



[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: August 21, 2002

Posted: August 30, 2002

[name and address redacted]

Re: OIG Advisory Opinion No. 02-12

Dear [name redacted]:

We are writing in response to your request for an advisory opinion about a proposed Internet-based chronic disease management business (the “Proposed Arrangement”) that would (i) contract with managed care organizations and employer-based health plans to enroll their members in an on-line clinical compliance program and (ii) sell advertising on its web site to advertisers, including, but not limited to, pharmacies and pharmaceutical companies. 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 (“CMP”) 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, or under the CMP provision prohibiting inducements to beneficiaries, section 1128A(a)(5) of the Act.

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 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, but that 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, nor would the OIG impose CMPs on [name redacted] in connection with the Proposed Arrangement for violations of the prohibition against inducements to beneficiaries under section 1128A(a)(5) of the Act.

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] (the “Requestor”) is a closely-held, Internet-based, behavior modification and drug regimen compliance company. None of its owners is a supplier or manufacturer of drugs.

Under the Proposed Arrangement, the Requestor would contract with managed care organizations and employer-based health plans (collectively, “MCOs”) to provide their enrollees with a drug and behavior compliance program through the Internet (the “Program”). Participating MCO enrollees (the “Members”) and their primary care physicians would receive incentives to reward their use of the Program. The Proposed Arrangement also contemplates marketing and advertising by health care companies and other advertisers (collectively, the “Advertisers”) through the Requestor’s web site. Advertisers would include, among others, pharmacies that buy advertising (the “Pharmacies”) and pharmaceutical companies that buy advertising and other marketing opportunities, as described below (the “Pharmaceutical Companies”). The different elements of the Proposed Arrangement are described and addressed separately below. The Proposed Arrangement is the subject of a pending patent application filed with the U.S. Patent Office.

A. The Behavior Modification Program

The Requestor would contract with MCOs to provide the Program to the Members. The Requestor would use various Internet-based methods to remind and encourage Members to take medications, refill prescriptions, and comply with behavior modification regimens prescribed by their physicians. The MCOs would pay the entire cost of the enrollment fee in one of two ways – either a fixed, per Member per month (“PMPM”) fee or a fee that represents a share of the savings to the MCO resulting from improved compliance, as measured by predetermined benchmarks. In either case, the Requestor has certified that

the enrollment fees would be consistent with fair market value in an arms-length transaction for the services provided by the Requestor.

Upon execution of a contract, consistent with otherwise applicable law, the MCO would identify its enrollees who could benefit from the Program.¹ Eligible persons may include (1) persons with chronic diseases, (2) users of pharmaceuticals taken over the long-term, such as hormone replacement and hypertension medication, and (3) persons with behavior modification regimens, e.g., smoking or weight loss programs. Consistent with otherwise applicable law, the Requestor would contact these individuals by mail, telephone, or electronic mail to advise them of their eligibility for the Program. Participation in the Program would be voluntary. If an MCO enrollee elects to enroll in the Program, the Requestor would direct him or her to the Requestor's web site and to his or her own secure personal page. Much of the Member's interaction with the Program would take place within this secure personal page, which would not contain any advertising.

An integral component of the Program is an incentive system that rewards Members' compliance with the individual pharmacologic and behavior modification regimens that have been prescribed by their physicians. Under the Program, Members would be awarded points for undertaking desired actions ("Points"). The Points would be redeemable only for goods and services that are not reimbursable, in whole or in part, by any Federal health care program. Except for the Points, Members would receive no remuneration, in cash or in kind, directly or indirectly, from the Requestor or any other party involved with the Program.

Another feature of the Program is that a Member may elect to involve his or her physician in the Program in order to encourage the physician to provide input and feedback regarding the Member's clinical progress under pre-existing medical orders. (The Requestor's web site would not be configured to allow physicians to render new diagnoses or write prescriptions on-line.) The physician and/or the physician's staff would also earn Points for participation in specific Program activities, but not for ordering, recommending, or arranging for the purchase or ordering of any item or service. Specifically, the physician would be awarded Points for reviewing monthly patient information and compliance results provided to the physician by the Requestor, but not

¹We express no opinion on the application of any privacy law or regulation to the Program, including, but not limited to, Title II, Subtitle F, section 264 of the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191, and the related regulations published at 65 Fed. Reg. 82462 (Dec. 28, 2000) and 67 Fed. Reg. 53182 (Aug. 14, 2002).

for prescribing any item or service. As with the Members' Points, the Points awarded to physicians would be redeemable only for goods and services that are not reimbursable, in whole or in part, by any Federal health care program. Except for the Points, the physician would receive no remuneration, in cash or in kind, directly or indirectly, from the Requestor or any other party involved with the Program.

