



[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: December 5, 2007

Posted: December 12, 2007

[Name and address redacted]

Re: OIG Advisory Opinion No. 07-16

Dear [name redacted]:

We are writing in response to your request for an advisory opinion regarding a home health agency's practice of providing prospective orthopedic patients with free educational videos containing instructions for postoperative home-based convalescence (the "Arrangement"). Specifically, you have inquired whether the Arrangement constitutes grounds for 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 anti-kickback statute.

You have certified that all of the information provided in your request, including all supplementary letters, 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 Arrangement does not constitute grounds for the imposition of civil monetary penalties under section 1128A(a)(5) of the Act; and (ii) while 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 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 Arrangement.

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 “Agency”) is a provider of home health care for, among others, postoperative total knee and hip joint replacement patients in [city and state names redacted] (the “City”). Many of the total joint replacement patients that the Agency works with participate in Medicare, Medicaid, or other Federal healthcare programs. Orthopedic surgeons typically refer a patient to the Agency for postsurgical care when the surgeon’s office schedules the patient’s operation. To do so, the surgeon, or his or her staff, completes the patient referral paperwork and sends it to the Agency. No payment of money, or allotment of goods or services, is provided by the Agency to the surgeon, or his or her staff, in connection with the referral. No surgeons have any financial or employment interest in the Agency.

Under the Arrangement, the Agency follows up each referral with an initial telephone call to the patient. During this call, the patient is reminded of his or her doctor’s referral to the Agency. The Agency confirms the information it has about the patient and reminds the patient of his or her right to opt for a different home health provider. Preparations are also made to send the patient an educational video in the days prior to surgery.

The Agency has produced two very similar sets of educational videos – one version for candidates for knee surgery and the other for hip surgery candidates. The videos inform prospective patients about restrictions and physical limitations that postsurgical total joint replacement patients typically encounter during home-based convalescence. The videos advise patients on issues such as optimal furniture placement, sleeping and bathing arrangements, strategies for negotiating stairs, as well as what clothing, durable medical equipment, and special items or tools best suit convalescents’ special needs. Viewers are also invited to consider the possibility that they may desire or need personal attendance during convalescence.

The videos are mainly comprised of scenes in which individuals, and sometimes families, demonstrate simple advance preparations for home-based convalescence and act out certain physical challenges of postsurgical recovery. At certain points, different individuals identified as former patients speak to the camera about their own home convalescence. Voiceover and visual placards identify the Agency as the videos’ producer at the outset and the very end of the videos. The Agency, its staff, and its

services otherwise go unmentioned, with no substantive promotional claims made on their behalf.¹

Neither medical advice nor diagnoses are given in the videos, which advise patients to consult their individual doctors and physical therapists about various issues addressed. Similar information content is available on the Internet and from other public sources without charge. The educational videos become the patients' to keep on receipt. No charge is made for the videos. According to the Agency, the videos have essentially zero resale value. The Agency does not require that the video be viewed in order for the patient to receive home health assistance.

II. LEGAL ANALYSIS

A. Law

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 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. 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 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.

Section 1128A(a)(5) of the Act provides for the imposition of civil monetary penalties against any person who gives something of value 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

¹ Throughout most of the video small, transparent letters write out the Agency's name in the lower right-hand corner of the screen.

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.” The OIG has previously taken the position that “incentives that are only nominal in value are not prohibited by the statute,” and has interpreted “nominal value to be no more than \$10 per item, or \$50 in the aggregate on an annual basis.” 65 F.R. 24400, 24410 – 24411 (April 26, 2000) (preamble to the final rule on the CMP).

B. Analysis

We begin with the application of the CMP to the facts presented. The threshold question is whether the Agency’s free educational videos on preparing for home-based convalescence from total joint replacement surgery constitute remuneration to the patient who receives them, and specifically whether their value is more than nominal. The absence of a paying market for such educational videos is not dispositive: such absence could indicate that the items have little or no value; that the items are simply novel or emerging in the marketplace; or that the market has been distorted by the availability of free items.

The value of the videos to the beneficiary is the appropriate focus under the CMP. The videos contain no medical advice or diagnoses by a surgeon, a physical therapist, or other health professional, pertaining to the individual patient’s condition. Instead, the videos only provide viewers with general suggestions and recommend that they obtain the personal advice of their health professionals about various issues. Similar information content is available on the Internet and from other public sources without charge. Based on the facts presented, it appears that a reasonable prospective patient in receipt of one of the Agency’s videos is not likely to believe that he or she had received an item worth more than \$10.00 or be willing to pay such an amount if the video were not provided for free. Notwithstanding, we have been presented with no firm evidence on which to base the conclusion that the videos are worth no more than \$10.00 to the prospective patient and therefore represent items that OIG deems to be of nominal value.

Lacking conclusive evidence whether the videos represent items of nominal value, we proceed to the next question under the CMP: whether the free educational videos are likely to influence patients to select the Agency as their provider of postoperative items and services payable by Medicare or Medicaid. We believe the answer is no for a combination of reasons. The patient does not receive a video until after his or her surgeon has referred his case to the Agency. In the context of the Arrangement, it is probable that this implicit endorsement of the Agency by the surgeon substantially informs the patient’s ultimate choice. The videos’ content is applicable to surgical patients regardless of which home health agency they choose, and similar content is widely available without charge on the internet and from other sources. No individually personalized safety or health care recommendations accompany the videos. For these reasons, we believe that in the overall context of the Arrangement, the videos’ influence over a patient’s choice of a home health agency is minimal.

Having concluded that the videos are unlikely to influence patients to select the Agency, it is not necessary to proceed to the third issue under the CMP (i.e., whether the Agency knows, or should know, that the Arrangement is likely to influence patients' selection of the home health agency for future services).

We believe that crucial differences distinguish the Agency's distribution of educational videos under the Arrangement from offers by home health agencies to provide free in-person and telephone preoperative home safety assessments for patients scheduled to undergo orthopedic surgery. In the latter situation, the surgeon's referral of the prospective patient to the home health agency leads to a personalized safety assessment of the patient's home for use in convalescence. The assessment is often performed by a trained and licensed physical therapist from the home health agency during a home visit or a telephone call. The patient typically receives the impression that the assessment constitutes a valuable service that contributes to a successful surgical outcome and recovery. The assessment also initiates a personal relationship between the preoperative patient and the agency's physical therapist, a connection that is likely to influence patients to choose the home health agency as their service provider. By contrast, the more modest and impersonal Arrangement poses substantially less risk.

For the reasons noted above, we would not impose sanctions on the Agency under the CMP in connection with the Arrangement. For the reasons set forth above, we also conclude that the Arrangement is unlikely to be a vehicle to pay unlawful kickbacks to patients and would therefore not impose administrative sanctions on the Agency in connection with the anti-kickback statute.

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that while 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 will not impose administrative sanctions on the Agency 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. 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 letter 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 in any matter involving an entity or individual that is not a requestor of 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 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 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 the [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/

Lewis Morris
Chief Counsel to the Inspector General