[*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, 2006

Posted: March 27, 2006

[Name and address redacted]

Re: OIG Advisory Opinion No. 06-01

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 customers with a free preoperative home safety assessment (the "Arrangement"). Specifically, you have inquired whether the Arrangement constitutes grounds for the imposition of sanctions under the civil monetary penalty ("CMP") provision for violations of the prohibition against inducements to beneficiaries under section 1128A(a)(5) of the Social Security Act (the "Act"), as well as under the exclusion authority at section 1128(b)(7) of the Act or the CMP 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.

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 the Arrangement could constitute grounds for the imposition of civil monetary penalties under section 1128A(a)(5) of the Act. We also conclude that the Arrangement potentially generates prohibited remuneration under the anti-kickback statute and that the Office of Inspector General ("OIG") could potentially 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. Any definitive conclusion regarding the existence of an anti-kickback statute violation requires a determination of the parties' intent, which determination is beyond the scope of the advisory opinion process.

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.

1. FACTUAL BACKGROUND

[Name redacted] ("Requestor") operates a nationwide network of home health care agencies. Requestor provides a variety of home health care services, including skilled nursing care, home health aide services, personal care assistance, home medical equipment, and rehabilitation services. Pursuant to the Arrangement, Requestor provides free preoperative home safety assessments for patients scheduled to undergo orthopaedic surgery.

When a preoperative patient is referred to Requestor, Requestor contacts the patient to arrange for the patient to receive a preoperative home safety assessment.[1] The preoperative home safety assessment is performed by one of Requestor's licensed physical therapists, either over the phone or in person at the patient's home. According to Requestor, the purpose of the assessment is to ascertain whether the patient's home is suitable for postoperative recovery. During the assessment, a physical therapist gathers basic information about the patient (e.g., past surgical history and history of falls) and basic information about the patient's residence (e.g., number of stories, number of steps, and presence of tripping hazards). The therapist conducting the assessment may also offer limited suggestions about simple home safety improvements (e.g., removing throw rugs and

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[1]Patients are referred to Requestor by their treating orthopaedic surgeon or a surgery scheduler. Requestor has certified that these individuals receive no remuneration directly or indirectly from Requestor. The referring surgeon or scheduler provides the patient with a written notice indicating that the Requestor will be contacting the patient to schedule a safety assessment. The surgeon or scheduler then contacts Requestor to request a home safety assessment for the patient. No opinion has been sought, and we express no opinion, regarding Requestor's arrangements with the individuals who refer patients to Requestor for the assessments.

placing a telephone in an accessible location), but the assessment does not include any skilled care, significant patient education, or exercise or other therapeutic instruction.[2]

During each assessment, the therapist provides the patient with written materials disclosing that the patient has no obligation to obtain home health services from Requestor, that other providers of home health care are available, and, should postoperative services prove both medically indicated and desired, the patient remains free to choose among the available home health care providers, with assistance from the hospital discharge planner. The therapist is required to review the materials with the patient as part of the safety assessment. Patients may ultimately select Requestor as their provider of home health services, but that selection is not finalized, and services are not scheduled, until after the patient undergoes surgery.

Preoperative home safety assessments are not a covered service under the Medicare or Medicaid programs. Some managed care payors cover in-home preoperative safety assessments for their beneficiaries, generally paying Requestor between $85 and $100 for each in-home assessment. Home safety assessments provided over the telephone are not generally reimbursed by third party payors, and Requestor is not aware of a commercial market for such services. Requestor has represented that the value of the telephone safety assessment, which generally takes ten to fifteen minutes, is less than $10, based on Requestor's salary costs for providing the services.

II. LEGAL ANALYSIS

A. Law

Section 1128A(a)(5) of the Act (the "CMP") provides for the imposition of civil monetary penalties against any person who gives something of value to a Medicare or Medicaid program 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 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

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[2]Requestor has certified that its representatives are trained to follow procedures that ensure that safety assessments do not occur until after a patient is referred to Requestor and that no skilled care, significant patient teaching, or exercise instruction are part of the safety assessment. These parameters are printed on the preoperative home safety evaluation form that representatives must discuss with each patient and complete after every safety assessment.

market value." The OIG has previously taken the position that "incentives that are only nominal in value are not prohibited by the statute,"[3] and has interpreted "nominal value to be no more than $10 per item, or $50 in the aggregate on an annual basis."[4]

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.

B. Analysis

The Arrangement, by which Requestor, a provider of postoperative home health care items and services, provides Medicare and Medicaid beneficiaries who are scheduled for surgery with free services, implicates both the CMP prohibiting beneficiary inducements and the anti-kickback statute. While the free preoperative home safety assessments are not covered by the Medicare or Medicaid programs, many of Requestor's postoperative home care items and services are covered. Arrangements whereby a prospective provider or supplier of Federally payable items and services offers beneficiaries a non-covered item or service free of charge implicate the fraud and abuse laws and must be closely scrutinized.

