TPMs do not restrict healthcare providers from using licensed clinical software on medical devices; they limit only what aspects of the software may be viewed, used, copied, and modified. In this way, TPMs provide critical protection to ensure the privacy of patient data and that appropriate users operate the proprietary OEM software.

Permitting an unauthorized, unregulated entity to circumvent protection measures to maintain, repair, or modify a medical device without FDA oversight and without the manufacturer's consultation presents serious risks to patients and healthcare providers. The devices use advanced technologies that, if not employed according to well-researched and regulated safety standards, can introduce dangers to users, including electrical shock, mechanical failure, improper dosing, infection, and burns. In addition, improperly calibrated and maintained devices can severely harm or kill patients by overexposing them to ionizing radiation. Other improperly serviced devices, such as imaging contrast agent power injectors, can cause fatal air embolisms. In addition to these direct safety risks, failure to maintain or repair these devices properly could cause interference with other equipment, a delay in care, and misdiagnosis.

Further, the act of circumventing TPMs to access medical device operating systems and software applications creates cybersecurity vulnerabilities that risk the functionality of devices and the privacy of confidential patient health information stored on them. Whenever a software hack tool is used to access a device for diagnostic and maintenance purposes, the device is modified, potentially compromising the integrity of the software. This can produce unintended consequences. For example, it may introduce security vulnerabilities to the device and to any networks to which the device is connected. And it may interfere with the device's operability as intended. By permitting the circumvention of TPMs, the Exemption increases the cybersecurity risk of highly regulated and confidential patient data, and it puts the functionality of life-saving medical equipment in jeopardy, raising patient safety concerns.

Finally, permitting an unauthorized, unregulated entity to circumvent TPMs to maintain, repair, or modify a

medical device without FDA oversight and without the manufacturer's consultation discourages manufacturer innovation by failing to protect their intellectual property.

For the foregoing reasons, we recommend the rescission of the DMCA exemption at 37 CFR 201.40(b)(17).

III. Conclusion

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

Thank you in advance for your consideration of AdvaMed's comments. Please do not hesitate to contact me with any questions at (202) 783-8700 or by email at cwhite@advamed.org.

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

EXHIBIT A

New AKS Safe Harbor for Value-Based Warranty Arrangements

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

(*) **Value-based warranties**. As used in section 1128B of the Act, "remuneration" does not include any value-based warranty remedy or value-based services provided by a seller of warranted items to a buyer of such warranted items in connection with a value-based warranty, each as defined in paragraph (*)(5) of this section, as long as the following standards (as applicable) are met—

(1) The terms and conditions of the value-based warranty remedy are fixed and disclosed in writing by the seller making such value-based warranty available, at or prior to the time of the buyer's first purchase or coverage of the seller's warranted items to which the value-based warranty relates.

(2) The value-based services to be provided or made available by the seller as part of such value-based warranty are identified in writing and disclosed by the seller to the buyer at or prior to the time of the buyer's first purchase or coverage of the warranted items to which the value-based warranty relates; provided, that with respect to value-based services described in paragraph (*)(5)(C)(i), such value based services shall instead be identified in writing and disclosed by the seller to the buyer at or prior to the time they are provided.

(3) In the case of the buyer:

(A) If and as required under any applicable Federal health care program statute, regulation, demonstration or contract pursuant to which such buyer furnishes or provides coverage for the warranted items to which such value-based warranty relates, the buyer appropriately reports and/or reflects the buyer's price and/or net cost for the warranted items to which the value based warranty relates, taking into account (i) any warranty price adjustment (as defined in paragraph (*)(5)(G) of this section) and (ii) the value reasonably attributed by the seller to each reimbursable item and/or service provided or made available by the seller as part of such value based warranty, as provided by the seller under paragraph (*)(4) below;

(B) The buyer does not report or reflect any cost for any warranty replacement items and/or services (as defined in paragraph (*)(5)(H) of this section) provided as part of a value-based warranty remedy under any Federal health care program, or otherwise seek reimbursement under any Federal health care program for such warranty replacement items and/or services; and

