

Re: AKS Safe Harbors for Value-Based Arrangements (VBAs)

On May 8, 2019, AdvaMed submitted a letter to the U.S. Department of Health and Human Services (HHS) with the attached proposals, described directly below, refining initial proposals offered in an Oct. 26, 2018 AdvaMed letter¹ to the HHS Office of Inspector General (OIG). The letter and follow-up were in response to an August 2018 OIG Request for Information regarding the Anti-Kickback Statute and Beneficiary Inducements Civil Monetary Penalty.²

1. *Revisions to Proposed Safe Harbors for VBAs.* Enclosed please find a document setting forth suggested revisions (Attachment 1) to the draft safe harbors for VBAs we proposed in our October 26, 2018 comments pursuant to OIG's Request For Information. Specifically, we have added text setting forth disclosure obligations for participants in value-based arrangements, to facilitate monitoring of such arrangements by HHS and State Medicaid agencies. These requirements are patterned upon similar provisions in existing safe harbors and OIG waiver programs, and would obligate participants to disclose specified documentation and information regarding the VBA to HHS, State agencies or their designees, upon request, as a condition of safe harbor protection.

We note that OIG and State agencies have broad powers under existing law to obtain documents and other information from organizations and individuals in the health care industry, e.g., through issuance of civil investigative demands. Those tools would remain available to OIG and State agencies as a supplement to the specified disclosure requirements included in the safe harbor text and as a means for OIG or a State agency to obtain any information they might require to confirm that a given arrangement in fact satisfies applicable safe harbor requirements.

2. *Recommended Preamble Language.* One of the major issues that we and other stakeholders have identified as impeding the adoption of beneficial VBAs is the explosion of *qui tam* litigation initiated by financially-motivated relators and their counsel under the False Claims Act (FCA). These cases all too often seek to characterize non-abusive and appropriate industry practices as health care fraud, based upon the extremely broad language of the Anti-Kickback Statute (AKS), as part of their efforts to pressure companies into settlements to avoid material litigation expenses. One important reason why we believe VBA safe harbors are needed is to help reign in such abusive litigation, and thereby reduce and remove the real-world deterrents that health care participants face when attempting to engage in legitimate VBAs necessary to coordinate care, control costs and improve outcomes.

While the adoption of VBA safe harbors, in theory, should provide the necessary protections for industry participants that structure their VBAs in compliance with the safe harbor requirements,

¹ https://www.advamed.org/sites/default/files/resource/advamed_letter_to_oig_re_aks_rfi.pdf

² 83 Fed. Reg. 43607 (August 27, 2018) (OIG-0803-N).

in practice the courts have too often proven unwilling to dismiss inappropriate *qui tam* cases at an early stage, forcing defendants to engage in burdensome and expensive discovery and otherwise subjecting companies to inappropriate costs, management diversion, and other risks. This is exemplified by a recent case in which a court denied DOJ's motion to dismiss a *qui tam* case that DOJ considered meritless.³ As a result, the safe harbors often are not actually safe in practice.

To bolster the real-world effectiveness of any VBA safe harbors that OIG determines to adopt, we recommend that OIG include language in the preamble to the proposed and final safe harbor regulations stating explicitly what should be self-evident: that an arrangement or business practice that satisfies the applicable conditions set forth in a safe harbor regulation is to be respected as compliant with the AKS for all purposes, including FCA actions. Such a statement would conform to longstanding OIG policy and is intrinsic to the very nature of safe harbors as defining non-abusive business practices which will not be subject to enforcement action.⁴

