



DEPARTMENT OF HEALTH AND HUMAN SERVICES  
**OFFICE OF INSPECTOR GENERAL**

WASHINGTON, DC 20201



*[We redact certain identifying information and certain potentially privileged, confidential, or proprietary information associated with the individual or entity, unless otherwise approved by the requestor.]*

**Issued:** September 10, 2018

**Posted:** September 17, 2018

[Name and address redacted]

**Re: OIG Advisory Opinion No. 18-10**

Dear [Name redacted]:

We are writing in response to your request for an advisory opinion regarding a surgical device and wound care product manufacturer's proposal to offer hospital customers a warranty program covering a suite of three products (the "Proposed Arrangement"). Specifically, you have inquired whether the Proposed Arrangement would constitute grounds for the imposition of sanctions under the exclusion authority at section 1128(b)(7) of the Social Security Act (the "Act"), or the civil monetary penalty provision at section 1128A(a)(7) of the Act, as those sections relate to the commission of acts described in section 1128B(b) of the Act, the Federal anti-kickback statute.

You have certified that all of the information provided in your request, including all supplemental submissions, is true and correct and constitutes a complete description of the relevant facts and agreements among the parties.

In issuing this opinion, we have relied solely on the facts and information presented to us. We have not undertaken an independent investigation of such information. This opinion is limited to the facts presented. If material facts have not been disclosed or have been misrepresented, this opinion is without force and effect.

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that, although the Proposed Arrangement could potentially generate prohibited remuneration under the anti-kickback statute if the requisite intent to induce or reward referrals of Federal health care program business were present, the Office of Inspector General ("OIG") would not impose administrative sanctions on [name

redacted] under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Proposed Arrangement. This opinion is limited to the Proposed Arrangement and, therefore, we express no opinion about any ancillary agreements or arrangements disclosed or referenced in your request for an advisory opinion or supplemental submissions.

This opinion may not be relied on by any persons other than [name redacted], the requestor of this opinion, and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

## **I. FACTUAL BACKGROUND**

[Name redacted] (“Requestor”) manufactures and sells surgical devices and wound care products. Under the Proposed Arrangement, Requestor would, under certain circumstances, refund hospitals for the aggregate purchase price of three of Requestor’s products (the “Warranty Program”).

The following conditions must be satisfied for a hospital to qualify for a refund under the Warranty Program:

- A patient must have had joint replacement surgery, as an inpatient, at the hospital and must have received each of the following products manufactured by Requestor: (i) a total knee or total hip implant, (ii) a wound therapy system, and (iii) an antimicrobial dressing (each, a “Product” and collectively, the “Product Suite”).
- A patient who received the Product Suite must have been readmitted to the same hospital where the joint replacement surgery was performed, as an inpatient, within 90 days following his or her joint replacement surgery due to a surgical site infection or for a revision of the implanted knee or hip system.<sup>1</sup>

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<sup>1</sup> If a hip or knee replacement fails, a patient may require a second surgery, known as a revision, where some or all of the implanted knee or hip system is removed and replaced. The Current Procedural Terminology codes for revisions of total hip arthroplasty (“THA”) and revisions of total knee arthroplasty (“TKA”) are on the Medicare inpatient-only procedure list. In other words, in order to receive Medicare payment, revision procedures must occur in an inpatient hospital setting.

- Each Product must have been used in a manner consistent with its instructions for use and other labeling, and the hospital must certify that the patient’s readmission resulted from the failure of one or more of the Products to perform as expected.<sup>2</sup>

When the above requirements are satisfied, Requestor would refund the hospital its aggregate purchase price for all three Products in the Product Suite,<sup>3</sup> regardless of which, or how many of the, Products actually failed to perform as expected. Requestor would provide this refund without regard to the patient’s insurance status and, to the extent the patient is insured, without regard to the third-party payor that covered the patient’s joint replacement surgery or the third-party payor’s payment methodology. Requestor asserts that, when hospitals use the Product Suite as indicated, it expects the combination of Products will reduce the likelihood of a surgical site infection or required revision of the implanted knee or hip system.