(C) The buyer does not submit a claim for separate payment for any value-based services provided or made available by the seller under the value-based warranty apart from the buyer's claim which includes the warranted items to which the value-based warranty relates.; and

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

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

ii. the amount of any such value-based warranty price adjustment and an itemization of

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

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

(4) In the case of the seller:

(A) If reasonably requested by the buyer in order to satisfy a reporting obligation of the buyer under paragraph (*)(3) of this section, such seller provides the buyer the value reasonably attributed by the seller to each reimbursable item and/or service provided by the seller under the value based warranty;

(B) Such seller does not submit a claim or otherwise seek reimbursement under any Federal health care program for any such value-based warranty remedy or value-based services provided or made available by it as part of the value-based warranty; and

(C) Such seller refrains from doing anything that would impede the buyer from meeting its obligations under paragraph (*)(3) of this section.

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

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

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

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

(5) For purposes of this paragraph (*):

(A) The term buyer means (i) a Federal health care program beneficiary who receives a warranted item under a Federal health care program, (ii) an individual or entity (such as a provider or supplier) which receives reimbursement under any Federal health care program for a warranted item provided or supplied by such person or entity and (iii) an entity (such as a Medicare Advantage organization or a Medicare Part D plan sponsor) which provides coverage and reimbursement for a warranted item and is fully or partially at risk for the cost of such

warranted item (on other than a fee for service basis);

(B) The term seller means an individual or entity which supplies or provides to a buyer, either directly or indirectly through one or more intermediaries (such as a wholesaler), one or more warranted items with respect to which such seller makes available a value-based warranty remedy to the buyer subject to the terms and conditions of the value-based warranty), and may also make available one or more value-based services to or for the benefit of such buyer or its patients;

(C) The term value-based services means analysis, software, equipment, information and/or services provided or made available by a seller as part of a value-based warranty, for a reduced charge or no charge (apart from the buyer's price or net cost for the warranted items to which the value-based warranty relates), reasonably necessary or appropriate for one or more of the following purposes:

i. Determining the terms of such value-based warranty before such terms are fixed and disclosed in writing (including, without limitation, determining one or more of the metrics to be used in the value-based warranty);

ii. Measuring, collecting, calculating and/or reporting the metric(s) upon which the value based warranty is based and/or the resulting value-based warranty remedy (if any) which is to be provided thereunder;

iii. Optimizing the effectiveness and clinical utility of the warranted items being provided or supplied by the seller under the value-based warranty (*e.g.*, training and/or process improvements); and/or

iv. Otherwise achieving the clinical and/or cost outcomes which, if not achieved, would trigger a value-based warranty remedy under the value-based warranty, including through provision of analysis, software, equipment, information and/or services to patients to facilitate such outcomes;

Provided, that in the case of value-based services described in clauses (iii) and (iv) of this definition, such services must meaningfully contribute to efforts to achieve clinical and/or cost outcomes in connection with conditions diagnosed or treated by one or more reimbursable items and/or services to which the value-based pricing arrangement relates, or to the use of one or more such reimbursable items and/or services (including, but not limited to, avoiding potential adverse outcomes related to such condition, diagnosis, treatment or use), in each case when such reimbursable items and/or services are appropriately used, and which do not knowingly induce the buyer to reduce or limit medically necessary items or services to the buyer's patients. Value-based services should not constrain physician medical judgment, patient freedom of choice, or clinical decision-making in any way.

