



[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: June 23, 2009

Posted: June 30, 2009

[Name and address redacted]

Re: OIG Advisory Opinion No. 09-07

Dear [Name redacted]:

We are writing in response to your request for an advisory opinion regarding a proposal to expand an existing program that provides free oral nutritional supplements to malnourished end-stage renal disease patients who are on dialysis (the “Proposed Arrangement”). Specifically, you have inquired whether the Proposed Arrangement would constitute grounds for the imposition of sanctions under the civil monetary penalty provision prohibiting inducements to beneficiaries, section 1128A(a)(5) of the Social Security Act (the “Act”), or under the exclusion authority at section 1128(b)(7) of the Act, or the civil monetary penalty provision at section 1128A(a)(7) of the Act, as those sections relate to the commission of acts described in section 1128B(b) of the Act, the Federal anti-kickback statute.

You have certified that all of the information provided in your request, including all supplemental submissions, is true and correct and constitutes a complete description of the relevant facts and agreements among the parties.

In issuing this opinion, we have relied solely on the facts and information presented to us. We have not undertaken an independent investigation of such information. This opinion is limited to the facts presented. If material facts have not been disclosed or have been misrepresented, this opinion is without force and effect.

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that: (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) while 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 letter 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”) and its affiliates operate numerous dialysis facilities in the United States. The facilities serve patients with end-stage renal disease (“ESRD”). Many of the Requestor’s ESRD patients are Federal health care program beneficiaries, and Federal health care programs cover a considerable portion of their treatment.

According to the Requestor,¹ malnutrition is prevalent in the ESRD patient population and has been linked to increased hospitalization, infection, and mortality. Serum albumin levels are common indicators of nutritional status. Consumption of oral nutritional supplements by ESRD patients, particularly at or around the time of dialysis treatment, can improve their nutritional status—as measured by indicators such as serum albumin levels—thus leading to decreased risks of hospitalization, infection, and mortality.

Notwithstanding these potential benefits, the Requestor asserts that many ESRD patients are unlikely to comply with physician recommendations to consume oral nutritional

¹ The Requestor has certified the validity of the propositions contained in this paragraph and provided numerous medical journal articles in their support. We have reviewed the articles provided by the Requestor. For purposes of this opinion, however, we rely solely on the Requestors’ certifications and nothing in this advisory opinion should be construed as an endorsement or conclusion as to the medical propriety of any of the propositions proffered by the Requestor and underlying the Proposed Arrangement.

supplements because, among other reasons, the supplements are particularly unpalatable. In fact, based on the Requestor's experience, many patients view the supplements as medicinal in nature and only consume them with the active encouragement and support of the patient's treating physician and/or the dialysis facility's patient care team. To promote patient consumption of physician-recommended supplements, the Requestor currently operates a program that provides free oral nutritional supplements (the "Supplements")² to eligible ESRD patients. The Requestor's current program limits the Supplements to 40 doses (approximately a three-month supply) per eligible patient, per year.³

Under the Proposed Arrangement, the Requestor would expand its current program and provide eligible patients with up to approximately 156 doses of the Supplements per year. The Proposed Arrangement would be subject to a number of limitations.

First, a patient would only be eligible to participate if the patient was in the Requestor's dialysis program and had a predialysis or stabilized, as appropriate, serum albumin level less than or equal to a target level set by the Requestor. (Such patients are referred to in this opinion individually as an "Eligible Patient" and collectively as "Eligible Patients.") The Requestor has certified that the target level would be set using, and would not exceed, the lower limit of the serum albumin clinical outcome goal related to protein-energy nutritional status currently recommended in the independently established National Kidney Foundation Kidney Disease Outcomes Quality Initiative guidelines.⁴ The Requestor has further certified that it would modify the target level in accord with any future changes in the clinical outcome goal recommended in such guidelines, or comparable successor clinical practice guidelines for ESRD patients independently established by the National Kidney Foundation (collectively, the "NKF Guidelines"), such that in no event would the target

² The Supplements currently come in three forms: (1) renal specific liquid nutritional high protein/high calorie formulation, (2) renal specific hydrolyzed protein liquid formulation, and (3) high protein bars.

³ No opinion has been sought, and we express no opinion, regarding the Requestor's existing program.