Moreover, such a statement would also help protect participants in VBAs against changes in policy by subsequent Administrations seeking to undermine the safe harbor protections, through issuance of new "interpretations" of the safe harbor requirements. For example, in a line of cases typically identified with *Auer v. Robbins*, 519 U.S. 452 (1997), courts have granted deference to regulatory interpretations by federal agencies (often referred to as "*Auer*" deference)—interpretations often first announced in the context of an enforcement action against a regulated person or entity.⁵ The Supreme Court is currently considering overruling *Auer*, in *Kisor v. Wilkie* (Dkt. No. 18-15). Notably, the Solicitor General has filed a brief arguing that *Auer* deference raises significant concerns and can cause practical hardship to regulated parties, and as such advocates that the doctrine be revised so that a reviewing court should defer to the agency's regulatory interpretation only if the regulation is ambiguous and the interpretation "was issued with fair notice to regulated parties; is not inconsistent with the agency's prior views; rests on the agency's expertise; and represents the agency's considered view, as distinct from the views of mere field officials or other low-level employees."⁶

³ *U.S. ex rel. CIMZNHCA, LLC v. UCB, Inc.*, No. 17-CV-765-SMY-MAB, 2019 WL 1598109, at *4 (S.D. Ill. Apr. 15, 2019) (finding the DOJ's decision to dismiss the non-intervened *qui tam* action as arbitrary and capricious). The district court rejected the DOJ's argument that the relator's allegations lacked merit and that continued prosecution of the case would be costly and contrary to governmental prerogatives.

⁴ For example, in prior OIG releases relating to potential safe harbor changes, the preamble of the proposed and final rules included statements that the safe harbors "have been developed 'to limit the reach of the statute somewhat by permitting certain non-abusive arrangements, while encouraging beneficial or innocuous arrangements'" and that "health care providers and others may voluntarily seek to comply with safe harbors so that they have the assurance that their business practices will not be subject to enforcement action under the anti-kickback statute, the CMP provision for anti-kickback violations, or the program exclusion authority related to kickbacks." 81 Fed. Reg. 88368, 88369 (Dec. 7, 2016); *see also* 84 Fed. Reg. 2340, 2345 (Feb. 6, 2019).

⁵ For example, in *Auer* itself, the Court deferred to a regulatory interpretation by the Secretary of Labor expressed in an amicus brief filed with the Court itself, in determining whether an exemption to overtime requirements under the Fair Labor Standards Act, 29 U.S.C. § 201 *et seq.*, was applicable.

⁶ Brief for the Respondent at 11-12, *Kisor v. Wilkie*, No. 18-15 (Feb. 25, 2019).

May 8, 2019

Page 3

While the Court will determine what changes, if any, it will make to the doctrine of *Auer* deference, we believe that a preamble statement by OIG will be helpful under any standard. In particular, a preamble statement would make clear the OIG's own regulatory interpretation of the safe harbor, favorable to parties whose conduct falls within the express safe harbor requirements, and indicate that new, unstated conditions for protections should not be implied. Under existing case law, deference to an agency's interpretation of a regulation is less likely when that interpretation contradicts a prior interpretation of the agency.⁷ Similarly, this preamble statement will make it more likely that courts will defer to this clearly-stated interpretation of the safe harbor by OIG, rather than requiring further litigation based upon a differing interpretation asserted by a *qui tam* relator.

Accordingly, please find enclosed with this letter a document containing three paragraphs offered for OIG to consider for inclusion in its preamble discussion of proposed and final safe harbor regulations (Attachment 2). In particular, these make clear that the "one purpose" test applicable to conduct outside of a safe harbor is not relevant to a business practice or arrangement for which applicable safe harbor conditions are satisfied. Instead, compliance with the safe harbor exempts the arrangement from further AKS scrutiny, consistent with frequently-stated OIG policy.

Enclosure:

Attachment 1 - Revisions to Proposed Safe Harbors for VBAs to Facilitate Monitoring & Auditing

Attachment 2 - Proposed Preamble Language to address One-Purpose Test Concern

⁷ See, e.g., *Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 153-57 (2012) (citing a regulatory preamble and a history of not enforcing the law consistent with the regulatory interpretation currently asserted by the Department of Labor, in part, as reasons for refusing to apply *Auer* deference to the current agency interpretation). Where such a contrary prior interpretation exists, courts are more likely to view the shift from that original position as only a "convenient litigating position" or "post hoc rationalization" that is not entitled to deference.

