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: March 20, 2012

Posted: March 27, 2012

[Names and addresses redacted]

Re: OIG Advisory Opinion No. 12-02

Dear [Names redacted]:

We are writing in response to your request for an advisory opinion regarding a proposal to operate a website that would display coupons and advertising from health care providers, suppliers, and other entities (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. We also analyze whether the Proposed Arrangement would constitute grounds for sanctions under the civil monetary penalty provision prohibiting inducements to beneficiaries, section 1128A(a)(5) of the Act.

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: (i) the Proposed Arrangement would not constitute grounds for the imposition of civil monetary penalties under section 1128A(a)(5) of the Act; and (ii) 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] (the "Requestor"), is an S-Corporation with two members: [name redacted] (the "Physician Member") and [name redacted]. As described in greater detail below, under the Proposed Arrangement, the Requestor would operate a website that includes coupons for health care items and services and advertising on behalf of individuals and entities operating in the health care industry.

First, the Requestor would contract with physicians and other health care providers and suppliers[1] who seek to post coupons for health care items or services on the website (collectively, "Providers"). Any Providers who are willing to enter into a contract with the Requestor and comply with the Provider Terms of Use ("Terms of Use") would be eligible to participate in the website.

The contract and the Terms of Use, which Providers must electronically acknowledge before participating in the website at any level, would specify the requirements related to permissible coupons. Coupons could include discounts on items or services that are reimbursable by Federal health care programs if such discounts comply with all applicable Federal health care program coverage and payment statutes, regulations, and guidance. As described in more detail below, Providers also would be prohibited from offering "free service" coupons; only coupons for a reduced price or a percentage

[1] Participation in the website would be open to providers, suppliers, and other entities in the health care industry, including, but not limited to, physicians, chiropractors, dentists, optometrists, psychologists, physical and occupational therapists, holistic care providers, pharmacies, hospitals, insurance companies, and other appropriate health care providers.

reduction on a designated item or specific service would be permitted. Moreover, Providers must give the same discount to any third party payor or insurance carrier that the Provider offers to the patient; thus, for example, Providers could not offer a coupon directed only at the patient's cost-sharing amount. The website would include information explaining that the coupons apply to the entire service, not just to the patient's cost-sharing obligation, and the coupons themselves would include similar language. The Requestor would monitor postings to ensure that coupons comply with the Terms of Use. If a Provider posts a coupon that does not comply with the Terms of Use (e.g., a coupon that offers a free service), the Requestor would alert the Provider of potential non-compliance and would remove the coupon from the website until the issue is resolved with the Provider.

The Requestor certified that it is not in a position to make any referrals to Providers that would post coupons on the website. Although one of the Requestor's members is a practicing physician, the Requestor certified that the Physician Member's name would not appear on the website and that he would not post any coupons for his own services on the website. The Requestor certified that providers or suppliers to whom the Physician Member makes referrals would not be permitted to participate in the Proposed Arrangement.[2] Other than the Requestor's contracts for advertising and posting coupons, the Requestor certified that the Physician Member would not have any financial relationships with persons or entities with whom the Requestor could contract under the Proposed Arrangement.[3]

Providers who wish to post coupons on the website would have the option of participating at one of five membership levels. The "Basic" level would be free and

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[2] In addition to this certification, we note that the Physician Member's practice is a subspecialty practice, and, therefore, the likelihood that the Physician Member would refer to any provider, practitioner, or supplier who might have contracted with the Requestor is small.

[3] The Physician Member could receive referrals from physicians with whom the Requestor contracts. We express no opinion regarding whether the Stark law would apply to, or would be violated by, referrals made between the Physician Member and a person or entity with whom the Requestor would contract under the Proposed Arrangement. The Centers for Medicare & Medicaid Services ("CMS") is the agency with authority to issue advisory opinions regarding the Stark law, and the issuance of an OIG advisory opinion is not intended to be, and should not be construed as, a determination that an arrangement falls within the scope of or complies with the Stark law.