The Requestor has certified that Members will be free to fill or refill prescriptions at any pharmacy. The Requestor would advise Members that, under the Program, they will not receive extra Points from the Requestor or any other financial reward from any Pharmacy or the Requestor for the purchase of any product from a Pharmacy under the Program, e.g., through the hyperlink (discussed more fully below). Further, the advertising contract between the Pharmacy and the Requestor would prohibit the Pharmacy from providing any benefit, in cash or in kind, to a person based on that person's participation in the Program or purchases from that Pharmacy under the Program.

Finally, nothing in the Program would affect a Member's cost sharing obligations for drug purchases. The Member's cost sharing amount would be set forth in the agreement that governs the MCO's coverage of a Member.² The Requestor would have no involvement in the determination of a Member's cost sharing obligations under the MCO's plan.

B. The Sale of Advertising on the Requestor's Web Site

To generate additional revenue, the Requestor would sell banner advertising on its web site and other promotional opportunities to health care and non-health care Advertisers, although the Advertisers that are Pharmacies would be limited to those pharmacies that participate in the MCOs' provider networks. In addition to banner advertising, the Requestor plans to charge Pharmacies for the privilege of including hyperlinks to the Pharmacies' own web sites, and to permit Pharmaceutical Companies to sponsor interactive discussions at the Requestor's web site (i.e., "chat room", "forum", or other

²As discussed below, the Pharmacies would be limited to those pharmacies that participate in the MCOs' provider networks. Accordingly, the Requestor anticipates that the Pharmacies would have agreements with MCOs, pursuant to which the MCOs would reimburse Pharmacies for all or a portion of the cost of each Member's prescription drugs as dictated by the applicable MCO's health plan. However, it is possible that a Member may order an item for which the MCO may not be financially liable and which may be separately reimbursable, in whole or in part, by a Federal health care program.

variants, hereafter referred to as a “chat room”).³

All sales would be pursuant to a written contract between the Requestor and an Advertiser, including Pharmacies and Pharmaceutical Companies, which would specify the type of advertising, the terms and conditions imposed on the advertising, and the precise amount of the fee (either flat or “per click”). The fee would be fixed and would not fluctuate based on the value, quality, quantity, or content of any sales transaction. Furthermore, the Requestor has certified that its fees charged to Advertisers would be consistent with fair market value in an arms-length transaction for the services provided by the Requestor.

All paid advertising would be clearly identified as such. The advertisements would be incorporated within the web site in such a way as to avoid any confusion between paid advertisements and substantive content through the use of identifying words, design, or placement. A disclaimer would affirmatively state that the inclusion of such advertisements does not constitute a guarantee, endorsement, or recommendation of the products, services, or companies appearing in such advertisements or accessible through such hyperlinks. In addition, pursuant to their advertising contracts with the Requestor, Advertisers would be prohibited from creating the implication on their web sites that the Requestor in any way or manner endorses or has co-branded with the Advertiser. Finally, the Requestor would not have any exclusive arrangements with any Advertiser. To the extent that technological capabilities allow, the Requestor would seek to contract with all interested advertisers and sponsors, except for pharmacies not participating in the MCOs’ provider networks.

Banner Advertising. The Requestor intends to sell banner advertising to both health care companies and non-health care companies. For banner advertising, the Requestor would charge a fixed, pre-determined amount. The Advertiser would supply the design and content of the advertisement, although the banner advertisement could not promote any controlled substance⁴ and must comply with the Health on the Net Foundation Code

³Under the Proposed Arrangement, eligibility for hyperlinks and chat room sponsorship is limited to Pharmacies and Pharmaceutical Companies, respectively. Accordingly, this opinion only addresses those relationships.

⁴See section 812 of the Controlled Substances Act (21 U.S.C. § 801 et seq.). The current official list of controlled substances can be found in section 1308 of the most recent issue of Title 21 Code of Federal Regulations (C.F.R.) Part 1300 to end (21 C.F.R. § 1308) and the final rules which were published in the Federal Register subsequent to the issuance of the C.F.R. provision.

of Conduct, discussed below. The purchase of a banner advertisement could include the purchase of a hyperlink embedded within the banner advertisement.