Requestor certified that the three Products in the Product Suite are not separately reimbursable under the Medicare Inpatient Prospective Payment System (“IPPS”).<sup>4</sup> Under the IPPS, Medicare classifies inpatient stays into Medicare severity diagnosis-related groups (“MS-DRGs”) and pays a prospectively determined rate for each MS-DRG. Medicare Part A payment for an MS-DRG generally includes payment for items and services furnished in connection with the inpatient stay.<sup>5</sup> In particular, Requestor certified that the payments for the three Products in the Product Suite are bundled into the

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<sup>2</sup> Requestor certified that, under the proposed Warranty Program, Requestor would continue to satisfy any recall obligations imposed by law, including, but not limited to, 21 C.F.R. Part 7, Subpart C. In addition, Requestor certified that the proposed Warranty Program would not impact any of Requestor’s contractual obligations related to recalls of the Products.

<sup>3</sup> It is likely that different hospitals would negotiate different prices for the Products. However, Requestor certified that an individual hospital’s purchase prices for the Products would not vary by patient, his or her insurance status, or his or her third-party payor.

<sup>4</sup> As of January 1, 2018, CMS removed total knee arthroplasty from the Medicare inpatient-only procedure list. However, under the Proposed Arrangement, Requestor would offer the Warranty Program only for Medicare beneficiaries who receive inpatient joint replacement procedures.

<sup>5</sup> Requestor certified that Medicare Advantage plans also make bundled payments for inpatient joint replacement surgeries. Medicaid reimbursement varies from state to state, and in certain infrequent instances, some of the Products may be separately reimbursable under a state’s Medicaid program. However, Requestor stated that Medicaid represents a very small percent of Requestor’s business.

payments for the MS-DRGs associated with the inpatient joint replacement surgeries. Medicare makes a separate payment to the physician who performed the surgery for his or her professional services. Requestor further certified that the Warranty Program would not require the patient, or any subsequent providers or suppliers, to purchase Requestor's wound therapy system or antimicrobial dressing after the hospital discharges the patient. In other words, any refund under the Warranty Program related to a Medicare beneficiary's joint replacement surgery would be only for products used during an inpatient stay and reimbursed through a bundled payment.

Requestor certified that it would report the existence of the Warranty Program fully and accurately on the invoice or statement it furnishes to hospitals when they purchase the Product Suite. Requestor also certified that the invoice or statement would include information:

- notifying the hospital that it must report any refunds obtained through the Warranty Program fully and accurately to Federal health care programs, in accordance with the rules governing the applicable Federal health care program; and
- informing the hospital that it must provide, upon request by the Secretary of the U.S. Department of Health and Human Services or a State agency, information regarding the Warranty Program provided to the hospital by Requestor.

In addition, Requestor explained that it expects that hospitals participating in the proposed Warranty Program would continue to comply with all legal obligations associated with Medicare cost reporting, including 42 C.F.R. § 412.89, which requires that if a "provider received full credit for the cost of a device," the credit should be reported to the Medicare program, and "the cost of the device [be] subtracted from the DRG payment."<sup>6</sup>

Requestor certified that it would not pay any remuneration to a hospital under the Proposed Arrangement other than the hospital's aggregate purchase price for all three Products in the Product Suite.

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<sup>6</sup> 42 C.F.R. § 412.89; *see also* 42 C.F.R. § 412.2(g) and *Medicare Claims Processing Manual*, CMS Pub. 100-04, Ch. 3, Sec. 100.8. MS-DRGs 469 and 470 (major joint replacement or reattachment of lower extremity with and without a major complication or comorbidity) are included on the list of MS-DRGs where Medicare policy requires a reduced payment to a hospital when a hospital received full credit for the cost of a device. *See* 72 Fed. Reg. 47,129, 47,251 (Aug. 22, 2007).