⁴ The current National Kidney Foundation Kidney Disease Outcomes Quality Initiative guidelines recommend an outcome goal of a predialysis or stabilized serum albumin level equal to or greater than approximately 4.0 g/dL, the lower limit of the normal range. Note that for purposes of this opinion, all references to measurements of serum albumin levels are to measurements derived using the bromocresol green method.

level ever exceed the lower limit of the then-currently recommended clinical outcome goal.⁵ Second, the Requestor would only provide the Supplements to an Eligible Patient at the request of his or her attending physician, when medically necessary for that patient. Third, the Requestor would deliver one dose of the Supplements to Eligible Patients when they visit the Requestor’s dialysis facility for treatment and would require that each Eligible Patient consume their dose at or around the time of their dialysis treatment while on the facility’s premises.⁶ Fourth, an Eligible Patient would no longer be eligible to receive, and the Requestor would cease providing, the Supplements when the patient’s serum albumin level reached or exceeded the lower limit of the clinical outcome goal then-currently recommended in the NKF Guidelines. Fifth, neither the Requestor nor its affiliates would advertise or promote the availability of the Supplements or the program to any potential patients. Finally, neither the Requestor nor its affiliates would claim the costs of the Supplements directly or indirectly on any Federal health care program cost report or claim or otherwise shift them to any Federal health care program.⁷

⁵ The target level could, however, be lower. For example, assuming the current clinical outcome goal for serum albumin levels of equal to or greater than approximately 4.0 g/dL, the Requestor could set the target level at 3.5 g/dL, but could not set it at 4.1 g/dL.

⁶ There is an exception to this limitation for certain Eligible Patients who engage in peritoneal dialysis or hemodialysis in their homes or other non-dialysis facility settings (“Eligible Home Patients”). The Eligible Home Patients make up a small percentage (approximately 6%) of the patients enrolled in the Requestor’s dialysis program. According to the Requestor, Eligible Home Patients who engage in these types of non-facility based dialysis visit a dialysis facility or home program center approximately once a month for general support services and to replenish their home dialysis supplies. Under the Proposed Arrangement, the Requestor would provide Eligible Home Patients with a one-month supply of the Supplements (i.e., approximately 13 doses) during their monthly visit. Although the Requestor has no practical means of observing the Eligible Home Patients’ consumption of the Supplements, the Requestor would continue with its prior practice of requiring each Eligible Home Patient to certify in writing that the Eligible Home Patient consumed all of the Supplements provided by the Requestor in order to receive each subsequent allotment of the Supplements. Further, the Requestor would recommend to the Eligible Home Patients that they consume the Supplements at or around the time of their dialysis treatment. However, no such recommendation would be made to continuous ambulatory peritoneal dialysis Eligible Home Patients because they receive dialysis on a generally continuous basis and, according to the Requestor, there seems to be no specific optimal time for consumption by these patients.

⁷ In general, oral nutritional supplements for ESRD patients are not reimbursable by Federal health care programs. We note, however, that there are limited circumstances in which they

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 (the “CMP”) 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 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

could be covered (e.g., state Medicaid program coverage or coverage under CMS’s ESRD demonstration project).

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

Providing ESRD patients with the Supplements implicates both the CMP prohibiting beneficiary inducements⁸ and the anti-kickback statute. We are particularly concerned that dialysis facilities might induce beneficiaries to obtain Federally payable items and services by offering them the Supplements when they are not, in fact, part of a targeted, properly structured, and clinically appropriate treatment modality.

As we have noted elsewhere, there are valid reasons for Congress’ determination to restrict the availability of “giveaways” in connection with Medicare and Medicaid providers. First, such programs can corrupt the clinical decision-making process. Second, there is potential harm to competing providers and suppliers who do not, or cannot afford to, offer incentives to generate business. Third, these practices could negatively affect the quality of care given to beneficiaries. As providers and suppliers race to the bottom of offering increasingly valuable goods or services, the incentive to cheat on the quality of the Medicare or Medicaid item or service increases proportionately. See generally OIG Special Advisory Bulletin on Offering Gifts and Other Inducements to Beneficiaries (August 2002), available at <http://oig.hhs.gov/fraud/docs/alertsandbulletins/SABGiftsandInducements.pdf>. These concerns notwithstanding, for a combination of the following reasons, we conclude that the Proposed Arrangement, if operated as certified by the Requestor, poses a low risk of fraud and abuse.

