



DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201



[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: July 20, 2015

Posted: July 28, 2015

[Names and addresses redacted]

Re: OIG Advisory Opinion No. 15-10

Dear [Names redacted]:

We are writing in response to your request for an advisory opinion regarding a hospital system's proposal to lease non-clinician employees and to provide operational and management services to a related psychiatric hospital for an amount equal to the hospital system's fully loaded costs (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, 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, although 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] and [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 for an advisory opinion or supplemental submissions.

This opinion may not be relied on by any persons other than [name redacted] and [name 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.

I. FACTUAL BACKGROUND

[Name redacted] (the “System”) is a non-profit health system in [state redacted] that owns multiple hospitals and other health care providers. The System and [name redacted] (the “Foundation”),¹ a non-profit corporation, are the sole members of the [name redacted], a non-profit psychiatric hospital (the “Center”), which is part of the System’s integrated health network. The System and the Center (the “Requestors”) are possible sources of referrals to each other. Medicare reimburses the Center under the inpatient psychiatric facility prospective payment system, and the Center and certain components of the System file cost reports with the Centers for Medicare & Medicaid Services (“CMS”).

The System and the Center are parties to a Master Services Agreement and an Employee Lease Agreement pursuant to which the System: (1) leases non-clinician employees to the Center for an amount equal to the System’s fully loaded costs (i.e., salary plus benefits and overhead expense) plus a two percent administrative fee, and (2) provides certain operational and management services to the Center in exchange for a fee equal to the System’s fully loaded costs to furnish those services plus a two percent administrative fee (the “Existing Arrangement”).² The Proposed Arrangement would be the same as the Existing Arrangement, except that the Center would pay only the System’s fully loaded

¹ The Foundation is a tax-exempt charitable organization operated by [name redacted] and [name redacted]. [Name redacted] and [name redacted] are the sole trustees, officers, and directors of the Foundation. No physician or other health care provider is a member, director, officer, or trustee of, or otherwise affiliated with, the Foundation.

² We have not been asked to opine, and we express no opinion, regarding the Existing Arrangement.

costs for the leased employees and purchased services, without any markup or administrative fee.

The Requestors certified that the services of the leased employees and the operational and management services cannot be obtained elsewhere at an aggregate cost lower than the cost under the Proposed Arrangement. According to the Requestors, the purpose of both the Existing and Proposed Arrangements is to integrate the Center into the System and to achieve cost efficiencies by eliminating duplicative administrative positions and functions. The Requestors anticipate that the Proposed Arrangement would decrease the Center’s labor and operational costs, which ultimately may result in reduced costs to Federal health care programs. The Requestors certified that all leased non-clinician personnel are the System’s bona fide employees.³

The Requestors certified that the remuneration that the Center would pay to the System during the term of the Proposed Arrangement would not vary based on the volume or value of referrals or other business generated between the parties. The aggregate compensation cannot be set in advance, however, because the System’s costs and the Center’s personnel, operational, and management needs may change during the term. In addition, according to the Requestors, the fully loaded costs charged to the Center for the leased employees and services (without the administrative fees) may be below fair market value in an arms-length transaction.

The Requestors assert that, because the Center and the System are related organizations, payments by the Center in excess of the fully loaded costs incurred by the System are not allowable costs to the Center. Applicable Medicare cost-reporting rules, set forth in 42 C.F.R. § 413.17 and the Provider Reimbursement Manual, CMS Publication 15-1 (the “Manual”) Chapter 10, state that the costs of services furnished to a provider by a related organization are includable in the “allowable cost” of the provider “at the cost to the related organization,” but such cost may not exceed the price of comparable services that could be purchased elsewhere. Costs for non-clinician employees and operational and management services are costs that typically would appear on a provider’s cost report as allowable costs.⁴ “Related” means that the provider—here, the Center—is, to a

³ All physicians on the Center and System medical staffs are bona fide employees of [name redacted] (the “Physician Group”), an entity that is not owned by the System or the Center. In addition to the Existing Arrangement, there exists a separate arrangement under which an entity controlled by the System leases clinician employees from the Physician Group, and then subleases those clinician employees to the Center. We have not been asked to opine, and we express no opinion, regarding this separate arrangement.

⁴ The Requestors certified that they would accurately reflect all costs under the Proposed Arrangement within their respective cost reports and would otherwise comply with applicable cost reporting rules and regulations. We note that the Manual, Chapter 10,

significant extent, associated or affiliated with, or has control of or is controlled by, the organization furnishing the services, facilities, or supplies. 42 C.F.R. § 413.17(b). “Control” exists if an organization has the power, directly or indirectly, to influence or direct significantly the actions or policies of an organization or institution. 42 C.F.R. § 413.17(b). Section 1000 of the Manual provides that the purpose of the related party principle is: (1) to avoid the payment of a profit factor to the provider through the related organization (whether related by common ownership or control), and (2) to avoid the payment of artificially inflated costs that may be generated from less than arms-length bargaining.