Hyperlinks. In conjunction with the purchase of banner advertisements, Pharmacies would be able to purchase hyperlinks to their own web sites, from which the Pharmacies may sell their products directly to Members. The Requestor's Internet server would be configured so that each Member would receive Pharmacy advertisements only for those Pharmacies in that Member's particular MCO network. For the Pharmacy hyperlinks, the Requestor would charge a "per click" fee -- specifically, a fixed fee for each time a hyperlink is used or for each time a purchase is made through the hyperlink.⁵ With respect to all advertising incorporating a hyperlink, the Requestor has certified that no web site visitor would be sent to a Pharmacy's web site without affirmatively "clicking" on the hyperlink (specifically, clicking on the advertisement or banner itself). Furthermore, all Pharmacies with hyperlinks would be prohibited from impeding visitors from returning directly to the Requestor's site. For example, Pharmacies would be prohibited from disabling the user's "back button" or otherwise redirecting the user to any site that the user did not expressly intend to visit.

In addition, the Requestor has certified that the Pharmacies' web sites must meet the following two requirements: (1) to effect a purchase, the visitor must make an affirmative election (*i.e.*, "accept/reject" or "purchase/cancel"); and (2) visitors must be able to review the pending purchase transaction prior to execution of the sale. These contractual safeguards would help ensure that a Member who employs a hyperlink to access a Pharmacy's web site makes a knowing and informed decision prior to the purchase of any good or service.

In addition to the hyperlinks provided through advertising, a Member's secure personal page would offer a listing of all pharmacy companies participating in the MCO's network, with optional hyperlinks for those companies with their own web sites, irrespective of whether they are Advertisers. The Requestor would neither solicit nor accept remuneration from any of the pharmacy companies in exchange for including their names and hyperlinks, if any, on the list. The only requirement for inclusion would be

⁵Under the Requestor's business model, the per click fee would be paid for each use of the hyperlink to the Pharmacy's site, regardless of whether a purchase is actually made. However, market conditions may require that the Requestor accept only a fixed fee per purchase, *e.g.*, the fee for a \$10 purchase would be equivalent to the fee for a \$100 purchase. Under the fixed-fee-per-purchase model, the Requestor would be paid only if a purchase is completed. The per transaction fee would not vary with the value or type of purchases made by visitors to the Pharmacy's site.

current membership in the MCO's network of participating pharmacy providers. The Member would be required affirmatively to elect to view the list by clicking on a prompt. The Requestor would provide this listing as a convenience to Members and to promote on-line prescription refilling for effective drug regimen compliance.

Sponsorships. In addition to buying banner advertising, Pharmaceutical Companies would be able to sponsor Internet chat rooms related to particular diseases accessible from the Requestor's web site. For sponsorships, the Requestor would charge a fixed, pre-determined amount. In exchange for this fee, a Pharmaceutical Company would be prominently identified as the "sponsor" of a chat room devoted to a particular disease. The operation of the chat room would be the sole responsibility of the Requestor. The sponsor would have no control or role in determining the content or operation of the chat room. Sponsors would be permitted to purchase banner advertising to run concurrently with a discussion. Such advertisements would be clearly identified as paid advertising and subject to the same restrictions as all other advertising, including the ban on exclusive arrangements with any Advertiser. Except for this banner advertising, the sponsor would have no interaction with the Members while they are in the chat room.

Code of Conduct. The Requestor has certified that it would comply with the Health on the Net Foundation Code of Conduct (the "Code of Conduct") for medical and health care web sites.⁶ The Code of Conduct contains several provisions that relate to advertising. For example, its provision on "Complementarity" requires that the visitor-web site relationship support, and not replace, the patient-physician relationship. Also, its "Transparency of Sponsorship" principle requires that the web site clearly identify the commercial and non-commercial organizations that have contributed funding or resources for the site. Its "Honesty in Advertising" principle requires the clear identification of advertising and its differentiation from the web site's substantive content. The Requestor has certified that it will enforce the provisions of the Code of Conduct in all advertising featured on its web site.

II. LEGAL ANALYSIS

A. Relevant Statutes

The anti-kickback statute makes it a criminal offense knowingly and willfully to offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services

⁶The OIG does not endorse any particular code of conduct or accrediting body. The Requestor selected the Code of Conduct from among a selection of voluntary ethical codes.

reimbursable by Federal health care programs. 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, covertly or overtly, 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. United States v. Kats, 871 F.2d 105 (9th Cir. 1989); United States v. Greber, 760 F.2d 68 (3d Cir.), 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 the 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 CMPs 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 Proposed Arrangement also may violate section 1128A(a)(5) of the Act, which prohibits a person from offering or transferring remuneration to a beneficiary that such person knows or should know is likely to influence the beneficiary to order items or services from a particular provider, practitioner, or supplier for which payment may be made by Medicare or a State health care program (i.e., Medicaid). For purposes of section 1128A(a)(5), “remuneration” includes transfers of items or services for free or for other than fair market value. See section 1128A(i)(6) of the Act. Where a party commits an act described in section 1128A(a)(5) of the Act, the OIG may initiate administrative proceedings to impose CMPs on such party.