Before a hospital could participate in the Warranty Program, it must execute an agreement enumerating the Warranty Program's requirements. That agreement would require the hospitals to:

- fully and accurately report any Warranty Program refunds to Federal health care programs, in accordance with the rules governing the applicable Federal health care program;
- provide, upon request by the Secretary of the U.S. Department of Health and Human Services or a State agency, information regarding the Warranty Program provided by Requestor;
- certify that physicians performing joint replacement surgeries at the hospital would, at all times, remain responsible for determining whether a specific medical device, including each of the three Products, is medically necessary and clinically appropriate for a particular patient; and
- provide Requestor with the right to perform audits to confirm a hospital's eligibility with respect to any patient for whom the hospital claimed or received a Warranty Program refund.

Finally, through the agreement, Requestor would reserve the right to terminate a hospital from the Warranty Program at any time with prior notice.

Requestor certified that, to obtain a refund through the Warranty Program, a hospital would be required to submit certain documentation, including: (i) a summary of the claimed refund amount, and (ii) a certification that all of the Warranty Program's requirements were satisfied, including that the Products were used in a manner consistent with their instructions for use and other labeling and that the patient's readmission resulted from at least one of the Products' failure to perform as expected.<sup>7</sup> When providing a refund to a hospital for the Product Suite, Requestor would provide the hospital with documentation detailing the refund calculation.

Finally, Requestor certified that the Warranty Program would contain no exclusivity

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<sup>7</sup> Requestor stated that the Warranty Program requires hospitals to make a determination as to the cause of a readmission, explaining that because hospitals have access to each patient's medical records, they are in the best position to make a determination regarding whether or not a patient's readmission resulted from the failure of one or more of the Products to perform as expected. As described here, when a hospital makes a claim under the Warranty Program based on a readmission, a hospital must submit a signed certification that the readmission resulted from failure of one of the items in the Product Suite.

requirements, nor would the Warranty Program include any quotas, minimums, or any other eligibility criteria tied to the volume or value of referrals. In addition, Requestor certified that it would not require hospitals participating in the Warranty Program to make any specific communications to physicians performing surgeries in the hospital encouraging or requiring the use of Requestor's Products when medically appropriate.

## II. LEGAL ANALYSIS

### A. Law

The anti-kickback statute makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a Federal health care program. See section 1128B(b) of the Act. Where remuneration is paid purposefully to induce or reward referrals of items or services payable by a Federal health care program, the anti-kickback statute is violated. By its terms, the statute ascribes criminal liability to parties on both sides of an impermissible "kickback" transaction. For purposes of the anti-kickback statute, "remuneration" includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind.

The statute has been interpreted 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). Violation of the statute constitutes a felony punishable by a maximum fine of \$100,000, imprisonment up to ten years, or both. Conviction will also lead to automatic exclusion from Federal health care programs, including Medicare and Medicaid. Where a party commits an act described in section 1128B(b) of the Act, the OIG may initiate administrative proceedings to impose civil monetary penalties on such party under section 1128A(a)(7) of the Act. The OIG may also initiate administrative proceedings to exclude such party from the Federal health care programs under section 1128(b)(7) of the Act.

The U.S. Department of Health and Human Services has promulgated safe harbor regulations that define practices that are not subject to the anti-kickback statute because such practices would be unlikely to result in fraud or abuse. See 42 C.F.R. § 1001.952. The safe harbors set forth specific conditions that, if met, assure entities involved of not being prosecuted or sanctioned for the arrangement qualifying for the safe harbor. However, safe harbor protection is afforded only to those arrangements that precisely meet all of the conditions set forth in the safe harbor.

The safe harbor for warranties, 42 C.F.R. § 1001.952(g), potentially applies to the Proposed Arrangement. Safe harbor protection is available if the buyer complies with the standards of 42 C.F.R. § 1001.952(g)(1)–(2) and the manufacturer or supplier complies with the following standards of 42 C.F.R. § 1001.952(g)(3)–(4):

- The manufacturer or supplier must either: (i) fully and accurately report the price reduction of the item (including a free item), which was obtained as part of the warranty, on the invoice or statement submitted to the buyer, and inform the buyer of its obligations under paragraphs (g)(1) and (g)(2); or (ii) where the amount of the price reduction is not known at the time of sale, fully and accurately report the existence of a warranty on the invoice or statement, inform the buyer of its obligations under paragraphs (g)(1) and (g)(2), and, when the price reduction becomes known, provide the buyer with documentation of the calculation of the price reduction resulting from the warranty.
- The manufacturer or supplier must not pay remuneration to any individual (other than a beneficiary) or entity for any medical, surgical, or hospital expense incurred by a beneficiary other than for the cost of the item itself.