ATTACHMENT 1
REVISIONS TO FACILITATE MONITORING AND AUDITING
REDLINE CHANGES FROM 10/26/18 ADVAMED SAFE HARBOR PROPOSALS

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; ~~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;

ATTACHMENT 1
REVISIONS TO FACILITATE MONITORING AND AUDITING
REDLINE CHANGES FROM 10/26/18 ADVAMED SAFE HARBOR PROPOSALS

- (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; 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

ATTACHMENT 1
REVISIONS TO FACILITATE MONITORING AND AUDITING
REDLINE CHANGES FROM 10/26/18 ADVAMED SAFE HARBOR PROPOSALS

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.

ATTACHMENT 1
REVISIONS TO FACILITATE MONITORING AND AUDITING
REDLINE CHANGES FROM 10/26/18 ADVAMED SAFE HARBOR PROPOSALS

- (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).

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.

ATTACHMENT 1
REVISIONS TO FACILITATE MONITORING AND AUDITING
REDLINE CHANGES FROM 10/26/18 ADVAMED SAFE HARBOR PROPOSALS

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. 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

ATTACHMENT 1
REVISIONS TO FACILITATE MONITORING AND AUDITING
REDLINE CHANGES FROM 10/26/18 ADVAMED SAFE HARBOR PROPOSALS

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 induce the buyer to 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 induce the buyer to 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.

ATTACHMENT 1
REVISIONS TO FACILITATE MONITORING AND AUDITING
REDLINE CHANGES FROM 10/26/18 ADVAMED SAFE HARBOR PROPOSALS

III. New AKS Safe Harbor for Value-Based Warranty Arrangements

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

(*) **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

ATTACHMENT 1
REVISIONS TO FACILITATE MONITORING AND AUDITING
REDLINE CHANGES FROM 10/26/18 ADVAMED SAFE HARBOR PROPOSALS

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

ATTACHMENT 1
REVISIONS TO FACILITATE MONITORING AND AUDITING
REDLINE CHANGES FROM 10/26/18 ADVAMED SAFE HARBOR PROPOSALS

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;

- (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

ATTACHMENT 1
REVISIONS TO FACILITATE MONITORING AND AUDITING
REDLINE CHANGES FROM 10/26/18 ADVAMED SAFE HARBOR PROPOSALS

- 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.

IV. Hypothetical Example—Value Based Warranty Arrangement

SCENARIO

General Hospital (Hospital) is experiencing high post-operative surgical site infection (SSI) rates for patients undergoing procedures in Hospital's general surgery service line. This has led to increased lengths of stay, the need for additional treatment and services, and in many cases costly hospital readmissions after discharge. Payors are denying reimbursement for the readmissions and other services, on the basis that the costs resulting from these SSIs are avoidable. Hospital is not able to otherwise absorb these costs and considers shutting down its general surgery services line altogether. There is an opportunity to materially improve clinical outcomes and reduce costs.

Medical Device Company (Company) develops, manufactures and sells a comprehensive solution to address the risk of SSIs (Solution). The Solution includes the use of: (1) a suture device that is designed and developed to reduce the risk of SSIs; (2) clinical experts to conduct confidential reviews of Hospital's current clinical practices to help identify potential risks for SSIs at the Hospital; (3) customized plans to

ATTACHMENT 1
REVISIONS TO FACILITATE MONITORING AND AUDITING
REDLINE CHANGES FROM 10/26/18 ADVAMED SAFE HARBOR PROPOSALS

help Hospital personnel adopt and implement evidence-based infection prevention strategies and protocols and enhance compliance with Hospital policies and procedures; and (4) patient educational resources designed to engage patients in their care from pre-admission through discharge to facilitate optimal wound healing post-surgery.