B. Remuneration for Behavior Modification & Drug Compliance Services

Payments by the MCOs to the Requestor for the provision of behavior modification and drug compliance services should not implicate the anti-kickback statute because the services are not generally reimbursable under the Federal health care programs. Requestor’s services to the MCO and its enrollees do not include the provision, referral, or recommendation of Federal health care program business, other than possibly the recommendation that Members see their own physicians or refill their prescriptions

according to pre-existing medical orders.⁷ To the extent such activity might come under the anti-kickback statute, we would not impose administrative sanctions on the Requestor in connection with the Proposed Arrangement. However, for purposes of this advisory opinion, we assume that the prescription and dispensing of medications to Members shall comply with all Federal and state laws and regulations. We also assume that both the prescribing physicians and the dispensing pharmacies shall be licensed to conduct such activities in the jurisdictions in which they conduct business, for example, that they shall comply with the law in each state in which the patient is receiving the medication.

The Requestor's awarding of Points constitutes remuneration to both Members and physicians, whose compliance activities create value for the Requestor by reducing MCO costs and, thereby, prompting the MCOs to reward the Requestor financially. However, neither the Members' nor the physicians' Program compliance activities are reimbursable by Federal health care programs.⁸ Rather, they are only tangentially related to the Federal health care programs in that the Members' treatment regimen may require the use of goods or services (*i.e.*, prescription drugs) that are paid for by the Federal health care programs. Even in these circumstances, however, the Requestor does not supply or otherwise profit directly from the reimbursable good or service. Also, beyond the Program, the Requestor has no other financial relationship with the Members or the physicians involving Federal health care program business. For these reasons, the awarding of Points for such compliance activities poses a minimal risk of Federal health care program fraud and abuse. Moreover, since the Points themselves are not redeemable for any item or service reimbursable by a Federal health care program, we need not determine whether the arrangements between the Requestor and the suppliers of the redeemable goods or services might implicate either the anti-kickback statute or the beneficiary inducement statute, described above.

⁷If the MCOs are qualified as either Medicare+Choice ("M+C") organizations or Medicaid MCOs under §§ 1851-1859 or § 1932 of the Act, then the non-Medicare and Medicaid covered services could be additional services that may be protected by the safe harbor for the increased coverage offered by such health care plans (*see* 42 C.F.R. § 1001.952(l)). The safe harbor only would protect the remuneration from the MCOs to their Members, not the remuneration between the MCOs and the Requestor.

⁸Where remuneration is paid for health care services that are not reimbursable by Federal health care programs, there may be concern that the remuneration is paid for non-Federal business in order to "pull through" Federal business. Under the Program, however, there appears to be no Federal business to pull through.

C. Advertising

Advertising activity, like any marketing, implicates the anti-kickback statute because, by its nature, it is meant to recommend the use of a product. With respect to the Requestor, the issue is whether Internet advertising by a health care provider creates the implication that the provider is recommending the advertisers' products to its clientele, among whom there are likely to be Federal health care program beneficiaries. In this way, the Requestor's marketing activities potentially implicate the anti-kickback statute.⁹ In evaluating such activities, we look at a number of factors, including, but not limited to:

- The identity of the party engaged in the marketing activity and the party's relationship with its target audience.
- The nature of the marketing activity.
- The item or service being marketed.
- The target population.
- Any safeguards to prevent fraud and abuse.

Customarily, accurate and non-deceptive print advertising in general circulation media (such as periodicals or broadcast media) does not raise anti-kickback concerns. In most respects, the Requestor's proposed advertising is comparable to advertisements in print media. Most importantly, the advertising would be essentially passive in nature, in that any contact with the Advertiser must be initiated by the customer. Moreover, all advertisements (including banners, hyperlinks, and sponsorships) would be clearly identified as paid advertising and separated from the web site's substantive content. To the extent that a Member initiates a contact with a Pharmacy by clicking on a hyperlink, the Requestor has taken steps to ensure the voluntariness of any consequent transaction.

With respect to the nature of the products and the target population, the site is primarily aimed at MCOs and their Members. With regard to the item or service being marketed, the site is selling advertising to any Advertiser that wishes to purchase space on the site, including both health care and non-health care companies, with the exception of

⁹This advisory opinion does not address the advertising content or any conduct of the Advertisers themselves, including, but not limited to, compliance with section 502(n) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 352(n)) and the implementing regulations at 21 C.F.R. § 202.1.

pharmacies that do not participate in the MCOs' networks. In short, the advertising activity is not materially different from print advertising in a health care-related publication, nor is it more targeted to Federal health care program beneficiaries.