would include only a basic profile listing, one coupon,[4] and tracking of the number of profile views and coupon downloads. Providers could view these statistics in the "My Account" area of the website. The "Bronze" level would entitle Providers to the same benefits as the Basic level, plus an additional coupon (for a total of two coupons), the use of profile/listing enhancement features (highlighting, shadowing, borders, and different font colors and types) on the website, and the use of five searchable keywords to enhance search results of their profile/listing on the website. "Silver" level members would receive all of the benefits offered to Bronze members as well as one additional coupon, the use of their logo or photograph on the website, and the use of ten searchable keywords. "Gold" level members would receive would receive all of the benefits of lower levels, plus one additional coupon, the use of fifteen searchable keywords, the "featured listing" benefit where the listing randomly appears first in local searches along with other Gold and Platinum listings, and a Google Maps™ feature. Finally, Providers opting for the highest level of membership ("Platinum") would receive all of the benefits of the lower levels, plus one additional coupon, the use of 20 searchable keywords, and a local advertising spot on the website.

The Requestor would charge a flat monthly fee for each level of membership (except for Basic, which is free). Fee-based memberships would be set up on an automatic recurring billing cycle so that the Providers would be eligible to offer up to the maximum number of coupons to which their membership level entitles them, until they cancel their membership. Providers would not incur any additional per-coupon or per-click fees.

Providers would create their coupons by using pull-down menus from which they could select only certain options. For example, the pull-down menu for the value of the coupon would be limited to a specific percentage or dollar-off amount (e.g., 5%, 10%, $20, or $50). Providers would also be able to choose the start and end dates for the coupons. The format would allow Providers to specify the service type to which the discount would apply. The Requestor certified that the pull-down format with a limited menu of options would facilitate the Requestor's monitoring of the content of coupons for compliance with the Terms of Use.

The Requestor also seeks to sell advertising on the website. Health care practitioners, hospitals, health care systems, insurance companies, drug companies, pharmacies, and other entities (collectively, "Advertisers") would be able to purchase space on the website to advertise[5] items or services that may be of interest to health care consumers. Although

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[4] Providers choosing to participate at the Basic level would not be required to post coupons; Providers could elect to use only the free profile listing.

[5] This 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

Providers posting coupons on the website also would be able to become Advertisers by paying increased fees, they would not be required to do so.[6] The advertisements could take various forms, such as banner or pop-up advertisements. The advertisements could appear on the Requestor's home page or could appear following a specific search (e.g., if a patient searches the site for coupons in a particular zip code, an advertisement posted by an Advertiser in or near that zip code could appear). Advertisers could include a link to their own website in the advertisements. However, any coupons or discounts offered on the Advertiser's own website would not be affiliated with the Requestor, and the Requestor would not permit links in advertisements that would take the patient directly to a discount (other than to coupons posted on the Requestor's website).

The Requestor's contracts with Providers and Advertisers would set forth the material terms, such as the agreement's duration, termination provisions, and monthly fee(s). The Requestor certified that aggregate compensation would be set in advance, consistent with fair market value in an arms-length transaction, and would not take into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under any Federal health care program. The Terms of Use would require that Providers and Advertisers comply with the discount safe harbor to the anti-kickback statute and would notify Providers and Advertisers that they may have an obligation to report discounts in accordance with that safe harbor. The Terms of Use also would require Providers to give an invoice that accurately reflects the discount provided to patients who submit their own claims and to notify those patients in writing of the their obligation to advise the Federal health care program to which they submit the claims of the discounts they received. The Requestor certified that it would refrain from doing anything that would impede the Providers' or Advertisers' abilities to comply with the discount safe harbor.

Health care consumers or potential consumers ("Customers") would pay no fee to access the website and could choose to do so anonymously. Customers would not pay anything up front for the coupons. Rather, a Customer would print the coupon or download it to a mobile device, and the stated discount would be applied if and when the Customer receives the service. The website also would advise patients who submit their own claims of their obligation to report any discounts when submitting the claim. The Requestor would not require Customers to create an account or otherwise register with the website to access the coupons. However, Customers who choose to register on the website by providing an email address would be able to receive alerts, announcements, and newsletters via email. The Requestor would not use for profit or sell these email

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the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 352(n)) and the implementing regulations at 21 C.F.R. § 202.1.

[6] Likewise, an individual or entity may elect to be an Advertiser without also participating as a Provider.

addresses and would maintain appropriate security software to protect any information provided by Customers.

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. 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.

