



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:** July 21, 2014

**Posted:** July 28, 2014

[Name and address redacted]

**Re: OIG Advisory Opinion No. 14-05**

Dear [Name redacted]:

We are writing in response to your request for an advisory opinion regarding a pharmaceutical manufacturer's direct-to-patient product sales program that allows eligible patients to purchase one of the manufacturer's brand-name products for a fixed cash price from an online retail pharmacy vendor outside of any applicable prescription drug insurance benefit (the "Arrangement"). Specifically, you have inquired whether the Arrangement constitutes grounds for the imposition of sanctions under the civil monetary penalty provision prohibiting inducements to beneficiaries, section 1128A(a)(5) of the Social Security Act (the "Act"), or under the exclusion authority at section 1128(b)(7) of 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 Arrangement potentially generates 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”) will 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 Arrangement. In addition, the OIG will not impose administrative sanctions on [name redacted] under section 1128A(a)(5) of the Act in connection with the Arrangement. This opinion is limited to the 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

Under the Arrangement, [name redacted] (the “Requestor”) sells one of its brand name products, [product redacted]<sup>1</sup> (the “Product”), to patients who have a valid prescription for the Product and are uninsured, have commercial prescription drug insurance, or are enrolled in Medicare Part D or another Federal health care program that provides outpatient prescription drug coverage (“Participants”), such as Medicaid, TRICARE, or U.S. Department of Veterans Affairs. The Arrangement provides Participants with a means of obtaining the Product on an outpatient basis in circumstances where it may not be readily available at retail pharmacies or covered by prescription drug plans, including Medicare Part D plans (“PDPs”).

The Product is an outpatient prescription drug that is eligible for coverage under Medicare Part D<sup>2</sup> but, according to the Requestor, is not included on most third party payor formularies due to the availability of generic equivalents.<sup>3</sup> Most third party payors that cover the Product place it on non-preferred formulary tiers and impose restrictions on coverage and reimbursement, including prior authorization and step therapy

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<sup>1</sup> [Product redacted]<sup>®</sup> is FDA-approved for [product description].

<sup>2</sup> The Product also may be covered by Medicaid, TRICARE, and the U.S. Department of Veterans Affairs. The Product is not covered by Medicare Part B.

<sup>3</sup> According to the Requestor, in 2013, approximately 87% of Medicare Part D beneficiaries did not have coverage for [Product]<sup>®</sup> through their PDPs.

requirements. When the Product is covered, third party payors typically limit beneficiary reimbursement to a maximum allowable cost that is at or near the cost of the Product's generic equivalents. The Requestor certified that Participants would face no clinical barriers to switching from the Product to the Product's generic equivalents. The Requestor does not enter into rebate agreements with third party payors, either directly or through their pharmacy benefit managers, for the Product, nor will it do so in the future.

Participants who are prescribed the Product may enroll in the Arrangement over the phone, via the internet, or by mail. Participants are required to identify their type of prescription drug insurance when they enroll. Participants must allow the Requestor to share information with third parties, including third party payors and the Centers for Medicare and Medicaid Services ("CMS"), as needed to facilitate the administration of the Arrangement.

With respect to Participants who are Medicare Part D beneficiaries ("Part D Participants"), the Requestor sends a written notice to the Part D Participant's PDP so the PDP may conduct appropriate drug utilization review and medication therapy management on behalf of the Part D Participant. Part D Participants agree upon enrollment to allow the Requestor to notify the PDP of their participation in the Arrangement. The published terms and conditions of the Arrangement provide that Part D Participants must agree to obtain the Product only through the Arrangement throughout the entire applicable Part D coverage year, if Part D coverage would otherwise be available. The published terms and conditions of the Arrangement provide that the Part D Participants will neither submit any claim for reimbursement for the Product purchased under the Arrangement to any third party payor, including Federal health care programs, nor include the amounts they pay for the Product under the Arrangement in any submission for true-out-of-pocket expenses ("TrOOP") calculations under a PDP.

