



[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: October 31, 2005

Posted: November 7, 2005

[name and address redacted]

Re: OIG Advisory Opinion No. 05-12

Dear [name redacted]:

Gentlemen:

We are writing in response to your request for an advisory opinion regarding your proposal to enter into a joint venture to establish a day treatment facility to provide psychiatric services to pediatric patients (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.

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 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, but that the Office of Inspector General (“OIG”) would not impose administrative sanctions on [names 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 formation of the joint venture described in the Proposed Arrangement and, therefore, we express no opinion about the future performance of the venture to the extent it differs from the predicted facts or 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 [names redacted], the requestors 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

[Names redacted] (the “Psychiatrists”) practice psychiatry in [State redacted]. Each Psychiatrist has an independent private psychiatric practice with a pediatric focus. Pediatric patients comprise about 60 percent of [name redacted]’s patient base and about 80 percent of the patients seen by [names redacted]. The Psychiatrists engage in similar types of psychiatric practice and rarely refer patients to each other.

Under the Proposed Arrangement, the Psychiatrists will form a partnership to establish a pediatric psychiatric day treatment facility. Psychiatric day treatment may be appropriate for some patients who require an intensity of therapy short of hospitalization. The planned facility will provide six hours of supervised care per day, including various forms of psychiatric and substance abuse therapy.

Under the Proposed Arrangement, each Psychiatrist will invest one third of the capital necessary to establish the facility and hold a one third ownership interest. No part of any Psychiatrist’s capital investment will involve a loan from the proposed facility. While all three owners will be in a position to refer patients to the facility, they will not be required to do so. The facility will not provide the Psychiatrists with information about the volume or value of business generated by their co-investors. Any returns on investment will be proportionate to each Psychiatrist’s respective capital contribution and will not, in any way, take into account the previous or expected volume or value of referrals or business otherwise generated by the Psychiatrist.

The Psychiatrists expect that the vast majority of patients will be referred to the facility by clinicians who are not affiliated with the facility, with business generated by Psychiatrist owners accounting for about five percent of total facility revenue. The facility will treat self-pay patients, patients covered by certain private health insurance plans, and patients enrolled in Medicaid health maintenance organizations (“HMOs”). The facility will not treat beneficiaries of any other Federal health care program besides Medicaid, and the only Medicaid patients who will be treated at the facility will be Medicaid HMO patients. The facility will not treat any fee-for-service Medicaid patients. The Psychiatrists estimate that no more than five percent of the facility’s patients will be Medicaid HMO patients, who will be accepted without regard to the particular managed care organization in which they are enrolled, provided they qualify clinically for the facility’s services. Revenue generated from the care of Federal health care program patients (i.e., Medicaid HMO patients) referred by the Psychiatrist owners is expected to account for no more than two percent of total facility revenue.

Patients whose payor status renders them ineligible for treatment at the facility will receive an initial evaluation and, if necessary, stabilization services and evaluation for potential transfer to another treatment facility. The Psychiatrists do not currently, and will not in the future, directly or indirectly own or control any other facility that provides comparable pediatric psychiatric day treatment services.

No patient will be admitted to the facility without first undergoing an evaluation to determine whether day treatment at the facility is appropriate. For patients referred by a clinician who does not have an ownership interest in the facility, the evaluator may be one of the Psychiatrist owners or another qualified health care provider. However, for patients referred to the facility by one of the Psychiatrist owners, the evaluator will be a qualified health care provider who does not have an ownership interest in the facility.¹ In some instances, the evaluator (whether one of the Psychiatrist owners or another qualified health care provider) will receive compensation for the evaluation directly from a third party payor. Where such compensation is not available, the evaluator will be compensated by the facility based on fair market value, consistent with an arm’s-length transaction, for the services rendered. The Psychiatrists have certified that compensation for these evaluations will not be determined in any manner that takes into account the results of the evaluation, including the determination

¹We express no opinion on any arrangements between the facility and the health care providers, who are not owners of the facility, performing the initial evaluations and other services at the facility.

as to whether or not day treatment is appropriate for the patient.² The Psychiatrist owners may perform additional services, besides the initial evaluations, that will be compensated by the facility. Any such services will be performed under a *bona fide* employer-employee relationship and be compensated based on fair market value, consistent with an arm's-length transaction, for the services rendered.

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.

²We are precluded by statute from opining on whether fair market value shall be or was paid for goods, services, or property. See section 1128D(b)(3)(A) of the Act. For purposes of this advisory opinion, we rely on the Requestors' certifications of fair market value. If the payments are not fair market value, this opinion is without force and effect.

B. Analysis

The OIG has longstanding concerns about health care ventures among investors who are potential sources of Federal health care program business for the venture or for co-investors. Returns on investments in the venture may be disguised remuneration paid in exchange for the Federal health care program business. Like any kickback scheme, such arrangements can lead to overutilization of services, increased costs for Federal health care programs, corruption of professional judgment, and unfair competition. The potential for risk under the Proposed Arrangement is especially high because 100 percent of the psychiatric day treatment facility will be owned by potential referral sources.³

Accordingly, we must carefully scrutinize the Proposed Arrangement in its entirety to determine whether, based upon a totality of the facts and circumstances presented, the potential risk of fraud and abuse is sufficiently mitigated. Having done so, we conclude that the Proposed Arrangement includes several factors that, taken together, adequately mitigate the risk of Federal health care program fraud and abuse.