We consulted with CMS regarding the application of 42 C.F.R. § 413.17 and the related Manual provision to the Proposed Arrangement. According to CMS, based on the Requestors’ certifications, the related organization rules apply to the Center and the System under the Proposed Arrangement. Although these rules do not prevent the Center from paying the System the administrative fee under the Existing Arrangement, Medicare would not reimburse the Center for any amount in excess of the System’s costs.

II. LEGAL ANALYSIS

A. Law

The anti-kickback statute makes it a criminal offense to knowingly and willfully 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. See, e.g., United States v. Borrasi, 639 F.3d 774 (7th Cir. 2011); United States

Section 1005, states that a related organization is permitted to include in its costs “all reasonable costs, direct and indirect, incurred in the furnishing of services, facilities, and supplies to the provider.” That same provision goes on to state that “[t]he intent is to treat the costs incurred by the supplier as if they were incurred by the provider itself.” Id. In issuing this opinion, we rely on the Requestors’ certifications that the System’s fully loaded costs, including overhead, are reasonable and would be allowable under applicable cost reporting principles if incurred by the Center. If such costs would not be allowable, this opinion is without force and effect.

v. McClatchey, 217 F.3d 823 (10th Cir. 2000); United States v. Davis, 132 F.3d 1092 (5th Cir. 1998); United States v. Kats, 871 F.2d 105 (9th Cir. 1989); United States v. Greber, 760 F.2d 68 (3d Cir. 1985), 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.

The Department of Health and Human Services has promulgated safe harbor regulations that define practices that are not subject to the anti-kickback statute because such practices would be unlikely to result in fraud or abuse. See 42 C.F.R. § 1001.952. The safe harbors set forth specific conditions that, if met, assure entities involved of not being prosecuted or sanctioned for the arrangement qualifying for the safe harbor. However, safe harbor protection is afforded only to those arrangements that precisely meet all of the conditions set forth in the safe harbor.

The safe harbor for personal services and management contracts, 42 C.F.R. § 1001.952(d), potentially applies to the Proposed Arrangement. Two conditions of this safe harbor are that the aggregate compensation to be paid to the agent over the term of the agreement must be set in advance and the compensation must be consistent with fair market value in arms-length transactions. 42 C.F.R. § 1001.952(d)(5).

B. Analysis

The Proposed Arrangement would implicate the anti-kickback statute because the System would charge the Center, a possible source of referrals, a rate which may be below fair market value for leased employees and operational and management services, and that below-fair-market-value rate may be remuneration in exchange for the Center's referrals of Federal health care program business to the System. The Proposed Arrangement cannot meet the requirements of the personal services and management contracts safe harbor, because the compensation may be less than fair market value, and it cannot be set in advance. The fact that the Proposed Arrangement does not fit in a safe harbor does not end the inquiry, however. We must examine the totality of the facts and circumstances of the Proposed Arrangement to determine the risk posed under these particular circumstances. We conclude that it has a low risk of fraud and abuse for the following reasons.

First, the parties structured the Proposed Arrangement in a manner they believe is supported by applicable Medicare cost reporting rules for related parties. Under these principles, because the parties are related organizations, payments to the System in excess

of the System’s costs for employees and services would not be allowable costs for the Center.⁵ The Requestors propose for the Center to pay the System only its allowable costs.

Second, the Requestors certified that the Proposed Arrangement would achieve (1) cost efficiencies between two related entities that are part of an integrated health system and (2) a reduction in the Center’s labor and operational costs. While these cost savings are not directly passed through to Federal health care programs, they are included in cost reports for use, along with other data, to update reimbursement amounts under Medicare’s inpatient psychiatric facility prospective payment system. Moreover, cost savings that are not derived from stinting on patient care or other abuses are generally beneficial to a health care system as a whole, which indirectly benefits Federal health care programs.

Third, we recognize that, because the Requestors are related parties, they may have existing incentives to refer to each other. However, there is no evidence suggesting that the Proposed Arrangement would increase these incentives, or that any purpose of the Proposed Arrangement is to induce referrals.

These facts, combined with the absence of other indicia of remuneration to induce referrals, lead us to conclude that the Proposed Arrangement is sufficiently low risk under the anti-kickback statute.

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that, although 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] and [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 for an advisory opinion or supplemental submissions.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

⁵ See 42 C.F.R. § 413.17 and Section 1005 of the Manual.

- This advisory opinion is issued only to [name redacted] and [name 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 by a person or entity other than [name redacted] and [name redacted] to prove that the person or entity did not violate the provisions of sections 1128, 1128A, or 1128B of the Act or any other law.
- 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 (or that provision's application to the Medicaid program at section 1903(s) 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] and [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] and [name redacted] with respect to any action that is part of the Proposed Arrangement 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,

/Gregory E. Demske/

Gregory E. Demske
Chief Counsel to the Inspector General