At the end of the Part D coverage year, the Requestor automatically re-enrolls Part D Participants for the next entire Part D coverage year unless a Part D Participant affirmatively opts out of the Arrangement as of the end of the year. The Requestor intends to continue the Arrangement for multiple Part D coverage years.<sup>4</sup>

Participants purchase the Product directly from [name redacted] (the "Pharmacy"), an online retail pharmacy vendor that serves as the Requestor's dispensing agent under the Arrangement.<sup>5</sup> The Pharmacy is licensed in all fifty states and operates primarily as a

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<sup>4</sup> Because there is no clinical barrier to switching to a generic equivalent of a Product, if the Requestor discontinues the Arrangement, Participants can choose to obtain generic equivalents of the Product.

<sup>5</sup> The Pharmacy is an independent retail pharmacy that is an in-network pharmacy for a variety of third-party payors, including PDPs.

mail order pharmacy. The Pharmacy routinely dispenses a wide variety of products to its patients, including, but not limited to, the Product and other items sold by the Requestor.<sup>6</sup>

The Requestor contracted with the Pharmacy to dispense the Product to Participants under the Arrangement on its behalf because the Requestor is not licensed to dispense medications. The Requestor supplies the Product to the Pharmacy pursuant to a bailment arrangement, whereby the Requestor retains title to, and bears the risk of loss for, the Product until the Pharmacy dispenses it to Participants. Pursuant to a written service agreement between the parties (the “Agreement”), the Pharmacy must: (i) segregate all Product supplied by the Requestor for sale under the Arrangement from any product the Pharmacy purchases for commercial sale and dispenses outside of the Arrangement; (ii) comply with all applicable laws (including all state pharmacy laws) and perform the services in accordance with all industry standards; (iii) refrain from offering any inducement to a health care provider to prescribe, or switch Participants to, drugs sold by the Requestor, including the Product, and (iv) allow the Requestor to audit the Pharmacy to confirm compliance with the terms of the Agreement.

The Arrangement operates entirely outside of all Federal health care programs. The Agreement prohibits the Pharmacy from filing any claim for payment under any Federal health care program, or any commercial prescription drug insurance plan, for any Product sold to Participants under the Arrangement and instead requires the Pharmacy to process Participants as cash-paying customers. The Pharmacy dispenses the Product to Participants in exchange for a fixed cash price set by the Requestor. The Pharmacy collects the cash payment from the Participant and sends the full amount of the cash payment to the Requestor.

The Requestor does not have an exclusive distribution agreement with the Pharmacy for the Product. The Requestor sells the Product through its existing distribution channels, and patients who are not participating in the Arrangement may purchase the Product with a valid prescription at retail pharmacies where it is sold for a non-discounted price.

The Agreement specifies the fees the Requestor must pay the Pharmacy for each service the Pharmacy performs. The Requestor pays the Pharmacy a flat monthly fee to operate a toll-free customer service number for the Arrangement, a flat monthly fee for Product storage in excess of twenty-one days, and a flat fee per transaction or per occurrence for Product ordering and warehousing, Participant enrollment, dispensing, shipping,

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<sup>6</sup> Participants must allow the Pharmacy to share information with third parties, including third party payors and CMS, as needed to facilitate the administration of the Arrangement.

inventory management, and physician and Participant communication.<sup>7</sup> The Requestor also paid a flat, one-time fee for initial program start-up services based on the estimated cost to provide each service. Those services included web development, information technology system development, call script recording, and costs associated with transitioning the Requestor's demonstration program to the Pharmacy.<sup>8</sup> The Requestor certified that the various fees it pays, and has paid, were arrived at through arm's-length negotiations; the amounts are consistent with fair market value in an arm's-length transaction; and do not take into account the value or volume of referrals or other business generated between the parties. The Requestor also certified that the fees are based on an independent third party valuation.<sup>9</sup>

Participants learn of the Arrangement from their health care professionals and the Requestor's website. Health care professionals receive information regarding the Arrangement from the Requestor's sales representatives, and the Requestor provides information to professionals at medical conferences and through medical journal advertisements. The Requestor also uses online banner advertisements to inform Participants about the Arrangement.

