



[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 24, 2008

Posted: October 2, 2008

Re: OIG Advisory Opinion No. 08-14

Dear [names redacted]:

We are writing in response to your request for an advisory opinion regarding your substance abuse treatment center's use of motivational incentives to reward a patient's achievement of certain treatment-related goals. Specifically, you have inquired whether your use of motivational incentives in this context (the "MI Program") 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, or under the civil monetary penalty provision prohibiting inducements to beneficiaries, section 1128A(a)(5) 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 MI Program would not constitute grounds for the imposition of civil monetary penalties under section 1128A(a)(5) of the Act, and, while the MI Program 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] in connection with the MI Program 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).

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”) is a non-profit 501(c)(3) organization that provides outpatient treatment services for individuals with psychoactive substance abuse dependence. Many patients treated by the Requestor are Federal healthcare program beneficiaries, and Federal healthcare programs cover a considerable portion of their treatment costs.

A prospective patient presenting at the Requestor is screened and his or her substance abuse problems assessed. The Requestor’s clinicians then plan a course of treatment (the “Treatment Plan”) for a suitable candidate. Treatment Plans typically extend over several months and incorporate certain standard core elements, including weekly medication and counseling sessions and urine testing for biomarkers of recent substance abuse. The Requestor has certified that all Treatment Plans established for individual patients are first clinically determined to be medically necessary and appropriate. Before the Treatment Plan commences, clinicians inform the treatment candidate that his or her eventual success will depend on regular attendance at, and cooperation with, his or her Treatment Plan’s scheduled events.

According to the Requestor, some patients fail to make progress, or even deteriorate, after starting treatment. A patient’s inability to maintain regular attendance or to adequately cooperate with testing and counseling can undermine his or her Treatment Plan. In response, the Requestor’s clinicians may recommend the introduction of motivational incentives into the patient’s care. Motivational incentives might be introduced, among other reasons, in order to help a patient overcome difficulty with achieving abstinence, or maintaining attendance and participation in his or her Treatment Plan activities. The Requestor has certified that under the MI Program, it only introduces motivational incentives for substance abuse patients after a clinician’s determination that motivational incentives are clinically indicated for the individual.

The Department’s National Institute on Drug Abuse (“NIDA”) and the Substance Abuse and Mental Health Services Administration’s (“SAMHSA”) Center for Substance Abuse

Treatment promote the use of motivational incentives by substance abuse clinicians as a means to improve treatment outcomes for difficult substance abuse cases. NIDA sponsored research into implementation of motivational incentives in clinical practice that was conducted by its National Drug Abuse Treatment Clinical Trials Network. The Requestor, a part of this network, developed and refined its MI Program in connection with this research. NIDA and SAMHSA have jointly published training curricula and treatment planning materials for the therapeutic use of motivational incentives based on their research findings.¹ The Requestor has certified that the MI Program follows the same therapeutic guidelines as, and is operated in a manner consistent with, the NIDA and SAMHSA publications.²

Under the MI program, the motivational incentives awarded are gift certificates redeemable at certain grocery stores, food outlets, and gas stations, for items of about \$5 – \$10 value, or gift items and foods of similarly modest value. Motivational incentives never take the form of cash. A patient can only earn motivational incentives for a limited time, typically a period of between one and three months. The total motivational incentives awarded to an individual patient are not expected to exceed \$200.00 per month, and in most cases would be substantially less.

Clinicians give patients rewards for their achievement of specific treatment-related goals. Such goals can include, among other things, completion of a week or more of consistent attendance at planned events, active participation in counseling sessions, or the provision of a drug-free urine sample. The Requestor has certified that motivational incentives are only awarded to the patient once he or she has “earned” them through achievement of specific,

¹ In 2001, NIDA and SAMHSA’s Center for Substance Abuse Treatment developed their joint “Blending Initiative,” which seeks to move the application of important scientific findings, including those related to motivational incentives, into mainstream addiction treatment practice. See <http://www.nattc.org/aboutUs/blendingInitiativeNew.html>. The Blending Initiative makes available literature, bibliographic materials, and contact resources pertaining to motivational incentives therapy, among other subjects. See <http://www.nida.nih.gov/blending/PAMI.html>.

