AdvaMed
Advanced Medical Technology Association

January 27, 2023

By Electronic Submission via www.regulations.gov

Ms. Susan Edwards
Office of Inspector General, Regulatory Affairs
Department of Health and Human Services
Attention: OIG-1122-N
Room 5527, Cohen Building
330 Independence Avenue SW
Washington, D.C. 20201

Re: OIG-1122-N: Solicitation of Proposals for New and Modified Safe Harbors and Special Fraud Alerts

Dear Ms. Edwards:

The Advanced Medical Technology Association (AdvaMed) appreciates this opportunity to submit proposals for additional or modified safe harbor provisions under the federal Anti-Kickback Statute (AKS)[1] and Special Fraud Alerts in response to the Solicitation of Proposals for New and Modified Safe Harbors and Special Fraud Alerts, published by the Office of the Inspector General of the Department of Health and Human Services (OIG) at 87 Fed. Reg. 72953 (November 28, 2022).

As further discussed below, we recommend OIG develop additional and modified safe harbor regulations related to value-based arrangements and contingency management interventions, as well as a new Special Fraud Alert related to group purchasing entities.

AdvaMed

AdvaMed is a trade association that represents the world's leading innovators and manufacturers of medical devices, diagnostic products, digital health technologies, and health information systems. Together, our members manufacture much of the life-enhancing and life-saving health care technology purchased annually in the

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

United States and globally. AdvaMed members range from the largest to the smallest medical technology producers and include hundreds of small companies with fewer than 20 employees. Our members are committed to the development of new technologies and services that allow patients to lead longer, healthier, and more productive lives. The devices made by AdvaMed members help patients stay healthier longer and recover more quickly after treatment and enable clinicians to detect disease earlier and treat patients as effectively and efficiently as possible.

Safe Harbors for Value-Based Arrangements

A. Medical Technology Manufacturers Are Uniquely Poised to Drive Value-Based Care Solutions

AdvaMed's members, which include medical device manufacturers and manufacturers, distributors, and suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS), have a key role to play in achieving the transformation of health care to value-based care. Medical technology manufacturers are experts in how their technologies can impact clinical outcomes and have the specialized knowledge to design, and/or collaborate with providers and payors in the design of, solutions to improve outcomes and optimize care in a cost-effective manner—often using data generated from the devices to help facilitate care coordination.

Accomplishing these improvements requires providing tools and services (beyond just selling a device) to help coordinate and optimize care, in order to further establish shared accountability across the continuum. Examples of these tools and services include education, training, care pathways, protocols, data analytics, supply-chain optimization, and care coordination services, which may involve nurse call centers, monitoring and/or diagnostic technology. Medical technology manufacturers also recognize that to significantly address cost inefficiencies within a system, providers often need support in identifying the opportunities for cost-saving efficiencies and care improvements, and in designing and operationalizing systems and arrangements to realize such improvements and efficiencies. Device manufacturers and DMEPOS companies are well-positioned to help in this regard as their equipment has countless touchpoints with patients and clinicians daily. As such, medical technology manufacturers may help to identify workflow efficiencies and improvements to management and communications processes, and in some cases, offer the support of health care economists, health policy specialists, supply chain

experts, data analysts, systems experts, and others to help facilitate the development and evolution of efficient and effective health delivery networks to responsibly achieve the goals of value-based care. The end goal of all of this is to achieve much-needed coordination and shared accountability in an otherwise fragmented delivery environment.

While we believe such active participation of medical technology companies is essential to improve outcomes and control costs within our health care system (and also believe that many providers fully share this view), AdvaMed and its members also strongly support a legal framework that protects against fraud and abuse. That commitment is reflected in, among other things, our development of the AdvaMed Code of Ethics[2] to help ensure that interactions between manufacturers and providers are consistent with the AKS and do not inappropriately influence medical decision-making, so that medical decisions are centered on the best interests of the patient. What's more, AdvaMed members employ many highly-skilled compliance professionals who regularly engage in relevant trainings and monitoring across their respective organizations.

We commend OIG's establishment of additional and modified safe harbors under the AKS to encourage and protect arrangements that promote care coordination and advance the delivery of value-based care, while also protecting against the harms caused by fraud and abuse.[3] We also appreciate that certain of these safe harbors include a pathway to protect digital technology arrangements involving device manufacturers and DMEPOS companies. However, as previously communicated, and indeed as referenced by the Agency in the preamble to the Final Rule,[4] we believe that additional modifications to the safe harbor regulations are necessary and appropriate in order to further advance value-based care.