The Requestor certified that it communicates, and will continue to communicate, with Participants only with regard to the Product or related disease state; it does not, and will not, communicate with Participants regarding any other products or services it or the Pharmacy offers. Additionally, the Requestor does not, and will not, market or promote any of its products or services that are not part of the Arrangement to Participants, nor will it market or promote the Pharmacy or its services (other than the services provided by the Pharmacy under the Arrangement) to Participants.<sup>10</sup> According to the Requestor,

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<sup>7</sup> Fees under the Agreement for communication between the Pharmacy and a physician or Participant are only paid for order notifications, shipment notifications, and email reminders, and to communicate with physicians or Participants to verify a prescription if the Requestor or the Pharmacy receives a Participant's enrollment application without a prescription.

<sup>8</sup> The Requestor may pay additional flat fees based on estimated costs of providing additional changes or updates to web development, information technology system development, and call script recording.

<sup>9</sup> The Requestor certified that there is no tie between the Pharmacy's compensation under the Arrangement and the Pharmacy's sale of any of the Requestor's other products.

<sup>10</sup> The Requestor would continue to advertise its products, including the Product, through direct-to-consumer advertising to the general public. We have not been asked to opine and express no opinion regarding the Requestor's advertising of its products, including the Product, outside of the Arrangement.

the Pharmacy has agreed not to market or promote any of the other products or services the Pharmacy offers to Participants.

The Requestor's sales price for [product redacted]<sup>®</sup> under the Arrangement is [amount redacted] for a 30-day supply, which is substantially lower than the Requestor's wholesale acquisition cost ("WAC") of [amount redacted] for a 30-day supply.<sup>11</sup>

## 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 or purchases 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. Borrasi, 639 F.3d 774 (7th Cir. 2011); 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 \$25,000, imprisonment up to five 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.

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<sup>11</sup> The Requestor certified that it includes the sales price of the Product under the Arrangement in reporting its best price to CMS. See section 1927(c)(1) of the Act. However, we have not been asked to opine, and express no opinion regarding the Requestor's charges for the Product to Federal health care programs that cover it, including charges to any PDPs.

The 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 personal services and management contracts, 42 C.F.R. § 1001.952(d) potentially applies to the Arrangement.<sup>12</sup> In relevant part for purposes of this advisory opinion, this safe harbor requires the aggregate compensation paid for services to be set in advance and consistent with fair market value in arm's-length transactions.

Section 1128A(a)(5) of the Act (the “CMP”) provides for the imposition of civil monetary penalties against any person who offers or transfers remuneration to a Medicare or State health care program (including Medicaid) beneficiary that the benefactor knows or should know is likely to influence the beneficiary’s selection of a particular provider, practitioner, or supplier of any item or service for which payment may be made, in whole or in part, by Medicare or a State health care program. The OIG may also initiate administrative proceedings to exclude such party from the Federal health care programs. Section 1128A(i)(6) of the Act defines “remuneration” for purposes of section 1128A(a)(5) as including “transfers of items or services for free or for other than fair market value.” We have also stated, “[t]he OIG does not believe that drug manufacturers are “providers, practitioners, or suppliers” for the limited purposes of section 1128A(a)(5), unless the drug manufacturers also own or operate, directly or indirectly, pharmacies, pharmacy benefits management companies, or other entities that file claims for payment under the Medicare or Medicaid programs.” OIG Special Advisory Bulletin on Offering Gifts and Other Inducements to Beneficiaries (Aug. 2002), available at: <http://oig.hhs.gov/fraud/docs/alertsandbulletins/SABGiftsandInducements.pdf>.

## **B. Analysis**

The Requestor operates the Arrangement entirely outside of all Federal health care programs. This means that Participants obtain the Product without using their Medicare outpatient prescription drug benefit or any other Federal health care program benefit.

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<sup>12</sup> Although the Arrangement involves a discount, the discount safe harbor, 42 C.F.R. § 1001.952(h), does not apply. This safe harbor excludes from the definition of “remuneration” a discount on an item or service for which payment may be made in whole or in part under a Federal health care program. The discount in the Arrangement does not apply to items for which a claim for payment would be filed with a Federal health care program.