Company wants to offer Hospital the Solution through a value-based health care (VBHC) program, that includes offering a warranty for failing to achieve patient clinical results specified as targets at the time of sale of the Solution.

The VBHC program is negotiated and structured as follows:

- In order to prepare for the adoption and implementation of the VBHC program, Hospital and Company will establish through a monitoring process an Infection baseline rate that includes patients who experience an SSI after undergoing a procedure in Hospital's general surgery service line during a defined 12-month measurement period (Infection Baseline Rate). Any services provided by Company to assist in determining the Baseline Infection Rate are set forth in a written document provided by Company to Hospital.
- Company and Hospital agree that clinically, implementation of the Company's Solution should lead to a reduction in SSIs compared to the Hospital's Infection Baseline Rate.
- Company sells the Solution to Hospital pursuant to a written agreement with a warranty providing that if the Hospital implements the Solution as set forth in the Agreement and does not achieve at least a 5% decline in SSI's compared to the Infection Baseline Rate during any subsequent 12-month measurement period, Company will compensate Hospital (in accordance with rates specified in the agreement) for specified types of documented medical, surgical, hospital or other directly related items and services provided by Hospital in treating patients who received the suture device included in the Solution and experienced an SSI, not to exceed \$X per patient; provided the following requirements are met: (a) such items and services are supplied, provided and paid for in accordance with the terms and conditions of the warranty; (b) such items and services are not billed by any person to any Federal health care program; and (c) such items and services are medically necessary.
- The term of the agreement is 5 years and there are 5 pre-defined 12-month SSI measurement periods.
- If at least the 5% decline is achieved during a measurement period, no warranty remedy is available with respect to patients experiencing an SSI during that period.

ANALYSIS

This innovative arrangement would satisfy the requirements under our proposed new safe harbor for value-based warranty arrangements.

Like the value-based pricing arrangement hypothetical in Attachment A, any value-based services provided in connection with determining the Baseline Infection Rate (and therefore the terms of the value-based warranty) would be set forth in writing and disclosed by the Company to the Hospital prior to the time any such services are provided, consistent with paragraphs (*) (2) and (*) (5) (C) (i).

ATTACHMENT 1
REVISIONS TO FACILITATE MONITORING AND AUDITING
REDLINE CHANGES FROM 10/26/18 ADVAMED SAFE HARBOR PROPOSALS

The Solution consists of a bundle of reimbursable items and/or services (the suture device) and several types of value-based services. Notably, these include patient educational resources, consistent with paragraph (*) (5)(C)(iv), which allows for provision of information to patients to achieve the targeted clinical outcome (here, the 5% reduction in SSI rates).

The terms and conditions for the value-based warranty remedy are set forth in writing as required under paragraph (*) (1). As required by paragraph (*) (D), the remedy is conditioned upon a clinical outcome (determined using a measurable metric) associated with the value of the Company's reimbursable item and/or service (the suture device) when appropriately used, and does not knowingly induced the Hospital to reduce or limit medically necessary items or services to its patients. The value-based warranty remedy falls within paragraph (*) (5)(H), as medical, surgical, hospital or other services and related items provided to a buyer by a seller (or by 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 such warranted item...." The arrangement specifically requires that items and services be provided and paid for in accordance with the terms and conditions of the warranty, that they not be billed by any person to any Federal health care program, and that they be medically necessary. Notably, Company could compensate Hospital for: (a) an amount that would exceed the cost of the Solution itself if the targeted clinical outcome of 5% reduction in SSI is not met; and (b) a Solution that is not actually deemed "defective," but rather the Solution just did not meet the negotiated, targeted outcome. Each of the Company and the Hospital would retain and provide to the Secretary or a State agency upon request the terms and conditions of the value-based warranty remedy, the SSI for each period, and an itemization of the documented medical, surgical, hospital or other services paid for by Company under the warranty.

