



*[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:** August 7, 2009

**Posted:** August 14, 2009

[Name and address redacted]

**Re: OIG Advisory Opinion No. 09-12**

Ladies and Gentlemen:

We are writing in response to your request for an advisory opinion regarding a proposal for a government entity to subsidize copayments for outpatient prescription drugs owed by certain financially needy Medicare Part D enrollees (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 the [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 the [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**

The [name redacted] (the “Requestor”) is a political subdivision operating under [State code citation redacted]. It consists of 18 members appointed by county commissioners, the [State agency redacted], and the [State agency redacted]. The duties of the Requestor are defined by State law. It functions as the planning agency for alcohol, drug addiction, and mental health services for the counties in its service district. It must assess needs for mental health and drug or alcohol treatment within the service district, set priorities and plan for the operation of necessary programs. The resulting plans must be approved by the State agency responsible for mental health or alcohol/drug abuse services, as appropriate.

The plans are implemented through contracts between the Requestor and individual providers for the provision of public mental health and drug and alcohol treatment services. The Requestor is prohibited by State law from providing any direct service or from administering or directing the daily operation of providers except in emergency situations.

Individual providers under contract with the Requestor are independent corporations (“Mental Health Centers” or “Centers”) that have been certified to provide services by the [State agency redacted] or the [State agency redacted]. Not every provider of mental health services within the jurisdiction of the Requestor has a contract with the Requestor; however, all that have been certified by the appropriate State entity are eligible to apply for such a contract. Funding for these services comes from a combination of Federal and State subsidies and local property taxes. The Requestor purchases services for approximately 5,000 residents, of whom 1,100 are considered to be severely mentally disabled. This

means that they have at least one diagnosis of a major mental illness and often have a history of multiple psychiatric hospitalizations.

Residents who receive services ordinarily are required to contribute to their costs on a sliding scale, according to income. This sliding scale does not apply to services that are reimbursable by Medicare or Medicaid, however. Medicaid pays the entire allowable cost for its beneficiaries. Medicare beneficiaries owe copayments, but the Mental Health Centers may choose to waive copayments, on the basis of financial need. See 42 C.F.R. § 1001.952(k). At the end of a fiscal year, the Requestor awards subsidies to the Mental Health Centers for the difference between the Centers' income from various sources, including Medicare, and their costs.<sup>1</sup>

The Mental Health Centers that contract with the Requestor do not dispense medication, except where a Center receives samples from pharmaceutical companies or medication from the "Central Pharmacy." The Central Pharmacy is a State-operated and subsidized program that provides medication to individuals through providers designated by the Requestor or other similar boards in other localities. Individuals without insurance or other resources are eligible to receive medication provided by the Central Pharmacy.

Individual patients who receive services pursuant to contracts between the Requestor and Mental Health Centers, and who receive prescriptions for medication from those Centers, fill the prescriptions in local pharmacies selected by the patients, unless the individual patient is in an in-patient unit or receives medication through the Central Pharmacy.

Some patients who are served pursuant to the Requestor's contracts with Mental Health Centers are eligible for Medicare Part D drug benefits. The Requestor has certified that sometimes these patients have difficulty obtaining these benefits, because the patient is unable to navigate the plan enrollment and selection process, or the patient is unable to afford the copayments for the drugs. A patient who fails to get needed medication may deteriorate and require in-patient care. In some cases, a patient who is eligible for Part D benefits, having failed to obtain them, may receive drugs provided by the Central Pharmacy, thus reducing the resources that would otherwise be available to uninsured patients.

The Requestor has established a procedure for screening patients who receive prescriptions for psychotropic medication from psychiatrists at its contractor providers. Each Mental Health Center under contract with the Requestor screens patients with prescriptions to determine if they are covered by insurance, including Medicare Part D. If a patient is eligible for Medicare Part D but has not enrolled, the Mental Health Center assists the patient to select and enroll in a Part D plan. The patient always has the option of paying for

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<sup>1</sup>The Requestor has certified that these subsidies have been approved by CMS.

the medication privately or through insurance without participating in the screening. Under the Proposed Arrangement, if a patient is eligible for Medicare Part D, the Mental Health Center would make an additional determination as to whether the individual is eligible, on the basis of financial need, for a Part D copayment subsidy from the Requestor. A patient would be eligible for a Part D copayment subsidy from the Requestor if he or she would be eligible, on the basis of income and if not a Medicare beneficiary, for subsidized services from the Mental Health Center. If a patient is determined to be eligible, the Mental Health Center would inform him or her that the Center would pay part or all of the copayment to the pharmacy of the patient's choice for medications covered under Part D.<sup>2</sup> The copayment subsidy would not be advertised.