Neither the Pharmacy nor any Participant files any claims for payment for the Product with Medicare or any other Federal health care program, and the price Part D Participants pay does not count toward their TrOOP or total Part D spending for any purpose. Additionally, the Arrangement is limited to a Product that is not included on most third party payor formularies due to the availability of generic or other clinically equivalent products. These factors, as well as other aspects of the Arrangement, lead us to conclude that the Arrangement contains safeguards sufficient to ensure that there is minimal risk of fraud and abuse.

### **1. Civil Monetary Penalties Law**

The Arrangement potentially implicates the CMP because the Pharmacy, on behalf of the Requestor, provides remuneration to beneficiaries in the form of a discount on the price of the Product. We must determine whether a discount is likely to induce beneficiaries to select the Pharmacy to supply items, for which payment may be made, in whole or in part, by Medicare or a State health care program. Here, the discount applies to a Product for which no payment would be made by Medicare or Medicaid. As stated above, neither the Pharmacy nor any Participant files any claims for payment for the Product, and the assistance does not count toward the Part D Participant's TrOOP or total Part D spending for any purpose.

For the following reasons, we do not believe that the availability of a discount on the Product is likely to influence a beneficiary to select the Pharmacy to supply other products, which may be payable by Medicare or Medicaid. First, Participants are not required to purchase any items other than the Product from the Pharmacy. Second, the Requestor certified that it would not use the discount offered under the Arrangement as a vehicle to market other Federally reimbursable products it manufactures to Participants, nor would it permit the Pharmacy to use the Arrangement to influence Participants to choose the Pharmacy as their supplier for other Federally reimbursable products. Specifically, the Requestor certified that, except for direct-to-consumer advertising to the general public as noted above, it communicates, and will continue to communicate, with Participants only with regard to the Product or a related disease state; it does not, and will not, communicate with Participants regarding any other products or services it or the Pharmacy offer. The Requestor does not, and will not, market or promote any of its products or services that are not part of the Arrangement to Participants, nor will it market or promote the Pharmacy or its services (other than the services provided by the Pharmacy under the Arrangement) to Participants. Likewise, the Requestor certified that the Pharmacy has agreed not to market or promote any of the other products or services the Pharmacy offers to Participants. Therefore, we will not subject the Requestor to administrative sanctions under the CMP in connection with the Arrangement.



## **2. Federal Anti-kickback Statute**

The Arrangement implicates the anti-kickback statute for two reasons. First, the Requestor provides remuneration to Participants in the form of a discount on the price of its Product, which may potentially induce Participants who are Federal health care program beneficiaries to purchase other products manufactured by the Requestor for which payment may be made by a Federal health care program. The discount could also induce them to switch to the Product, and then the Requestor could terminate the Arrangement, increasing the likelihood that beneficiaries would return to their PDPs or other Federal health care program outpatient prescription benefit to purchase the Product. This could lead to higher costs for beneficiaries as well as increased costs to Federal health care programs. Second, under the Agreement, the Requestor provides remuneration to the Pharmacy, which may have the ability to arrange for or recommend the purchase of the Requestor's other products for which payment may be made by a Federal health care program.

No safe harbor protects the Arrangement. The Arrangement does not satisfy the requirements of the personal services and management contracts safe harbor because the Requestor pays the Pharmacy for many services under the Agreement on a per transaction basis. Because of this payment methodology, the aggregate payment to the Pharmacy under the Agreement is not set in advance for purposes of the safe harbor. However, the absence of safe harbor protection is not fatal. For the reasons set forth below, we deem the overall risk under the anti-kickback statute to be sufficiently low.

### **a. Remuneration Provided to Beneficiaries**

We believe that the risk the Requestor offers a discounted Product to Participants to induce them to purchase (a) Requestor's other products or (b) the Product when it is reimbursed by a Federal health care program is sufficiently low for the following reasons.