First, it appears unlikely that the Proposed Arrangement is being established to serve as a vehicle to compensate the Psychiatrists for referrals of Federal health care program beneficiaries, in particular Medicaid HMO patients, to the facility. Fewer than five percent of the facility's patients will be beneficiaries of Federal health care programs, and all of those Federal beneficiaries will be enrollees of Medicaid HMOs. The vast majority of these Medicaid HMO patients will be referred to the facility by providers who are not owners of the facility. Only a small part of the facility's revenue (i.e., no more than two percent) is expected to derive from Medicaid HMO patients referred to the facility by a Psychiatrist owner. Also, all patients referred by a Psychiatrist owner will undergo an independent evaluation by an evaluator whose compensation is not contingent on the results of the evaluation. Moreover, each Psychiatrist will make a substantial capital contribution, no part of which will be in the form of a loan from the proposed facility, and any returns on investment will be proportionate to each Psychiatrist's respective capital contribution and will not be calculated in any way that takes into account previous or expected volume or value of referrals or business otherwise generated by the Psychiatrist. Information regarding the volume or value of business generated by each Psychiatrist will not be shared with the other Psychiatrists. Finally, all compensation for services rendered by the Psychiatrists and other clinicians to the facility will be paid based on fair market value, consistent with an arm's-length transaction, for the services rendered. No compensation to the Psychiatrist

³The safe harbor for small entity investment interests, 42 C.F.R. § 1001.952(a)(2), does not protect an arrangement, like this one, in which the entire investment interest is held by investors who are in a position to refer patients to the entity.

owners or other referring clinicians will be tied in any way to the volume or value of patient referrals.

Second, it also appears unlikely that the Proposed Arrangement is being established to serve as a vehicle to reward referrals of Federal health care program beneficiaries by the investors to one another. Each Psychiatrist owner has an independent private practice providing similar psychiatric services to a similar patient population. Thus, each Psychiatrist is, in his private practice, a competitor of the others, with a corresponding incentive to retain patients rather than refer them to a co-investor.

Third, the risk that the proposed ownership structure will drive overutilization of items or services reimbursed by a Federal health care program or result in excessive Federal expenditures is minimal. No more than five percent of the proposed facility's patients are expected to be beneficiaries of Federal health care programs, and all of these beneficiaries will be enrollees in capitated Medicaid managed care plans.⁴ The Psychiatrist owners anticipate that no more than two percent of the facility's revenues will derive from Medicaid HMO patients referred to the facility by a Psychiatrist owner. Approximately 95 percent of patients treated will initially be referred to the facility by a clinician who has no ownership stake in the facility. For the patients who are initially referred by a Psychiatrist owner, an independent clinician must determine the appropriateness of treatment at the facility before the patient may be admitted. Thus, the limited number of Federal health care program beneficiaries referred by the Psychiatrist owners (expected to account for no more than two percent of the facility's revenues), the fact that these patients will be enrollees in Medicaid managed care plans, and the requirement for an independent clinical evaluation prior to admission, in combination, serve as useful safeguards against the Psychiatrists' ownership interests driving overutilization or inflated costs.

We have a longstanding concern that, in many circumstances, segregating Federal and non-Federal business into legally separate providers of services may result in (i) inflated charges for services provided to Federal beneficiaries or (ii) payments for referrals to the entity serving Federal beneficiaries being channeled through the non-Federal entity. However, while the Proposed Arrangement excludes some Federal health care program beneficiaries, several features mitigate the risks of abuse typically associated with "carve outs" of Federal health care program business. The facility's line of business – pediatric psychiatric day treatment – inherently limits the universe of potential Federal health care program patients to children, a group primarily represented in the Medicaid population. In this case, the only Federal health care program beneficiaries who will be treated at the facility will be clinically-

⁴We note that these HMOs may require pre-authorization for services provided by the facility.

eligible children enrolled in a Medicaid HMO. However, while Medicaid fee-for-service beneficiaries (and other pediatric Federal beneficiaries) will be referred elsewhere, the Psychiatrists have certified that they do not, and will not, directly or indirectly own or control any other facility that provides comparable services. In combination, these features reduce the risk that the facility would serve as a vehicle for inflating charges to Federal health care program beneficiaries (or selecting only high-paying Federal beneficiaries) or for channeling payments for referrals of Federal health care program beneficiaries to an affiliated entity.

Based on the totality of facts and circumstances presented, a combination of factors sufficiently mitigates the risk posed by the formation of the Proposed Arrangement. Our conclusion derives from the particular facts presented. In the instant case, we might have reached a different conclusion if, by way of example only, the facility were being established to treat a higher percentage, or different type, of Federal health care program beneficiary, or other significant factors had been different. Importantly, this opinion is without force and effect if the business model or actual performance of the Proposed Arrangement departs from the predicted facts as certified in your request and supplemental submissions. The Psychiatrists and the facility remain responsible for compliance with all Federal, state, and local requirements, including rules and regulations regarding the appropriateness of therapy provided, documentation, and billing.

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that 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, but that the OIG would not impose administrative sanctions on [names 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 formation of the joint venture described in the Proposed Arrangement and, therefore, we express no opinion about the future performance of the venture to the extent it differs from the predicted facts or 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 [names redacted], the requestors 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 [names 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 [names 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