The distinguishing characteristic here is that the Requestor is a health care provider to enrollees of MCOs as part of the enrollees' health plan benefits. Traditionally, marketing by health care providers (sometimes referred to as "white coat" marketing) is subject to closer scrutiny, since health care providers are in a position of trust and may exert undue influence when recommending health-care related items or services, particularly to their own patients. Patients typically believe that their health care providers furnish and recommend products or services that are in the patients' best medical interests. One of the purposes of the anti-kickback statute is to help ensure that the exercise of this independent medical judgment is not corrupted by financial considerations. Accordingly, we need to examine whether the Requestor's sale of space on the web site to other companies for advertising of health care products could be misconstrued as a recommendation of advertised goods and services by the Requestor.

In this case, we examine the nature of the Requestor's activities in relation to the goods and services being sold. Unlike a salesperson or even an advertising agency that designs an advertisement, the Requestor's role is limited to the sale of space on a web site. In the circumstances presented, there is little likelihood that viewers of the Requestor's web site would confuse the Requestor's role as a participant on the enrollee's health care team with its role as a seller of advertising on its web site, so long as the advertising is clearly identified and distinguished from the substantive content of the site and the advertising does not create the implication that the Requestor in any way or manner endorses or has co-branded with the Advertiser. Given the ubiquity of paid advertising, and the advertising safeguards to be implemented by the Requestor, we believe that viewers should be able to distinguish paid advertising from a substantive recommendation.

For the foregoing reasons, we conclude that we would not impose administrative sanctions on the Requestor in connection with the advertising fees, even those that accrue on a "per click" or "per purchase" basis, so long as these fees represent fair market value for advertising and do not vary based on the volume or value of business generated from the advertising.¹⁰

With respect to the listing of MCO-participating pharmacy providers (including their

¹⁰ Of course, the above-discussed web site features do not in themselves guarantee truthful and non-misleading advertising content. To the extent that any advertising contains untrue or deceptive information, this advisory opinion would not protect it.

hyperlinks, if any) on the Member's secure personal page, the Requestor would receive no remuneration from the pharmacy companies for their inclusion on the list. Instead, the listing is a single feature of the on-line clinical compliance program purchased by the MCO for its Members. All of the MCO's participating pharmacy providers would be listed as a convenience to the Member (he or she must affirmatively elect to see the list) and to promote on-line prescription refilling for effective drug regimen compliance.

The analysis related to the sponsorships is similar to that of advertising. Although the audience is likely to be more targeted, the identification of the sponsorship relationship should clearly dispel any suggestion that the sponsor's prominence on the web site is attributable to anything other than a monetary payment. The operation and editorial content of the chat room would be the sole responsibility of the Requestor. The Requestor has certified that the sponsors' only involvement in the chat room would be the payment of the sponsorship fees, a "brought to you by" acknowledgment of their sponsorships, and, as discussed above, concurrent advertising. They would have no control or role in determining the content of the discussion group itself. In these circumstances, the payment of a fixed, fair market value fee in order to be prominently identified on the web site as a sponsor does not raise any significant concerns under the anti-kickback statute.

Our conclusion here does not mean that Internet advertising and marketing relationships, as well as the substantive content of health care web sites, do not raise serious concerns. The chat rooms would be targeted toward a vulnerable, disease-specific population that could be subject to manipulation through the chat room discussion. For example, the "webmaster" in charge of moderating the chat room could steer the discussion toward the products of the sponsor or other Advertiser or toward criticism of an Advertiser's competitors. In addition, the Requestor could track Members' purchases and tailor the chat room topics to coincide with their buying habits. The use or misuse of patient or viewer information for marketing using direct e-mail and other "push" technologies raises other concerns. This list of potential abuses is not exhaustive, and this advisory opinion does not address any such conduct, including the webmaster's conduct.

III. CONCLUSION

Based on the facts certified in the request for an advisory opinion and supplemental submissions, we conclude that 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, but that 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, nor will the OIG impose CMPs on [name redacted] in connection with the Proposed Arrangement for violations of the prohibition against inducements to beneficiaries under section 1128A(a)(5) of the Act.

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 in any matter involving an entity or individual that is not a requestor to this opinion.
- 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.
- 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 Proposed Arrangement described in this letter and has no applicability to other arrangements or proposed arrangements, even those that 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, 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 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,

\S\

D. McCarty Thornton
Chief Counsel to the Inspector General