



[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: September 29, 2006

Posted: October 6, 2006

[Name and address redacted]

Re: OIG Advisory Opinion No. 06-15

Dear Ladies and Gentlemen:

We are writing in response to your request for an advisory opinion regarding an arrangement between [name redacted] and [state agency redacted], under which [name redacted] will disburse pay-for-performance financial incentives on behalf of [state name redacted]'s Medicaid program (the "Arrangement"). Specifically, you have inquired whether the Arrangement constitutes 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.

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 Office of Inspector General ("OIG") will 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 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.

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] (“Requestor”) sells products and services relating to managed care.¹ The subject of this advisory opinion concerns certain administrative services rendered by Requestor to the [state agency redacted] (the “Department”) of [state redacted] (the “State”), in connection with the State’s Medicaid program.

On March 18, 2005, Requestor and the Department entered into the [agreement name redacted] (the “Agreement”), pursuant to which Requestor agreed to develop and implement on behalf of the Department a disease management program (the “[program name redacted]”) that includes a physician pay-for-performance program (the “Pay-for-Performance Program”).²

The Department’s [program name redacted] is the State’s enhanced primary care case management and disease management program for certain State Medicaid beneficiaries. The [program name redacted] includes a disease management component to provide more comprehensive and systematic care to chronically ill beneficiaries suffering from asthma, diabetes, chronic pulmonary disease, coronary artery disease, and congestive heart failure.

The Department implemented the Pay-for-Performance Program component of the [program name redacted] pursuant to a Medicaid waiver, which was approved by the Centers for Medicare & Medicaid Services (“CMS”). Central to the Pay-for-Performance Program are payments by the Medicaid program to physicians for ordering or recommending certain specified services (e.g., prescribing medications that have been

¹ Requestor’s parent company, [name redacted], operates businesses in the pharmaceutical, medical supply, and health care technology areas, among others. Requestor is in the pharmaceutical segment of the parent company.

² The Department had sought and received proposals from various providers of disease management services, and ultimately chose Requestor to develop and implement the [program name redacted], including the Pay-for-Performance Program, on the Department’s behalf pursuant to a competitive bidding process.

shown to reduce disease exacerbations or improve clinical outcomes) with the goal of reducing overall medical costs by achieving better health outcomes for patients.³

The Agreement contains the Department's requirement that Requestor disburse the Department-approved financial incentives to Medicaid providers participating in the Pay-for-Performance Program in the form of checks drawn on a [Requestor's name redacted] bank account.⁴ Each check is branded at the top with the [program name redacted] name, and directly underneath, the words "Pay for Performance Program." The memo line will indicate the date of service for which payment is being made. The payment criteria and amounts are set forth in the agreements between the [program name redacted] and physicians participating in the Pay-for-Performance Program, and Requestor has no discretion or independent authority to determine or revise payment amounts. The funds that Requestor disburses to physicians under the Pay-for-Performance Program come from the State's Medicaid program. Requestor earns a fair market value fee for the administrative services it provides, and it will return to the Department any Pay-for-Performance Program payments advanced to it that are not disbursed to physicians. The Department will receive detailed reports on all of the disbursements from time to time and may audit Requestor's performance to ensure compliance with the Agreement.

In order to prevent the misimpression that it is Requestor paying physicians for their participation in the Pay-for-Performance Program, as opposed to the Department and the State Medicaid program, the parties' marketing materials, provider agreements and other documents describing the Pay-for-Performance Program accurately and prominently identify the Department and/or the [program name redacted] as the payor of the financial incentives and to refer to Requestor as a mere contractor or administrator of the Pay-for-Performance Program.

³ Requestor has certified that the Pay-for-Performance Program does not favor or reward the use of Requestor's products or services (or those of its parent company or any affiliate), and that no payments under the Pay-for-Performance Program will be made to induce or reward the utilization of Requestor's products or services (or those of its parent company or any affiliate). The State's Medicaid program drug formulary is separate from the Pay-for-Performance Program, and Requestor played no part in its development or design.

⁴ According to the Department, it requires this payment structure in order to comply with certain State laws governing the State Medicaid program.

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.

B. Analysis

We begin by emphasizing that this advisory opinion addresses the narrow question of whether the Arrangement, under which Requestor disburses Pay-for-Performance Program payments to physicians on behalf of the Department, implicates the anti-kickback statute. We are specifically not opining on Requestor’s role in designing the Pay-for-Performance Program, nor are we opining on other elements of the Agreement or the Pay-for-Performance Program.

The question of whether the Arrangement implicates the anti-kickback statute arises because of the appearance that Requestor is making payments to physicians by issuing Pay-for-Performance Program checks drawn on Requestor’s bank account. Ideally, this ostensible problem would be solved by drawing payments from a State bank account, but State law governing the State’s Medicaid program forecloses that option.

It is the substance – not the form – of an arrangement that governs under the anti-kickback statute. Superficial appearances are not controlling. In the specific circumstances of the Arrangement, Requestor's duties as a payment administrator for the State's Pay-for-Performance Program do not implicate the anti-kickback statute. We reach this conclusion based on a combination of the following factors.

First, the payments are not made with Requestor's money; they are funded by the State.

Second, Requestor does not have control or discretion over the payments. When Requestor issues checks to physicians pursuant to the Arrangement, it is in every respect acting as an agent of the State: it is disbursing the State's funds, according to the State's rules, for the State's purposes, under the State's supervision. Moreover, because payments to physicians under the Pay-for-Performance Program do not reflect the use of Requestor's products or services, there will be no nexus between the payments and Requestor's products and services. Thus, in these circumstances, Requestor is not using another party's funds to disguise payments for referrals.

Third, the parties have taken meaningful steps to minimize any misimpression by physicians that Requestor is paying them for referrals of Medicaid business. With respect to marketing materials, provider agreements and other documents describing the Pay-for-Performance Program, the parties have taken care to identify accurately the Department and/or the [program name redacted] as the payor of the financial incentives and to refer to Requestor as a mere contractor or administrator of the Pay-for-Performance Program. Each check issued under the Arrangement will be branded with the name of the [program name redacted] and the Pay-for-Performance Program. Finally, the Department supervises all payments and has the right to audit Requestor's performance under the Agreement.

For the foregoing reasons, we conclude that, in the specific circumstances of the Arrangement, Requestor's duties as a payment administrator for the Pay-for-Performance Program do not implicate the anti-kickback statute. We note that there is nothing talismanic about Requestor's status as a payment administrator that leads to this conclusion; for example, we might reach a different conclusion were we to consider a similar arrangement whereby an administrator had power to control payments that related to its products.

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that the OIG will 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 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 [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