ATTACHMENT 1
REVISIONS TO FACILITATE MONITORING AND AUDITING
REDLINE CHANGES FROM 10/26/18 ADVAMED SAFE HARBOR PROPOSALS

V. New AKS 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

ATTACHMENT 1
REVISIONS TO FACILITATE MONITORING AND AUDITING
REDLINE CHANGES FROM 10/26/18 ADVAMED SAFE HARBOR PROPOSALS

choices to patient populations (including previously underserved populations), in each case consistent with quality of care, physician medical judgment, and patient freedom of choice.

(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:

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

(B) 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.

VI. Hypothetical Example—Value Based Risk-Sharing Arrangement

SCENARIO

A multi-site hospital system (System) enters into a ten-year, master value-based risk sharing agreement with a medical device vendor (Vendor) for the acquisition and maintenance of devices and technology and provision of consulting services. The System's goal is to jointly evaluate with the Vendor the System's operations across departments to identify opportunities to improve patient care and/or operational efficiencies in multiple clinical applications. The Vendor's evaluation includes a review of the System's number and type of currently installed devices, operational workflows, and relative efficiencies of the installed systems (including various installed instrument protocols, staffing levels and types), its use of available data analytics, and other available software technology solutions. This evaluation activity was memorialized in a contemporaneous writing and disclosed to the System.

The written agreement establishes a process for jointly evaluating and benchmarking the System's current operations over the term and pursuing specific mutually developed projects intended to improve operations and/or patient outcomes. Each such project under the agreement (Project) is set forth in a written statement of work (Project SOW) that details (1) pre-identified clinical and/or economic target metrics tailored to promote the targeted improved patient outcomes and/or reduction of the costs of health care delivery during a defined time period – e.g., improvement of quality of patient care through efficient utilization of devices and staffing resources, and (2) joint allocation of financial risk based on the relative success of the Project in achieving the targeted metrics and the relative contributions of each party.

Upon conclusion of each Project, the parties measure the outcome(s) against the pre-defined metrics, which are evidence-based and may be benchmarked to publicly available statistics. To the extent that the metrics/targets are met or exceeded, the System would pay the Vendor an amount determined in accordance with the written formula set forth in the agreement based on achieved metrics in the Project. Conversely, to the extent metrics/targets are not met, the Vendor would receive no compensation or transfer an underachievement amount to the System, also as determined based upon the formula and terms and conditions set forth in the agreement.

ATTACHMENT 1
REVISIONS TO FACILITATE MONITORING AND AUDITING
REDLINE CHANGES FROM 10/26/18 ADVAMED SAFE HARBOR PROPOSALS

An example of a Project may target outcome improvements in the System's treatment of cardiac care patients in the various clinical settings. The Project may include the following:

- Using device utilization data to reduce the number of installed devices necessary to deliver at least the same volume and quality of care from 30 to 25;
- Re-deploying the remaining devices and re-training the device operators to achieve a more efficient workflow, resulting in the capacity to treat 15% more patients in the initial twelve-month period;
- Re-designing the patient scheduling system to make the fleet of medical devices more efficient in meeting patient demand and device operator availability and quality of patient care;
- Implementing uniform operational protocols for each type of device across the fleet, enabling technicians to safely and effectively operate the devices in a consistent manner across the System; and
- Incorporating new technology solutions into the System's existing workflows to improve the quality of the patient experience or to foster necessary follow-up care, particularly for vulnerable patient populations (such as the elderly or chronically ill).

ANALYSIS

The hypothetical arrangement described here would satisfy the requirements under our proposed new safe harbor for Value-Based Risk-Sharing Arrangements ("VBRSA").