## **B. Analysis**

Under the proposed Warranty Program, Requestor would offer hospital customers something of value in exchange for the purchase of the Product Suite, which could be reimbursable by a Federal health care program. As a result, the Proposed Arrangement implicates the anti-kickback statute. The safe harbor for warranties protects remedial actions by manufacturers and suppliers to address products that fail to meet bargained-for requirements. As a threshold matter, we consider whether the Warranty Program, which involves a bundle of the three Products in the Product Suite, could qualify for protection under the warranties safe harbor. We conclude that it could not, as the warranties safe harbor does not apply to bundled items. Specifically, the warranties safe harbor protects remuneration consisting of “any payment or exchange of anything of value under a warranty provided by a manufacturer or supplier of an item to the buyer (such as a health care provider or beneficiary) of the item,” as long as the buyer and seller comply with the safe harbor’s requirements.<sup>8</sup> The safe harbor’s text clearly refers to one item, not a bundle of items, as contemplated by the Proposed Arrangement.

The warranties safe harbor’s protection of one item, as opposed to a bundle of items, becomes clearer when comparing the warranties safe harbor to the discount safe harbor, 42 C.F.R. § 1001.952(h). In the context of the discount safe harbor, both the safe harbor

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<sup>8</sup> 42 C.F.R. § 1001.952(g) (emphasis added).

text and the preamble to the safe harbor<sup>9</sup> support the concept of allowing bundled discounts when the goods or services are reimbursed by the same payment methodology. In particular, for the purposes of the discount safe harbor, a discount can include “[s]upplying one good or service without charge or at a reduced charge to induce the purchase of a different good or service, [if] the goods and services are reimbursed by the same Federal health care program using the same methodology and the reduced charge is fully disclosed to the Federal health care program and accurately reflected where appropriate, and as appropriate, to the reimbursement methodology.”<sup>10</sup> Thus, the discount safe harbor directly addresses the circumstances under which a bundle of items (or services, or both) would satisfy the conditions of the safe harbor. In contrast, neither the warranties safe harbor nor its preamble address the permissibility, or associated protections, in relation to a bundle of items.

Although we can conceive of factual circumstances, such as the Proposed Arrangement, where warranty arrangements involving bundles of items pose a sufficiently low risk of fraud and abuse under the anti-kickback statute, not all warranty arrangements involving bundles of items would pose low risk. For example, a warranty arrangement involving a bundle of items that were separately reimbursable could result in overutilization of one or more items included in the bundle and could unnecessarily increase costs to Federal health care programs. Unlike the discount safe harbor, the warranties safe harbor includes no conditions that would mitigate the fraud and abuse risk of warranty arrangements involving bundled items. Because the warranties safe harbor expressly refers to one item, not a bundle of items, and also lacks the protections found in the discount safe harbor in regards to bundled items, the warranties safe harbor does not apply to the Proposed Arrangement.

Arrangements that do not fit in a safe harbor must be evaluated on a case-by-case basis, based on the totality of the facts and circumstances. For the combination of the following reasons, we conclude that the Proposed Arrangement poses a sufficiently low risk of fraud and abuse under the anti-kickback statute.

First, Medicare reimburses hospitals, the Product Suite’s buyers, through one bundled payment for all of the items and services the hospitals furnish in connection with an inpatient stay for a joint replacement surgery. None of the Products in the Product Suite are separately reimbursable by Medicare under the IPPS. Requestor further certified that the Warranty Program would not require the patient to continue to use Requestor’s wound therapy system or antimicrobial dressing after the hospital discharges the patient. As a consequence, all three Products in the Product Suite would be covered by one Medicare payment to the hospital. Hospitals’ inability to separately bill for each Product

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<sup>9</sup> 64 Fed. Reg. 63,518, 63,530 (Nov. 19, 1999).