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[3] Preamble to the final rule on the CMP, 65 FR 24400, 24410 (April 26, 2000).

[4] Id. at 24411.

We begin with the application of the CMP to the facts presented. The threshold question is whether a free preoperative home safety assessment constitutes remuneration to the beneficiary who receives it. The in-home safety assessments appear to be valuable services for which Requestor is paid $85 to $100 by some insurers. With respect to the telephonic safety assessments, determining whether the assessments have economic value to patients is more problematic. The absence of a paying market for such services is not dispositive: such absence could indicate that the service has little or no value; that the service is simply novel or emerging in the marketplace; or that the market has been distorted by the availability of free services.

The Requestor urges that, even if the telephonic assessments have value to the beneficiary, they do not implicate the CMP because the value is nominal. We are not persuaded by the facts presented. Although the telephonic assessments may cost Requestor less than $10 to provide, the value to the beneficiary – the appropriate focus under the CMP – may exceed that amount. Under the Arrangement, Requestor delivers the free services in a manner that would lead a reasonable beneficiary to believe that he or she is receiving a valuable service, and that may actually comprise a valuable service. The telephonic safety assessment is recommended to the patient by his or her treating orthopaedic surgeon or a surgery scheduler and is conducted by a trained and licensed physical therapist. These characteristics, at a minimum, reasonably create an impression that the telephonic assessment is of substantial value and will contribute to successful surgical outcome and recovery. Thus, based on the facts presented, we cannot conclude that the telephonic assessments are of nominal value for purposes of the CMP. Accordingly, we must conclude that both the in-home and free safety assessments are potential remuneration to beneficiaries.

The next question under the CMP is whether the free home safety assessments are likely to influence beneficiaries to select the Requestor as their provider of postoperative items and services payable by Medicare or Medicaid. We believe the answer is yes. The beneficiary's own surgeon (or a surgery scheduler) has recommended Requestor for the safety assessment, and it would be reasonable and probable that a beneficiary would assume that his or her health care professional similarly recommends the Requestor's postoperative services. During the home safety assessment, Requestor's physical therapist has an opportunity to initiate a personal relationship with the beneficiary, and it is reasonable and probable that a beneficiary would select a provider of postoperative care with whom the beneficiary is already familiar. The fact that the assessment is offered without charge increases the chances that a beneficiary will, in fact, schedule a recommended safety assessment, thus maximizing opportunities for Requestor's physical therapists to become acquainted with the beneficiary before the beneficiary selects his or her postoperative home care provider. While receipt of the free preoperative assessment from Requestor does not obligate beneficiaries to retain

Requestor as their provider of postoperative home health care services, it is certainly likely to influence beneficiaries to select Requestor to provide postoperative services.[5]

The final issue under the CMP is whether the Requestor knows or should know that the Arrangement is likely to influence beneficiaries' selection of the Requestor for postoperative items and services. The structure and operation of the Arrangement – including offering the service without charge, obtaining a recommendation from the patient's own health care professional, and using physical therapists to perform the services – appear calculated to generate postoperative business for the Requestor. Moreover, the free safety assessments are only offered to patients who are scheduled for surgery and, thus, expected to require covered home health care services in the near future. Thus, we believe it is probable that the Requestor knows or should know that the free safety assessments are likely to generate Medicare and Medicaid payable business for the Requestor.

In sum, for the reasons set forth above, we conclude that the Arrangement potentially violates the CMP. No statutory exception to the CMP applies in these circumstances. Moreover, also for the reasons set forth above, we conclude that the Arrangement potentially violates the anti-kickback statute.[6]

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that the Arrangement may constitute grounds for the imposition of civil monetary penalties under section 1128A(a)(5) of the Act. We also conclude that the Arrangement potentially generates prohibited remuneration under the anti-kickback statute and that the OIG could potentially 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. Any definitive conclusion regarding the existence of an anti-kickback violation requires a

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[5]Requestor relies on freedom of choice disclosures made to the beneficiaries to safeguard against improper influence. While such disclosures further the desired goal of informed decision-making, we do not believe that such disclosures are sufficient to safeguard against improper beneficiary inducements.

[6]This opinion is limited to a home health agency giving beneficiaries preoperative home safety assessments free of charge. Nothing in this opinion addresses whether or not a patient would benefit from receiving a preoperative home safety assessment or whether a home health agency could sell preoperative home safety assessments for an appropriate fee.

determination of the parties' intent, which determination is beyond the scope of the advisory opinion process.

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 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.

Sincerely,

/s/

Lewis Morris
Chief Counsel to the Inspector General