First, the safe harbor provides that remuneration does not include participant activities that are reasonably necessary or appropriate to determine the terms and/or the metrics to be used in the VBRSA before such terms are set forth in a written agreement. In the hypothetical, the parties engage in a necessary and targeted review of the System's number and type of installed devices, workflows (including staffing and protocols), use of data analytics and software technology. This review is necessary and appropriate to develop the metrics to be included in the written VBRSA that ultimately is entered into by the parties as described in the hypothetical. The review activity was memorialized in a contemporaneous writing and disclosed to the System consistent with the safe harbor writing requirement for activities to determine the terms of a VBRSA.

Second, the safe harbor requires the VBRSA to be set forth in writing. In the hypothetical, the VBRSA is set forth in a written "framework agreement" that describes the process and governance for the parties to jointly evaluate and mutually develop projects intended to improve/operations and/or outcomes and pursuant to which each such project shall be set forth in a written statement of work ("Project SOW"). The framework agreement defines the costs for the products and services the System is acquiring under the framework agreement and describes the means for determining applicable benchmarks, performance metrics, and the methodology for calculating the risk sharing remuneration under each future Project SOW.

Third, under the terms of the VBRSA framework agreement, each Project SOW establishes in writing and in advance of the performance of the Risk-Sharing Arrangement: (i) the specific clinical and/or economic benchmarks and the metrics to measure clinical and/or economic target results designed to promote improved patient outcomes (e.g., recommended follow-up care for at risk patient populations) and/or (ii) the reduction of the costs of health care delivery (e.g., increased efficiency allowing redeployment of unneeded capital or staff or decreased patient wait times). Each Project SOW also specifies the financial risk to be

ATTACHMENT 1
REVISIONS TO FACILITATE MONITORING AND AUDITING
REDLINE CHANGES FROM 10/26/18 ADVAMED SAFE HARBOR PROPOSALS

borne by each party based on the parties' respective contributions to the arrangement. Moreover, each Project SOW describes with specificity the respective roles and responsibilities of the System and the Vendor to design and implement improved processes and/or tools in order to achieve the agreed upon target goals.

The transfer of value – from Vendor to System for underachievement or from System to Vendor for overachievement – in the hypothetical is designed to drive reduced costs and/or improve patient outcomes by incentivizing the Vendor and the System to work together to achieve the desired reduced costs and/or improved patient care as described by the parties in the written agreement.

Each of the Vendor and the System would be required to provide, upon request of the Secretary or a State agency, the agreement and each Project SOW, together with the amount of any underachievement or overachievement payment and the manner in which it was determined.

ATTACHMENT 2
PROPOSED PREAMBLE LANGUAGE
TO ADDRESS ONE-PURPOSE TEST CONCERN

[NOTE: We presume that, like most OIG releases relating to potential safe harbor changes, the preamble of the proposed and final rules will include statements that the safe harbors “have been developed ‘to limit the reach of the statute somewhat by permitting certain non-abusive arrangements, while encouraging beneficial or innocuous arrangements’” and that “health care providers and others may voluntarily seek to comply with safe harbors so that they have the assurance that their business practices will not be subject to enforcement action under the anti-kickback statute, the CMP provision for anti-kickback violations, or the program exclusion authority related to kickbacks.” 81 FR 88368, 88369 (Dec. 7, 2016); *see also* 84 FR 2340, 2345 (Feb. 6, 2019). The following text makes reference to such statements.]

As we have noted above, the safe harbors have been developed to permit certain non-abusive or beneficial arrangements and are intended to specify terms and conditions which, if satisfied with respect to a business practice, will result in that business practice not being subject to an enforcement action under the anti-kickback statute, the CMP provision for anti-kickback violations, or the program exclusion authority related to kickbacks. However, we have received comments expressing commenters’ belief that, in a number of cases, compliance with applicable safe harbor conditions as stated in the regulatory text has not always been “safe,” in practice.