(D) The term value-based warranty means an agreement or other arrangement under which a seller makes available one or more value-based warranty remedies to a buyer, conditioned upon and/or calculated based upon one or more clinical and/or cost outcomes (determined using one or more measurable metrics) which are associated with the value of the seller's warranted item purchased or used by such buyer when appropriately used, and which does not knowingly induce the buyer to reduce or limit medically necessary items or services to the buyer's patients;

(E) The term value-based warranty remedy means a warranty price adjustment and/or warranty

replacement items and/or services provided by a seller to a buyer under a value-based warranty, in accordance with the terms and conditions of such value-based warranty;

(F) The term warranted items means items for which payment may be made, in whole or in part, under a Federal health care program, which are manufactured, supplied and/or provided by a seller, and for which such seller makes available any value-based warranty remedy under a value-based warranty;

(G) The term warranty price adjustment means a payment made by a seller to a buyer (other than a Federal health care program beneficiary) as a reduction to such buyer's price or net cost for one or more warranted items under a value-based warranty. A warranty price adjustment under this paragraph (*)(5)(G) may include, without limitation, the seller's payment to a buyer of all or a portion of amounts which the buyer owes or fails to receive under a payment arrangement to which the buyer is subject with respect to warranted items, or of costs otherwise borne by the buyer, as a result (directly or indirectly, wholly or in part) of the intended clinical and/or cost outcome not having been achieved (or only partially achieved); and

(H) The term warranty replacement items and/or services means (i) one or more items supplied or provided to a buyer (including, but not limited to, a Federal health care program beneficiary) by a seller (or by a third party at a seller's expense) to replace or supplement a warranted item, and/or (ii) medical, surgical, hospital or other services and related items provided to a buyer by a seller (or by a buyer or a third party at a seller's expense) in connection with the replacement or supplementation of a warranted item or as an alternative or supplemental treatment to the use of the warranted item, provided the following requirements are met: (x) such items and/or services are supplied, provided and/or paid for in accordance with the terms and conditions of the value-based warranty; (y) such items and/or services are not billed by any person to any Federal health care program; and (z) such items and/or services are medically appropriate.

EXHIBIT B

New AKS Safe Harbor for Value-Based Pricing Arrangements

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

(*) **Value-based pricing arrangements**. As used in section 1128B of the Act, "remuneration" does not include any value-based price adjustment or value-based services provided in connection with a value-based pricing arrangement, each as defined in paragraph (*)(5) of this section, as long as the following standards (as applicable) are met—

(1) The terms and conditions of the value-based price adjustment are fixed and disclosed in writing by the seller or buyer making such value-based price adjustment available, at or prior to the time of the buyer's first purchase or coverage of the seller's reimbursable items and/or services (as defined in paragraph (*)(5)(C) of this section) under the value-based pricing arrangement. For such purposes, terms and conditions shall be deemed fixed if the formula or other objective mechanism for determining the amount of the value-based price adjustment is set forth in such written document.

(2) The value-based services to be provided or made available by the seller as part of such value-based pricing arrangement are identified in writing and disclosed by the seller to the buyer at or prior to the time of the buyer's first purchase or coverage of reimbursable items and/or services under the value-based pricing arrangement; provided, that with respect to value-based services described in paragraph (*)(5)(D)(i), such value-based services shall instead be identified in writing and disclosed by the seller to the buyer at or prior to the time they are provided.

(3) In the case of the buyer:

(A) If and as required under any applicable Federal health care program statute, regulation, demonstration or contract pursuant to which such buyer furnishes or provides coverage for the reimbursable items and/or services to which such value-based pricing arrangement relates, the buyer appropriately reports and/or reflects the buyer's price and/or net cost for the reimbursable items and/or services to which the value-based pricing arrangement relates, taking into account (i) any such value-based price adjustment provided to or by the buyer as part of such value-based pricing arrangement, and (ii) the value reasonably attributed by the seller to each reimbursable item and/or service provided or made available by the seller as part of such value-based pricing arrangement, as provided by the seller under paragraph (*)(4) below;

(B) The buyer does not submit a claim for separate payment for any value-based services provided or made available by the seller under the value-based pricing arrangement apart from the buyer's claim which includes the reimbursable items and/or services included in the value-based pricing arrangement; and

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

i. the terms and conditions of any such value-based price adjustment as fixed and

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

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

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

(4) In the case of a seller:

(A) If reasonably requested by the buyer in order to satisfy a reporting obligation of the buyer under paragraph (*)(3) of this section, such seller provides the buyer the value reasonably attributed by the seller to each reimbursable item and/or service provided by the seller under the value-based pricing arrangement;