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[2] AdvaMed Code of Ethics on Interactions with Health Care Professionals, https://www.advamed.org/wp-content/uploads/2022/03/2022-AdvaMed-Code-of-Ethics-Digital.pdf

[3] 42 C.F.R. § 1001.952(d)(2) (outcomes-based payment arrangements); 42 C.F.R. § 1001.952(ee) (care coordination arrangements to improve quality, health outcomes, and efficiency); 42 C.F.R. § 1001.952(ff) (value-based arrangements with substantial downside financial risk); 42 C.F.R. § 1001.952(gg) (value-based arrangements with full financial risk); 42 C.F.R. § 1001.952(hh) (arrangements for patient engagement and support to improve quality, health outcomes, and efficiency). *See also* 85 Fed. Reg. 77684 (Dec. 2, 2020) (Final Rule).

[4] 85 Fed. Reg. 77684, 77694 (". . . Another commenter urged OIG to promulgate a safe harbor in this final rule specific to value-based arrangements with manufacturers for the purchase of pharmaceutical products (as well as medical devices and related services). . . We did not propose, and thus are not finalizing, a safe harbor specifically for value-based arrangements with manufacturers for the purchase of their products. We may consider this topic, along with value-based contracting and outcomes-based contracting, for future rulemaking.")

First, we propose that OIG adopt an additional safe harbor to address value-based pricing arrangements to both protect price adjustments and provide a mechanism under which services would be bundled with product(s) being sold or leased, subject to appropriate safeguards, where the arrangement is dependent upon the achievement of a measurable clinical and/or cost outcome.

Second, we propose that OIG modify the safe harbor for value-based arrangements with substantial downside financial risk and the safe harbor for value-based arrangements with full financial risk to protect the participation of medical technology manufacturers in arrangements subject to such safe harbors.

B. Proposal for Establishing New Safe Harbor for Value-Based Pricing Arrangements

The existing safe harbors do not address value-based arrangements with medical technology manufacturers for the purchase of their products; instead, OIG indicated it would consider this issue in future rulemaking.[5] AdvaMed recommends that OIG now do so and that it adopt a new safe harbor for "value-based pricing arrangements" in order to encourage and enable broader engagement in appropriate value-based arrangements. The text of our proposed safe harbor is set forth in Attachment A to this letter. We have also included in Attachment A a hypothetical scenario that illustrates the type of arrangements that our proposed safe harbor would protect. This proposed safe harbor is consistent with proposals we have previously shared with OIG.

Some of the key points of the proposed safe harbor can be summarized as follows:

- The value-based pricing arrangements safe harbor would protect value-based pricing adjustments, defined as a payment made by a seller to a buyer (or by a buyer to a seller) that is conditioned and/or calculated based upon one or more clinical and/or cost outcomes (determined using one or more measurable metrics) that are associated with the value of seller's reimbursable items and/or services when appropriately used.[6]

[5] *See, e.g., id.*

[6] "Base" discounts provided under the arrangement—i.e., those not dependent upon a clinical/cost outcome—would also be included in the definition of value-based pricing adjustments, so that they

- Eligible "buyers" would include providers and payors, and eligible "sellers" would include manufacturers, suppliers, and providers.

- The safe harbor would protect a wide variety of value-based price adjustments, including, but not limited to, rebates provided by manufacturers to payors or providers if the manufacturer's product fails to meet a clinical goal, and value-based reimbursement arrangements between payors and providers.

- It would allow for the provision of "value-based services," defined to include analysis, software, equipment, information, and/or services reasonably necessary or appropriate for the purposes of determining the terms of the arrangement, operationalizing the arrangement (e.g., measuring and reporting relevant outcomes metrics), optimizing the effectiveness and clinical utility of the products or services at issue, or otherwise achieving the clinical or cost outcomes upon which the arrangement is based (including through the provision of software, equipment, information or services to patients and providers).

- It would permit bundled arrangements subject to specified conditions, and appropriate cost-reporting requirements (with the seller's assistance in providing reasonable allocations, when requested by the buyer).

- Other requirements must be satisfied, including setting forth in writing the terms and conditions of the arrangement and the services to be provided, and compliance with prohibitions on duplicative reimbursement claims.

Importantly, and consistent with the factors OIG takes into account when considering new safe harbors,[7] we are convinced that adoption of this safe harbor would not be likely to result in overutilization, underutilization, skewed medical decision-making,

would also be subject to protection, subject to satisfaction of the same cost-reporting and other requirements. See paragraph (*)(5)(F)(i) in Attachment A.