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 discounts, 42 C.F.R. § 1001.952(h), is potentially applicable to the Proposed Arrangement. The discount safe harbor distinguishes between three possible parties to a transaction: sellers, offerors, and buyers. The safe harbor further distinguishes the obligations based on the type of buyer, which could be certain types of

managed care organizations, cost-reporting buyers, or individuals or entities in whose name a request for payment would be submitted for the discounted item or service and payment.

Section 1128A(a)(5) of the Act 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 (including Medicaid). 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."

B. Analysis

The Proposed Arrangement involves two activities that implicate the anti-kickback statute: (i) selling advertising space on the website to health care providers and suppliers that may bill Federal health care programs, and (ii) posting Providers' coupons for health care items or services. The coupons also could implicate the civil monetary penalty provision prohibiting inducements to beneficiaries.

Both posting coupons and advertising on the Requestor's website would constitute advertising activities. Advertising activity, like any marketing, is meant to induce the use of an item or service. Where the advertised items or services are reimbursable, in whole or in part, by a Federal health care program, the anti-kickback statute is implicated. In evaluating marketing or advertising, we consider a number of factors, such as: 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; and any safeguards to prevent fraud and abuse. For the combination of the following reasons, the Proposed Arrangement is sufficiently low risk under the anti-kickback statute.

First, the Requestor is not a health care provider or supplier. The Requestor would simply operate a website that hosts advertising and coupons. Even though one of the Requestor's members is a practicing physician, his name would not appear anywhere on the website, nor would the site claim to be operated by a doctor or other health care provider or supplier. Therefore, the Proposed Arrangement is distinguishable from potentially problematic arrangements involving marketing by health care providers and suppliers. Marketing by health care providers and suppliers (particularly "white coat" marketing by health care professionals such as physicians) is subject to closer scrutiny,

because health care providers and suppliers are in a position of trust and may exert undue influence when recommending health care-related items or services.

Second, the payments from Providers and Advertisers to the Requestor do not depend in any way on Customers using the coupons or obtaining services from the Providers or Advertisers. Instead, Providers and Advertisers would pay a set fee, consistent with fair market value[7] in an arms-length transaction, to purchase the space for advertisements or for services associated with posting coupons. The fee would not take into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under any Federal health care program. Providers would be able to access statistics regarding the number of times their profiles were viewed and Customers downloaded their coupons, but the fees charged would not vary based on these statistics. Moreover, providers or suppliers to whom the Physician Member could make referrals would not be permitted to participate in the Proposed Arrangement.

Third, the advertising under the Proposed Arrangement may take the form of banner or pop-up advertisements on a publicly accessible website. Only Customers who choose to register with the site to receive additional alerts, announcements, or newsletters would provide any personal information, and even those Customers would provide only an email address, which would not be shared with Providers or Advertisers. However, no account is necessary to access the site and, other than an advertisement potentially being linked to a specific search performed by the Customer (e.g., a zip code or a provider type), the advertisement would not be directed at the Customer visiting the website.

Fourth, the structure of, and limitations associated with, the coupons decreases risk under the anti-kickback statute. Certain types of "coupon" offers raise the risk of overutilization. For example, if a beneficiary bought a pre-paid coupon for Service X, when that beneficiary walks into the offering provider's office requesting Service X—having already paid for Service X—the offering provider might feel pressured to render Service X, even if it isn't medically necessary. In contrast, the coupons in the Proposed Arrangement are more akin to those that come to consumers by mail. The Customer would not have paid for the service and would have no up-front investment; the risk that a Provider's medical judgment would be improperly influenced to render medically unnecessary or inappropriate services based on the Customer's possession of a coupon is low.

Customarily, accurate and non-deceptive print advertising in general circulation media (such as periodicals or broadcast media) does not raise anti-kickback concerns. The

[7] We are precluded by statute from opining on whether fair market value shall be or was paid for goods, services, or property. See 42 U.S.C. § 1320a-7d(b)(3)(A).

advertising and coupons proposed by the Requestor are the online equivalent of print advertisements. The advertisements and coupons are simply displayed on the Requestor's site, not targeted to the particular Customer using the website (except to the extent that an advertisement may be keyed to certain search terms entered by a patient), and would not appear to a patient to be endorsed by any particular health care provider, practitioner, or entity other than the Advertiser or Provider itself.