<sup>10</sup> 42 C.F.R. § 1001.952(h)(5)(ii).



should encourage them to closely examine available products and select the combination of items that results in both the best value and the best clinical outcomes for their patients,<sup>11</sup> therefore reducing the risk of overutilization and inappropriate use of the Products and diminishing concerns of increased costs to the Medicare program.

Second, Requestor certified that it would meet all of the obligations of a seller under the warranties safe harbor, as specified in 42 C.F.R. § 1001.952(g)(3)-(4). Specifically, Requestor certified that it would report the existence of the Warranty Program fully and accurately on the invoice or statement it would furnish to hospitals when they purchase the Product Suite, and, when any refund amount becomes known, would provide the hospital with documentation of the refund calculation. Requestor certified that the invoice or statement would include information: (i) notifying the hospital that it must report any refund obtained through the Warranty Program fully and accurately to Federal health care programs in accordance with the rules governing the applicable Federal health care program, and (ii) informing the hospital that it must provide, upon request by the Secretary of the U.S. Department of Health and Human Services or a State agency, information regarding the Warranty Program provided to the hospital by Requestor. By complying with these requirements, Requestor would put hospitals on notice of their obligation to appropriately report any refund they obtained through the Warranty Program, thereby increasing the transparency of the program and diminishing the concern of increased costs to Federal health care programs. In addition, Requestor explained that it expects that hospitals participating in the proposed Warranty Program would comply with all applicable cost reporting requirements, including the Medicare policy that requires a reduced payment to a hospital when a hospital received full credit for the cost of a device under MS-DRGs 469 and 470. This should further reduce the concern of inappropriately increased costs to Federal health care programs.

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<sup>11</sup> Other Federal policies may encourage optimal clinical outcomes for patients undergoing joint replacement surgery. In particular, Section 3025 of the Affordable Care Act added section 1886(q) to the Social Security Act establishing the Hospital Readmissions Reduction Program, which requires CMS to reduce payments to IPPS hospitals with excess readmissions for certain, applicable conditions, effective for discharges beginning on October 1, 2012. CMS finalized the expansion of the applicable conditions beginning in Fiscal Year 2015 to include a hospital-level readmission measure for patients undergoing elective primary THA and TKA procedures. In implementing this measure, CMS stated, “[t]his measure aligns with our priority objectives to promote successful transitions of care for patients from the acute care inpatient setting to the outpatient setting. We further believe that this measure, which consists of one of the most frequently performed procedures on the Medicare population, will also reduce short-term readmission rates, while at the same time, improve the care provided to patients.” 78 Fed. Reg. 50,496, 50,664 (Aug. 19, 2013).

Third, Requestor would require each hospital to certify that the physicians performing joint replacement surgeries at the hospital would, at all times, remain responsible for determining whether a specific medical device, including each of the three Products, is medically necessary and clinically appropriate for a particular patient. In addition, Requestor would require hospitals seeking a refund to certify that each Product in the Product Suite was used in a manner consistent with each Product's instructions for use and other labeling. These two requirements, in combination, decrease the risk that the Products would be used in a clinically inappropriate or medically unnecessary manner.

Fourth, if the proposed Warranty Program works as intended and reduces the incidence of readmissions following joint replacement surgery due either to a surgical site infection or to a revision of the implanted knee or hip system, patients and Federal health care programs would benefit. In essence, the proposed Warranty Program would warrant that an undesirable result, namely, readmission after a joint replacement surgery, will not occur. The proposed Warranty Program would rely on the hospital—the entity that has access to the applicable joint replacement patient's medical records and medically trained professionals on staff—to make a case-by-case determination regarding whether or not the Warranty Program's requirements would be satisfied in regards to a particular patient. Although it may not be possible to state with medical certainty that a readmission due either to a surgical site infection or to a revision of the implanted knee or hip system was caused by one or more of the Products, Requestor has asserted that the Products, used in combination, are designed to reduce the incidence of infection-related readmissions and required revisions. We therefore believe that the Warranty Program is reasonably related to the use of the Product Suite and that, in the absence of other obvious causes of an infection or required revision, a hospital could make a valid claim that the infection or required revision resulted from the failure of the Product Suite to perform as expected. Under these circumstances, we are reluctant to chill innovative and potentially beneficial arrangements.