[7] Factors include access to health care services; quality of health care services; patient freedom of choice; competition; cost to Federal health care programs; overutilization of health care services; provision of services in medically underserved areas/to medically underserved populations; and financial benefits to health care providers that may influence their decisions with respect to ordering or making referrals for health care items or services. *See* 87 Fed. Reg. 72953, 72954.

unfair competition, or other fraud and abuse concerns. Nothing in this safe harbor would create an incentive for providers to over-utilize or under-utilize products or services. The proposed definition of "value-based pricing adjustment" expressly requires that the arrangement "not knowingly limit the buyer's ability to make decisions in the best interest of the buyer's patients or induce the buyer to furnish medically unnecessary items or services, or reduce or limit medically necessary items or services to the buyer's patients," which is consistent with the value-based safe harbors finalized under the Final Rule. Medical decision-making will be more appropriate, not less, given the increased flexibility to make decisions based upon value and outcomes, not just nominal price.

In addition, under this proposed safe harbor, competition will be more fair, not less, as value is increasingly taken into account. In particular, smaller manufacturers with innovative products will be able to compete by offering a price tied to their products' performance—creating a win-win for buyers and sellers. Further, adoption of our proposed value-based pricing arrangement safe harbor should reduce costs to Federal health care programs by promoting competition on the right basis—clinical outcomes and cost savings. And the proposed safe harbor prohibits sellers and buyers from submitting claims for separate reimbursement of value-based services, apart from the reimbursement for reimbursable items and/or services to which they relate; as such, there should be no separate Federal costs for such services.

C. Proposal for Modifying Existing Safe Harbors to Include Medical Technology Manufacturers

In addition to our proposal to establish a new safe harbor for value-based pricing arrangements, we also propose that the safe harbors for value-based arrangements with substantial downside financial risk and with full financial risk be modified to include protection for monetary and in-kind remuneration exchanged by manufacturers of devices and medical supplies and DMEPOS companies, excluding physician-owned distributors (PODs).

As discussed above, the active participation of medical technology manufacturers in a variety of value-based arrangements is essential to improving clinical outcomes, controlling costs, and encouraging innovation within our health care system, as the OIG has acknowledged.[8] But such active participation is at risk of being stifled as a

[8] *See* 85 Fed. Reg. 77684, 77711 ("we recognize that manufacturers of devices and medical supplies may play an important role in some value-based arrangements, including by offering digital health

result of the fact that medical technology manufacturers are currently ineligible for protection under all of the available value-based safe harbors. In particular, OIG's current exclusion of device manufacturers and DMEPOS companies from protection under the two value-based safe harbors requiring assumption of risk discourages beneficial and appropriate value-based arrangements not otherwise protected by the digital technology pathway available under the care coordination and management safe harbor and the patient engagement and support safe harbor.

This result is inconsistent with the fact that medical technology manufacturers can and do provide solutions that enable the achievement of all four of the value-based purposes recognized under the current value-based safe harbors - (1) coordinating and managing care; (2) improving quality of care; (3) reducing costs; and (4) transitioning to a value-based health care system – and therefore should be eligible for protection under all of the current value-based safe harbors, subject to the required conditions of each safe harbor, not just those value-based safe harbors related to the first value-based purpose.

That said, we appreciate OIG has some concerns regarding extending protection under the two current value-based safe harbors requiring assumption of risk to certain entities, including medical device manufacturers and DMEPOS companies. We are happy to discuss additional safeguards for these safe harbors specific to medical technology manufacturers and to otherwise work with OIG to ensure that any fraud and abuse concerns are appropriately mitigated.

technologies that can improve coordination and management of care") and 77713 ("We are persuaded by commenters that DMEPOS companies may have an important role in value-based arrangements, particularly in the context of post-acute care, and that they provide an array of health technology services, such as remote patient monitoring, that may facilitate the coordination and management of patient care."). *See also* OIG Advisory Opinion No. 22-04 (concluding that OIG would not impose sanctions under the AKS or the Beneficiary Inducements CMP, section 1128A(a)(5) of the Social Security Act, with respect to a program pursuant to which a *digital health company* provides individuals access to digital contingency management and related tools to treat substance use disorders, which program is funded by health care providers and suppliers (among other customers), using a *pay-for-performance payment model* (*i.e.*, the digital health company is paid based on a patient achieving certain agreed-upon targets for abstinence); illustrating the importance of and appropriate involvement by medical technology companies participating in value-based arrangements, aka performance-based payment arrangements).

Safe Harbor for Contingency Management Interventions

Pursuant to the Consolidated Appropriations Act, 2023,[9] the OIG is required to conduct a review of whether to establish a safe harbor for evidence-based contingency management ("CM") incentives and the parameters for such a safe harbor.[10] AdvaMed supports the establishment of a safe harbor for CM incentives, which should enable and protect participation by medical technology manufacturers, including medical device and DMEPOS companies, but excluding PODs.