Commenters point in particular to the numerous *qui tam* cases brought by private party relators under the False Claims Act, 31 U.S.C. § 3729 *et seq.* (FCA), in which the Department of Justice (DOJ) often declines to intervene, and assert that courts’ interpretation of certain safe harbor requirements has created confusion and ambiguity about what practices will be found to be eligible for safe harbor protection.¹ Commenters assert that courts have in some cases effectively imposed requirements that are not set forth in the safe harbor text itself, or implicitly ignored safe harbor compliance on the basis that the practice at issue—despite complying with the safe harbor—might have been intended to generate Federal health care program business. Industry participants indicate that some courts’ failure to dismiss, based upon the pleadings, *qui tam* cases alleging an anti-kickback statute violation due to conduct that falls within a safe harbor, will effectively continue to stand as a barrier to participation in safe harbor-compliant value-based arrangements unless participants have adequate assurances that safe harbor compliance will be recognized and appropriately applied to result in such dismissals, in practice.

Our intent in creating the new safe harbors proposed here is to promote participation in beneficial value-based arrangements by removing the barriers which the broad prohibitions of the anti-kickback statute may create. Accordingly, we wish to reiterate our longstanding view that conduct which complies with the express requirements of a safe harbor should be treated as compliant with the anti-kickback statute for all purposes, including FCA actions. Once an arrangement or business practice satisfies the applicable conditions set forth in a safe harbor regulation, the fact that the

¹ We note that, pursuant to Section 1128B(g) of the Act (42 U.S.C. 1320a-7b(g)), a claim that includes items or services resulting from a violation of the anti-kickback statute constitutes a false or fraudulent claim for purposes of the FCA.

ATTACHMENT 2
PROPOSED PREAMBLE LANGUAGE
TO ADDRESS ONE-PURPOSE TEST CONCERN

conduct might otherwise constitute a basis for a violation of the anti-kickback statute becomes irrelevant.² As such, the fact that a party engaging in a safe harbor-compliant arrangement may intend to generate more business for which payment may be made under a Federal health care program, and therefore could—absent safe harbor compliance—violate the “one purpose” test, is irrelevant for purposes of forming a basis for a violation of the anti-kickback statute.³ We believe it is appropriate to reiterate these views with the intent of helping to alleviate the concerns which commenters have identified.

² We note that, with respect to a related issue, the Department of Justice (DOJ) has recently adopted policies intended to ensure that “guidance” documents are not used to create rights or obligations of persons or entities outside of the federal government which are not set forth in an applicable statute or regulation. Memorandum from Attorney General Sessions on “Prohibition on Improper Guidance Documents,” dated November 16, 2017 (Sessions Memo), and Memorandum from Associate Attorney General Brand on “Limiting Use of Agency Guidance Documents in Affirming Civil Enforcement Cases,” dated January 25, 2018 (Brand Memo). For example, the Sessions Memo states that DOJ-issued guidance documents “should not be used for the purpose of coercing persons or entities outside of the federal government from taking any action beyond what is required by the terms of the applicable statute or regulation.” Further, the Brand Memo provides that guidance documents issued by federal agencies outside of DOJ “cannot create binding requirements that do not already exist by statute or regulation,” and instructs all heads of DOJ civil litigating components that DOJ “may not use its enforcement authority to effectively convert agency guidance documents into binding rules” through affirmative civil enforcement. Consistent with these requirements, we do not intend for any guidance documents issued by OIG to create any safe harbor requirements which are not set forth in the regulatory text as adopted; instead, any changes to safe harbor requirements will be adopted through notice and comment rulemaking and reflected in amended regulatory text.

³ The anti-kickback statute has been interpreted by courts to cover any arrangement where one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals. *See, e.g., United States v. Nagelvoort*, 856 F.3d 1117 (7th Cir. 2017); *United States v. McClatchey*, 217 F.3d 823 (10th Cir. 2000); *United States v. Davis*, 132 F.3d 1092 (5th Cir. 1998); *United States v. Kats*, 871 F.2d 105 (9th Cir. 1989); *United States v. Greber*, 760 F.2d 68 (3d Cir. 1985), *cert. denied*, 474 U.S. 988 (1985).