Additional Risks Associated with Coupons

Under the Proposed Arrangement, the Requestor would be compensated for its services associated with providing space on the website for advertising and posting coupons. The above analysis addresses the Requestor's activities with respect to those advertising services, including the advertising aspect of hosting the coupons. However, the content of coupons raises an additional risk that is not inherent to general advertisements: health care providers and suppliers may offer discounts on items or services that are reimbursable by Federal health care programs. For the following reasons, we believe that the Proposed Arrangement includes sufficient safeguards to mitigate risks associated with the Requestor's role in posting the potential discounts.

First, the coupons would be for a reduced price or percentage reduction on a particular item or service, and any discount would inure to the payor as well as the patient. Therefore, third party payors, including Federal health care programs, would benefit from reduced costs associated with the coupons. Moreover, although Customers redeeming coupons would receive a beneficial discount, their cost-sharing obligations would not be waived entirely.

Second, the Terms of Use would require Providers to comply with the discount safe harbor. To that end, the Requestor's website would provide all of the notifications that would be required if the Requestor were an "offeror" of a discount under the safe harbor.[8] To qualify for protection under the discount safe harbor, buyers and sellers have certain reporting obligations intended to ensure that any discounts are shared with Federal health care programs. Under the Proposed Arrangement, Providers would be "sellers," and Customers would be "buyers" for purposes of the discount safe harbor. Should a Federal health care program beneficiary access a coupon from the website, the beneficiary may elect to purchase the discounted service from the particular Provider that posted the

[8] The Requestor is not the type of entity that is intended by the term "offeror" in the safe harbor. As explained in the preamble to the final regulation, "[a]n 'offeror' may be any individual or entity that provides a discount on an item or service to a buyer, but that is not the seller of the item or service." 64 Fed. Reg. 63,518, 63,528 (Nov. 19, 1999). The Requestor would not actually provide any discounts; the Requestor would operate a website where the discounts are displayed.

coupon. The website and the coupons themselves would explain that the discount must apply to the entire item or service, and not just the Customer's cost-sharing obligation. The Requestor certified that it would notify all Providers of their obligation to comply with the discount safe harbor by including the obligations in the Terms of Use, which Providers must acknowledge. The Requestor would further obligate Providers to inform any Federal health care program beneficiaries who submit their own claims of the beneficiaries' obligation to report such discounts.

Although the Requestor cannot certify whether the Providers and Customers would meet their obligations to qualify for protection under the discount safe harbor, the Requestor certified that it would give these parties the information and notices necessary to facilitate their compliance, which reduces the risk of program abuse. We note, however, that this opinion protects only the Requestor with respect to the Requestor's transactions with Providers and with Customers. Because the Providers and Customers are not jointly requesting this opinion, and thus have provided us with no certifications that they intend to comply with the discount safe harbor under the Proposed Arrangement, we cannot opine on whether these parties would be protected under the safe harbor.[9]

For the combination of the foregoing reasons, the payments from the Providers and Advertisers for the Requestor's services associated with the Proposed Arrangement would pose an acceptably low risk of fraud and abuse under the anti-kickback statute. The Requestor's role in posting the coupons also would be unlikely to improperly influence a beneficiary to choose a particular provider or supplier. The Requestor would post coupons from any provider or supplier that enters a contract and agrees to the Terms of Use, and the coupons would be available to any Customer who accesses the site. As explained above, the Requestor operates essentially as a conduit to transmit advertising, rather than as a person or entity transferring remuneration to a beneficiary to influence his or her choice of a particular provider or supplier.

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) the Proposed Arrangement would not constitute grounds for the imposition of civil monetary penalties under section 1128A(a)(5) of the

[9] In addition to not opining on any liability of Providers or Customers under the Proposed Arrangement, we express no opinion regarding any potential liability of the Requestor under the False Claims Act if the Requestor knows or should know that the Providers are not providing Federal health care programs with their share of the coupon discounts, notwithstanding any requirements imposed in the Terms of Use or other sources of information.

Act; and (ii) 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 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,

/Lewis Morris/

Lewis Morris
Chief Counsel to the Inspector General