(B) The seller does not submit a claim or otherwise seek reimbursement under any Federal health care program for any reimbursable items and/or services or value-based services which it provides or makes available as part of the value-based pricing arrangement, apart from its reimbursement under such value-based pricing arrangement; and

(C) Such seller refrains from doing anything that would impede the buyer from meeting its obligations under paragraph (*)(3) of this section.; and

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

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

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

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

(5) For purposes of this paragraph (*):

(A) The term buyer means (i) an individual or entity (such as a provider or supplier) which receives reimbursement under any Federal health care program for reimbursable items and/or services furnished by such person or entity, and (ii) an entity (such as a Medicare Advantage organization or a Medicare Part D plan sponsor) which provides coverage and reimbursement for reimbursable items and/or services and is fully or partially at risk for the cost of such

reimbursable items and/or services (other than on a fee-for-service basis);

(B) The term seller means an individual or entity which supplies to a buyer, either directly or indirectly through one or more intermediaries (such as a wholesaler), one or more reimbursable items and/or services and makes available a value-based price adjustment to the buyer, is the recipient of a value-based price adjustment made available by the buyer to the seller, and/or makes available one or more value-based services to or for the benefit of such buyer or its patients (in each case, subject to the terms and conditions of the value-based pricing arrangement);

(C) The term reimbursable items and/or services means items and/or services for which payment may be made, in whole or in part, under a Federal health care program;

(D) The term value-based services means analysis, software, equipment, information and/or services provided or made available by a seller as part of a value-based pricing arrangement, for a reduced charge or no charge (apart from the buyer's price or net cost for the reimbursable items and/or services to which the value-based pricing arrangement relates), reasonably necessary or appropriate for one or more of the following purposes:

i. Determining the terms of such value-based pricing arrangement before such terms are fixed and disclosed in writing (including, without limitation, determining one or more of the metrics to be used in the value-based pricing arrangement);

ii. Measuring, collecting, calculating and/or reporting the metric(s) upon which the value-based pricing arrangement is based and/or the resulting value-based price adjustment (if any) which is payable;

iii. Optimizing the effectiveness and clinical utility of the reimbursable items and/or services to which the value-based pricing arrangement relates (*e.g.*, training and/or process improvements); and/or

iv. Otherwise achieving the clinical and/or cost outcomes on which the value-based pricing arrangement is based, including through provision of analysis, software, equipment, information and/or services to patients to facilitate such outcomes;

Provided, that in the case of value-based services described in clauses (iii) and (iv) of this definition, such services must meaningfully contribute to efforts to achieve clinical and/or cost outcomes in connection with conditions diagnosed or treated by one or more reimbursable items and/or services to which the value-based pricing arrangement relates, or to the use of one or more such reimbursable items and/or services (including, but not limited to, avoiding potential adverse outcomes related to such condition, diagnosis, treatment or use), in each case when such reimbursable items and/or services are appropriately used, and which do not knowingly induce the buyer to reduce or limit medically necessary items or services to the buyer's patients. Value-based services should not constrain physician medical judgment, patient freedom of choice, or clinical decision-making in any way.

(E) The term value-based pricing arrangement means an agreement or other arrangement under which a seller provides a value-based price adjustment to a buyer, a buyer provides a value-based price adjustment to a seller, and/or a seller makes available value-based services, in each case in accordance with the requirements of this section;