Finally, Requestor certified that the Warranty Program would contain no exclusivity requirements, nor would the Warranty Program include any quotas, minimums, or any other eligibility criteria tied to the volume or value of referrals. Requestor also certified that it would not require hospitals participating in the Warranty Program to make any specific communications to physicians performing surgeries in the hospital encouraging or requiring the use of Requestor's Products. Based on these certifications, hospitals could be eligible for a refund under the Warranty Program while also maintaining the flexibility to purchase and offer various joint replacement and wound care products. Moreover, the Warranty Program would not require hospitals to communicate requirements regarding the Products to physicians performing joint replacement surgeries. As a consequence, the Warranty Program would not: (1) impede the hospitals' ability to make purchasing decisions that result in both the best value and the best clinical outcomes for their patients; or (2) require coercive communications from a hospital to physicians regarding the Products.

For the combination of the reasons set forth above, we conclude that the Proposed Arrangement poses a sufficiently low risk of fraud and abuse under the anti-kickback statute.

### **III. CONCLUSION**

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that the Proposed Arrangement would not generate prohibited remuneration under the anti-kickback statute. Accordingly, the OIG would not impose administrative sanctions on [name redacted] under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Proposed Arrangement. This opinion is limited to the Proposed Arrangement and, therefore, we express no opinion about any ancillary agreements or arrangements disclosed or referenced in your request for an advisory opinion or supplemental submissions.

### **IV. LIMITATIONS**

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [name redacted], the requestor of this opinion. This advisory opinion has no application to, and cannot be relied upon by, any other individual or entity.
- This advisory opinion may not be introduced into evidence by a person or entity other than [name redacted] to prove that the person or entity did not violate the provisions of sections 1128, 1128A, or 1128B of the Act or any other law.
- This advisory opinion is applicable only to the statutory provisions specifically noted above. No opinion is expressed or implied herein with respect to the application of any other Federal, state, or local statute, rule, regulation, ordinance, or other law that may be applicable to the Proposed Arrangement, including, without limitation, the physician self-referral law, section 1877 of the Act (or that provision's application to the Medicaid program at section 1903(s) of the Act).
- This advisory opinion will not bind or obligate any agency other than the U.S. Department of Health and Human Services.
- This advisory opinion is limited in scope to the specific arrangement described in this letter and has no applicability to other arrangements, even those which appear similar in nature or scope.

- No opinion is expressed herein regarding the liability of any party under the False Claims Act or other legal authorities for any improper billing, claims submission, cost reporting, or related conduct.

This opinion is also subject to any additional limitations set forth at 42 C.F.R. Part 1008.

The OIG will not proceed against [name redacted] with respect to any action that is part of the Proposed Arrangement taken in good faith reliance upon this advisory opinion, as long as all of the material facts have been fully, completely, and accurately presented, and the Proposed Arrangement in practice comports with the information provided. The OIG reserves the right to reconsider the questions and issues raised in this advisory opinion and, where the public interest requires, to rescind, modify, or terminate this opinion. In the event that this advisory opinion is modified or terminated, the OIG will not proceed against [name redacted] with respect to any action that is part of the Proposed Arrangement taken in good faith reliance upon this advisory opinion, where all of the relevant facts were fully, completely, and accurately presented and where such action was promptly discontinued upon notification of the modification or termination of this advisory opinion. An advisory opinion may be rescinded only if the relevant and material facts have not been fully, completely, and accurately disclosed to the OIG.

Sincerely,

/Robert K. DeConti/

Assistant Inspector General for Legal Affairs