CM interventions and incentive programs or arrangements qualify as a form of value-based care arrangements, also referred to as results-based, outcomes-based, or performance-based payment arrangements. Such programs offer payments and other benefits based on individual patient health outcomes and/or population health outcomes, and may be designed to increase shared accountability among stakeholders for quality of, access to, and/or the total cost of care, by conditioning payment or modifying pricing for health care items or services based upon clinical, economic, and/or patient-experience outcomes. As OIG has acknowledged, medical technology companies can and do play a vital role in CM interventions and incentive programs.[11]

Therefore, and for many of the same reasons discussed above with respect to the value-based arrangements safe harbors, any safe harbor(s) established by OIG related to CM interventions and incentives should include protection for monetary and in-kind remuneration provided by manufacturers of devices and medical supplies and DMEPOS companies, excluding PODs.

Group Purchasing Entities

Finally, and separate from the recommendations above regarding value-based arrangements and CM incentives, we also propose that OIG clarify the applicability of the group purchasing organization (GPO) safe harbor[12] to GPO-like entities (GPEs) that 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 and restore the integrity of the ownership requirements under the existing GPO safe

[9] H.R. 2617.

[10] *Id.* Sec. 4127 (amending Section 1128D(a) of the Social Security Act).

[11] *See* OIG Advisory Opinion No. 22-04, *supra* Note 8.

[12] 42 CFR § 1001.952(j).

harbor. The OIG may do so by, among other options, issuing a new Special Fraud Alert regarding GPEs.

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.[13]

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[14] 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 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)."[15]

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 captive, 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

[13] *See* 56 Fed. Reg. 35952, 35982.

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

[15] 42 CFR § 1001.952(j)(2).

the safe harbor. Unlike a traditional GPO, GPE members are often not free to seek out a competing GPO. 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 simply enabling a GPE to serve its agent function and provide services to its members. The GPE may sacrifice optimal discounting for higher fees while leaving the captive hospitals little choice but to use the higher-cost products. Additionally, with the higher amounts being collected and without the competitive threat of members leaving for other GPOs, there is less incentive for a GPE to operate in an efficient manner leading to waste. Such a structure could also lead to the inappropriate enrichment of GPE leadership. Providers beyond the GPE family may also be affected if manufacturers raise prices generally in the market to cover the costs of higher 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.[16]

[16] 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).

To 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, we recommend that OIG develop a Special Fraud Alert regarding GPEs. We also propose OIG refrain from issuing any further advisory opinions granting protection to such arrangements until further 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.

* * *

Thank you in advance for your consideration of the above proposals. We would be pleased to discuss these proposals in greater detail at your convenience. Please do not hesitate to contact me at (202) 783-8700 or cwhite@advamed.org with any questions.

Sincerely,

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

ATTACHMENT A

I. New AKS Safe Harbor for Value-Based Pricing Arrangements

AdvaMed proposes that OIG adopt a safe harbor for value-based pricing arrangements as follows:

(*) **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;

(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 6 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;

(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 6 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 consulting services to identify and help implement related 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 limit the buyer's ability to make decisions in the best interest of the buyer's patients or induce the buyer to furnish medically unnecessary items or services, or reduce or limit medically necessary items or services to the buyer's patients.

(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 limit the buyer's ability to make decisions in the best interest of the buyer's patients or induce the buyer to furnish medically unnecessary items or services, or 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).

II. Hypothetical Example—Value Based Pricing Arrangement

SCENARIO

A medical technology manufacturer's capital equipment is designed to assist a surgeon in achieving better clinical outcomes from certain surgeries, and there is evidence that demonstrates that the use of this equipment can reduce expensive complication rates substantially. However, the capital equipment is expensive, and its use during surgery is not separately reimbursed, so hospitals are reluctant to spend the money without additional assurances as to its value.

To incentivize investment in the capital equipment, the manufacturer is extending to hospitals a purchase agreement, which will provide for the capital equipment together with product training and on-site surgery support as well as a discount on all related consumables. The offered agreement also provides that should the complication rate not be reduced by a targeted amount compared to an established baseline within 18 months after training has been completed, then the manufacturer will provide a rebate to the hospital on the capital equipment and consumables used during surgeries performed within this period. This rebate will be calculated using a formula negotiated between the manufacturer and the hospital customer and reflected in the purchase agreement that takes into account baseline complication rates, percentage improvement required for no rebate to be payable, and requires a minimum number of cases having been completed to ensure statistical validity of the calculations. For example, if there are too few cases, the percentages may be skewed, and as such, no rebate will be payable. However, the agreement also establishes that surgeons are solely responsible for determining the circumstances under which the use of the capital equipment is clinically appropriate.