Several factors in the Proposed Arrangement effectively minimize the risk of abuse. First, the Requestor would only provide the Supplements to patients who have a medical need, as determined by their attending physician, and who meet the eligibility criteria (*i.e.*, they are patients in the Requestor’s dialysis program and have a serum albumin level less than or equal to the target level). The target level would be set using, and would not exceed, the lower limit of the serum albumin clinical outcome goal related to protein-energy nutritional status currently recommended in the independently established National Kidney Foundation Kidney Disease Outcomes Quality Initiative guidelines. The Requestor would modify the target level in accord with any future changes in the clinical outcome goal recommended in the NKF Guidelines, such that in no event would the target level ever exceed the lower limit of the then-currently recommended clinical outcome goal. Additionally, the Requestor would cease providing the Supplements when the patient’s serum albumin level reached or

⁸ For at least some beneficiaries, the aggregate annual market value of the Supplements could exceed \$50, and thus the Proposed Arrangement would not qualify as a “nominal” value program for purposes of the CMP.

exceeded the lower limit of the clinical outcome goal then-currently recommended in the NKF Guidelines. In these circumstances, the Supplements become an integral part of the clinical care provided to a patient. Second, patients generally view the Supplements as medicinal in nature, due in part to the fact that they are not very palatable. Third, the Proposed Arrangement is designed, and contains appropriate safeguards, to encourage compliance with physician recommendations to patients for the use of Supplements and to limit the potential for diversion. Further, the fact that the Supplements must be consumed in the facility increases the likelihood that the patient will actually consume the Supplements—because staff is available to observe and encourage consumption—and limits the patients’ ability to divert Supplements to others (e.g., family members) or re-sell them. The delivery of the Supplements individually, rather than in bulk, further limits the risk of diversion.⁹

Other aspects of the Proposed Arrangement contribute to our conclusion, including the fact that the availability of the Supplements or the program would not be advertised or promoted by the Requestor or its affiliates to any potential patients, including Federal health care beneficiaries. Also, the per patient aggregate annual market value of the Supplements would, as a practical matter, be capped by virtue of the fact that the number of doses would not exceed approximately 156 doses per year. Furthermore, the Supplements are not, ordinarily, reimbursed by Federal health care programs, so, in conjunction with the Requestor’s certification that neither it nor its affiliates would claim the costs of the Supplements directly or indirectly on any Federal health care program cost report or claim or otherwise shift them to any Federal health care program, the Proposed Arrangement presents only a limited risk for increased program expenses. Moreover, due to the specific combination of factors present in the Proposed Arrangement, there is only a limited risk that it would influence patients’ selection of a provider.

Finally, this opinion is premised on the Requestor’s certifications that the Supplements are only provided in cases when the patient meets objective clinical criteria for malnourishment and the use of the Supplements are clinically indicated for that particular patient.¹⁰

⁹ Although Eligible Home Patients would not consume the Supplements in the facility and would receive the Supplements in monthly batches, rather than individually, the limited percentage of Eligible Home Patients relative to the Requestor’s total patient population and the certification requirement, in combination with other safeguards, are sufficient to reduce the relative overall risk of diversion by the Eligible Home Patients, when viewed in the context of all of the facts and circumstances presented in the Proposed Arrangement.

¹⁰ Were the Supplements offered to patients who did not meet the objective clinical criteria or when not medically necessary, then this opinion would be without force and effect.

In sum, the above-listed conditions and safeguards are consistent with the stated purpose of the Proposed Arrangement to improve the nutritional status of patients that are malnourished and thereby reduce their risk of hospitalization, infection, and mortality. Taken as a whole, they also distinguish the Proposed Arrangement from problematic programs that offer free goods or other remuneration to beneficiaries as incentives to obtain Medicare and Medicaid reimbursable items and services.

We conclude that the Requestor's provision of the Supplements, in this particular context, would not be an impermissible inducement under section 1128A(a)(5) of the Act. Although providing the Supplements could implicate the Federal anti-kickback statute, in this particular context, and for the same reasons noted above, we would not impose administrative sanctions arising 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: (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) while 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 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 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 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 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