(F) The term value-based price adjustment means a reduction to or increase in a buyer's price or

net cost for one or more reimbursable items and/or services supplied by a seller under a value-based pricing arrangement, consisting of:

i. a discounted or bundled price or net cost initially payable by a buyer for one or more such reimbursable items and/or services, as set forth in the written document referenced in paragraph (*)(1) of this section, as part of a value-based pricing arrangement which also includes terms and conditions for a value-based price adjustment provided in accordance with clause (ii) of this definition and/or value-based services provided in accordance with clauses (iii) or (iv) of the definition of such term; and/or

ii. a payment made by a seller to a buyer, or to a buyer by a seller, as a reduction to or increase in the buyer's price or net cost for one or more such reimbursable items and/or services, which is conditioned and/or calculated based upon one or more clinical and/or cost outcomes (determined using one or more measurable metrics) which are associated with the value of the seller's reimbursable items and/or services purchased by such buyer under such value-based pricing arrangement when appropriately used, and which does not knowingly induce the buyer to reduce or limit medically necessary items or services to the buyer's patients, in accordance with terms and conditions set forth in the written document referenced in paragraph (*)(1) of this section.

Without limitation of the foregoing, a value-based price adjustment under this paragraph (*)(5)(F) may include, without limitation, (x) the seller's payment to a buyer of all or a portion of amounts which the buyer owes or fails to receive under a payment arrangement to which the buyer is subject with respect to reimbursable items and/or services, or of costs otherwise borne by the buyer, as a result (directly or indirectly, wholly or in part) of the intended clinical and/or cost outcome not having been achieved (or only partially achieved), or (y) the buyer's payment to the seller of all or a portion of amounts which the buyer receives under a payment arrangement to which the buyer is subject with respect to reimbursable items and/or services as a result (directly or indirectly, wholly or in part) of the intended clinical and/or cost outcome having been achieved (or partially achieved).

EXHIBIT C

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

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

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

(1) A Value-based Risk-Sharing Arrangement is a written agreement under which participants agree to:

i. contribute to the achievement of pre-identified and measurable clinical and/or economic target endpoints that are specifically designed to promote improved patient outcomes and/or reduction of the costs of health care delivery, while avoiding negatively affecting patient outcomes;

ii. implement associated processes and procedures that seek to optimize the delivery, efficiency, and/or quality of patient-centered care; and

iii. assume an allocation of the financial risk in achieving the targeted endpoints and/or outcomes, with consideration of the participants' respective contributions thereto.

Under this section, remuneration shall also not include participant activities reasonably necessary or appropriate to (i) determine the terms of such Value-Based Risk-Sharing Arrangement before such terms are set forth in a written agreement (including, without limitation, determining one or more of the metrics to be used in the Value-Based Risk-Sharing Arrangement) or (ii) measure, collect, calculate and/or report the metric(s) upon which the Value-Based Risk-Sharing Arrangement is based and/or the resulting economic benefit and/or exposure. The activities to determine the terms of a Value-based Risk-Sharing Arrangement shall be identified in writing and disclosed between the participants at or prior to the time such activities take place.

For purposes of this subparagraph, financial risk is defined as the economic benefit and/or exposure that each participant agrees to assume with regard to the other participant(s) and the amount of which is subsequently calculated with reference to a specified methodology, which benefits or exposures may include shared savings payments, underachievement payments, withholds, bonuses, and/or the like. The methodology to determine financial risk must be set forth in writing and in advance of the performance of the specific Risk-Sharing Arrangement and shall not be dependent upon the volume or value of any referrals or the purchase of any participant's goods or services which do not contribute to the achievement of pre-identified clinical and/or economic target metrics.

(2) A transfer of value may be exchanged between or among one or more participants under a Value-Based Risk Sharing Arrangement that is intended to:

i. drive or promote accountability for quality, cost, coordination, and overall care of patient populations, including patient populations that receive services that are reimbursed by different methodologies and/or by different payors; or

ii. manage and coordinate care for patients through arrangements approved by the entities in

the arrangement and administered, furnished, or arranged by such entities; or

iii. encourage efficient deployment and utilization of infrastructure and/or facilitate redesign or care process workflow to achieve higher quality and/or more efficient service delivery for patients, where efficient service delivery includes, among other things, redeployment of and training on the use of goods and services, appropriate reduction of costs or more optimal utilization of goods and services provided to patients, and/or expanded access to healthcare choices to patient populations (including previously underserved populations), in each case consistent with quality of care, physician medical judgment, and patient freedom of choice.

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

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

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

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