In order to appropriately establish the baseline prior to the execution of the purchase agreement, the manufacturer will enter into a planning agreement with a potential customer hospital whereby the manufacturer agrees to place equipment at no charge in the hospital's operating rooms to establish an understanding of current surgical

practices and calculate the baseline complication rate. The manufacturer will share this data with the hospital so that the parties may use the information in drafting the formula by which the value-based rebate will be calculated.

Both the purchase agreement and the planning agreement require the hospital to refrain from submitting a claim for separate payment to any payor for the services and information provided by the manufacturer under those agreements, and further to appropriately report its net cost for reimbursable items and services as appropriate.

ANALYSIS

This hypothetical arrangement would be permitted under the proposed safe harbor for value-based pricing arrangements.

First, pursuant to paragraph (*)(5)(D)(i) of the proposed safe harbor, the equipment and services provided under the planning agreement constitute value-based services for the purpose of "determining the terms of such value-based pricing arrangement before such terms are fixed and disclosed in writing", specifically, for the purpose of determining the baseline complication rate. As required under paragraph (*)(2), those value-based services are "identified in writing and disclosed by the seller to the buyer at or prior to the time they are provided."

Second, as required by paragraph (*)(1), the terms and conditions of the value-based price adjustment are fixed and disclosed in writing by the seller to the buyer at or prior to the buyer's first purchase of the reimbursable items and/or services under the arrangement, inasmuch as the "formula or other objective mechanism for determining the amount of the value-based price adjustment" is set forth in the purchase agreement executed by the manufacturer and the hospital.

The arrangement relates to a bundle consisting of reimbursable items and/or services (the capital equipment and consumables) as well as the training. Notably, the capital equipment and consumables are not necessarily reimbursed under the same Federal health care program and methodology (in particular, the consumables may be deemed reimbursed as part of the payment for each surgery). The training constitutes a value-based service under paragraphs (*)(5)(D)(iii) and (iv) as a service for the purpose of "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 for the purpose of "otherwise achieving the clinical and/or cost outcomes on which the value-based pricing arrangements are based (i.e., reduction of the complication rate). The services are appropriately included in the bundle since they "meaningfully contribute to ... the use of one or more" of the reimbursable items and/or services to which the value-based pricing arrangement relates (i.e., the equipment and consumables),

including "avoiding potential adverse outcomes" related to such use (i.e., complications), when such items are appropriately used, and do not "knowingly limit the buyer's ability to make decisions in the best interest of the buyer's patients or induce the buyer to furnish medically unnecessary items or services, or reduce or limit medically necessary items or services to the buyer's patients."

The value-based pricing adjustment includes both the upfront discount on the consumables (under paragraph (*)(F)(i), as a "discounted or bundled price or net cost initially payable by a buyer"), as well as the rebate payable if the percentage reduction in complications is not achieved (under paragraph (*)(F)(ii), as a "payment made by a seller to a buyer ... as a reduction to ... the buyer's price or net cost ... 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 seller's reimbursable items and/or services when appropriately used...."). The rebate also satisfies the requirement that it "not knowingly limit the buyer's ability to make decisions in the best interest of the buyer's patients or induce the buyer to furnish medically unnecessary items or services, or reduce or limit medically necessary items or services to the buyer's patients...."

Finally, in order for the hospital buyer to fall within the safe harbor, it must appropriately report and/or reflect its price or net cost taking into account the value-based pricing adjustment and value-based services, if and as required under applicable Federal health care program requirements, and the buyer must not submit a claim for separate payment for any of the value-based services apart from its claim for the reimbursable items and/or services to which such services relate. It must also retain and provide to the Secretary or a State agency (or its designee) upon request specified information relating to the value-based pricing adjustment, including the terms and conditions agreed in writing with the seller, the amount of the adjustment (both the upfront discount and any rebate), the value of the complications metric, and the manner in which the rebate (if any) was determined. In the case of the manufacturer seller, it must provide the hospital the value reasonably attributed by it to each reimbursable item and/or service (i.e., the equipment and consumables) included in the arrangement if reasonably requested by the hospital to satisfy a cost reporting obligation, it must not submit a claim for the reimbursable items and/or services or value-based services apart from its reimbursement (payment) under the value-based pricing arrangement (purchase agreement), and it must refrain from doing anything that would impede the hospital from meeting its foregoing obligations. It also must retain and provide information upon request of the Secretary or a State agency (or its designee), along the same lines as that required of the buyer.