When a Medicare beneficiary enrolled in Part D takes a prescription to be filled at a pharmacy, the pharmacy bills the beneficiary's Medicare drug plan for the cost of the prescription less the applicable copayment. Under the Proposed Arrangement, the pharmacy would, by pre-arrangement, bill the Mental Health Center for the copayment subsidy amount. Funds for the copayment subsidies would be provided by the Requestor to the Mental Health Centers. These funds could not be used for any other purpose by the Mental Health Centers; at the end of the fiscal year, any amounts not used for copayment subsidies would be returned to the Requestor. The subsidy payment from the Requestor is not contingent on a beneficiary's choice of any particular Part D plan.

## **II. LEGAL ANALYSIS**

### **A. Law**

Section 1128A(a)(5) of the Act 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

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<sup>2</sup>Financially needy Part D beneficiaries may be eligible for Medicare's own Low Income Subsidy program, by which they owe reduced copayments on their prescription drugs; however, even these Part D beneficiaries owe some copayment for each prescription, unless they are institutionalized or have reached catastrophic coverage. See 42 C.F.R. Part 423, Subpart P.

prohibited by the statute,” and 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).

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 first address whether the Proposed Arrangement violates the prohibition in Section 1128A(a)(5) against remuneration to a Federal health care program beneficiary that the donor knows or should know is likely to influence the beneficiary to choose a particular provider, practitioner, or supplier of items or services payable by Federal health care programs. Given the facts as certified by the Requestor, we conclude that the risk of such a violation is low. Here, the donor (the Requestor) would provide something of value (payment of the Part D copayment) that benefits the Federal health care program beneficiary. We conclude, however, that this remuneration is not likely to influence the beneficiary to choose any particular provider, practitioner, or supplier, for the combination of reasons discussed below.

First, the Requestor’s copayment subsidy would not be advertised, and the beneficiary would be screened for eligibility for the subsidy and informed of such eligibility by the Mental Health Center. At that time, the beneficiary would have selected the Mental Health

Center as a provider already and so would be unlikely to be influenced in this choice by the availability of the Part D subsidy.<sup>3</sup> Also, the subsidy is available on uniform terms to financially needy beneficiaries, regardless of which Mental Health Center the beneficiary chooses.

Second, while the provider may assist the beneficiary in enrolling in a Part D plan, the subsidy to be provided by the Requestor is not contingent upon the selection of any particular Part D plan.

Third, payment of the Requestor's copayment subsidy is not contingent upon the use of any particular pharmacy.

For the combination of these reasons, we conclude that the Proposed Arrangement is not likely to influence a beneficiary to choose a particular provider, practitioner, or supplier of items or services payable by Federal health care programs.

We note, in addition, that the Proposed Arrangement is part of a comprehensive regulatory scheme to care for the mental health needs of the residents of the counties served by the Requestor, a State agency. State law requires the Requestor to plan and make arrangements for items and services to meet these needs. Failure on the part of financially needy Medicare beneficiaries to obtain prescription drugs from pharmacies may result in additional costs to the Requestor and the State's taxpayers, which the Requestor believes can be avoided or reduced by the copayment subsidies. We are mindful that states and their agencies should have sufficient flexibility to carry out their responsibilities, using their limited resources, in an efficient and economical manner.

For the same reasons set forth above, we also conclude that we would not impose on the Requestor administrative sanctions under the anti-kickback statute, in connection with the Proposed Arrangement.

### **III. CONCLUSION**

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<sup>3</sup> In other circumstances, we might be concerned about the possibility of beneficiaries being influenced to choose a Mental Health Center by word-of-mouth transmission of information about the subsidy, which is only available to patients of the Centers. In the Proposed Arrangement, however, the population to whom the copayment subsidy would be available is limited to a relatively small group—the fraction of 5000 residents served by the Requestor who are low-income Medicare beneficiaries receiving prescriptions for psychotropic drugs—spread over several counties. We therefore conclude that word-of-mouth transmission of information about the subsidy is unlikely to influence a beneficiary's choice of a Mental Health Center as a provider.

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 sanctions under the civil monetary penalty provision prohibiting inducements to beneficiaries, 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 the [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 the [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 the [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 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,

/Lewis Morris/

Lewis Morris  
Chief Counsel to the Inspector General