² The Requestor has also certified that the MI Program operates in a manner consistent with the larger body of clinical literature in the field of addiction treatment. Similar therapeutic arrangements have been described in clinical literature under terms such as: “contingency management,” “contingency reinforcement,” “low-cost reinforcement,” and “voucher-based reinforcement therapy.” The Requestor provided us a digest of relevant research materials accompanied by a three page bibliography. We express no opinion about these other programs or arrangements.

verifiable goals identified in the patient's Treatment Plan. The opportunity to obtain motivational incentives will only conclude, or be discontinued, as the result of a clinical determination that the rewards are not clinically indicated. Less than 25% of patients at the Requestor receive motivational incentives. Use of motivational incentives is not advertised by the Requestor, nor is their potential use discussed with new patients.

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 ("CMP") 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, for enforcement purposes, 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

Providing substance abuse patients with motivational incentives, such as gift certificates or other items of value, implicates both the CMP prohibiting beneficiary inducements³ and the anti-kickback statute. We are particularly concerned that addiction treatment centers might induce beneficiaries to obtain Federally payable items and services by offering them incentives for accomplishment of ostensible treatment goals that 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 decision-making process, resulting, for example, in overutilization, increased costs, or inappropriate medical choices. 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 by offering increasingly valuable goods or services, the incentive to offset the cost of these inducements by cheating 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 MI Program, if operated as certified by the Requestor, poses a low risk of fraud and abuse.

Importantly, the MI Program follows the therapeutic guidelines of, and is consistent with, the training curricula and treatment planning materials for motivational incentives jointly published by NIDA and SAMHSA. Requestor’s MI Program was developed and refined in connection with NIDA’s government-sponsored research into implementation of motivational incentives as a treatment option. In these circumstances, the motivational incentives are integral to the clinical care provided to a patient.

³ For at least some beneficiaries, the aggregate, annual value of the motivational incentives could exceed \$50, and thus the MI Program does not qualify as a “nominal” value program for purposes of the CMP.

Several additional factors in the MI Program minimize the risk of abuse. The individual motivational incentives never take the form of cash; are only of about \$5 – \$10 value; typically are not expected to exceed, in the aggregate, \$200 per month or last for more than three months;⁴ and are only introduced into a patient’s treatment on the basis of a clinical determination that such incentives are clinically indicated for the particular patient’s treatment under an established Treatment Plan. A patient must “earn” the motivational incentives through active, verifiable participation in core elements of his or her Treatment Plan, such as providing drug-free urine samples and attending sessions.

Other factors that contribute to our conclusion include the fact that use of motivational incentives by the Requestor is not advertised, nor is their potential use discussed with new patients. The MI Program is a treatment option available for difficult substance abuse cases, not a marketing or promotional effort. The population for whom the motivational incentives are determined to be clinically indicated is less than 25% of the Requestor’s patients.

Finally, this opinion is premised on the Requestor’s certifications that the Treatment Plans established for patients are medically necessary and appropriate, and that motivational incentives are only given to a patient after a clinician’s determination that motivational incentives are clinically indicated for effective treatment of the individual.

In sum, the above-listed conditions are consistent with the stated purpose of the MI Program to enable the Requestor to provide effective substance abuse treatment consistent with NIDA and SAMHSA guidelines for therapeutic care for difficult substance abuse cases. Taken as a whole, they also distinguish the MI Program 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 use of motivational incentives, in this particular context, would not be an impermissible inducement to obtain covered items and services under section 1128A(a)(5) of the Act. Although the MI Program may 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.

⁴ Were the motivational incentives awarded to individuals routinely to approach a total value of \$200.00 per month or be offered to patients for longer than three months, then this opinion would be without force and effect.

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that the MI Program would not constitute grounds for the imposition of civil monetary penalties under section 1128A(a)(5) of the Act, and, while the MI Program 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] in connection with the MI Program 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).

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 MI Program, 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 MI Program 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 MI Program 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