First, the Requestor certified that it would not use the discount offered under the Arrangement as a vehicle to market other Federally reimbursable products it manufactures to Participants, nor would it permit the Pharmacy to use the Arrangement to influence Participants to choose the Pharmacy as its supplier for other Federally reimbursable products.

Second, the Requestor certified that most third party payors do not cover the Product due to the availability of generic equivalent products; therefore, most Medicare Part D beneficiaries do not have coverage for the Product. Furthermore, the few PDPs that cover the Product place it on non-preferred formulary tiers and impose restrictions on coverage and reimbursement, including prior authorization and step therapy requirements. Therefore, few Part D Participants would be able to purchase the Product through their PDPs if the Arrangement terminated. Additionally, the Requestor certified

that no clinical barriers prevent Participants from switching from the Product to its generic equivalents. If the Arrangement is terminated, Participants will have the option of purchasing different, clinically equivalent, lower cost drugs. Thus it appears unlikely that a purpose of the Arrangement is to induce the Participants to later purchase the Product with the assistance of Federal health care programs.

#### **b. Remuneration Provided to the Pharmacy**

Next we analyze the remuneration provided under the Arrangement by the Requestor to the Pharmacy. We believe the Arrangement is distinguishable from problematic arrangements under which parties “carve out” referrals of Federal health care program beneficiaries or business generated by Federal health care programs from otherwise questionable financial arrangements. For the following reasons, we find that the risk the Requestor would provide payment to the Pharmacy for services provided outside of any Federal health care program under the Arrangement in order to induce the Pharmacy to arrange for or recommend the purchase of the Requestor’s products that are payable by Federal health care programs to be sufficiently low.

First, in analyzing the risks of the payment methodology we rely on the Requestor’s certifications that: the fees were arrived at through arm’s-length negotiations; the fees are consistent with fair market value in an arm’s-length transaction; and do not take into account the value or volume of referrals or other business generated between the parties.<sup>13</sup> Further, the per transaction fee takes into account only items and services provided by the Pharmacy that are necessary to dispense the Product and does not include marketing or other items or services not integral to dispensing the Product. Arm’s-length, fair market value fees for reasonable services actually rendered that relate to services not reimbursable by Federal health care programs, such as the fees described herein, are less likely to be remuneration to induce referrals.

Second, the Arrangement is distinctive from other “carve-outs” because we have no facts indicating that the remuneration provided by the Requestor to the Pharmacy under the Agreement is for the purpose of arranging for or recommending the Requestor’s other products. Certain aspects of the relationship between the parties lessen the likelihood that the Requestor would offer the Agreement to the Pharmacy in order to influence referrals. For example, the Requestor and the Pharmacy have agreed not to offer, market, or promote any of their products or services, other than the Product offer under the Arrangement and the services required to dispense the product. Additionally, the

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<sup>13</sup> We are not authorized to opine on whether fair market value shall be, or was paid or received for any goods, services, or property. See section 1128D(b)(3) of the Act. We rely on the Requestor’s certification that the fees represent fair market value in an arm’s-length transaction. If the fee is not fair market value, this opinion is without force and effect.

Pharmacy must refrain from offering any inducement to a health care provider to prescribe, or switch Participants to the Product, or any of the Requestor's other products, and the Requestor may audit the Pharmacy to confirm compliance with the terms of the Agreement.

Our conclusions with respect to both the anti-kickback statute and the CMP are based on the particular facts of this Arrangement. We might reach a different conclusion on different facts; for example, if the Product had no generic equivalents, or was covered by more plan formularies, or more generously by some plan formularies, so that a Federal health care beneficiary might be induced by the discount to use a product under a similar arrangement until he or she could move to a different plan with a formulary that covered the drug, or required a lower copayment.

### **III. CONCLUSION**

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that, although the 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 OIG would not impose administrative sanctions on the Requestor 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 Arrangement. In addition, the OIG would not impose administrative sanctions on the Requestor under section 1128A(a)(5) of the Act in connection with the Arrangement. This opinion is limited to the 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 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 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 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 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,

/Gregory E. Demske/

Gregory E. Demske  
Chief Counsel to the Inspector General