



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: October 3, 2016

Posted: October 11, 2016

[Name and address redacted]

Re: OIG Advisory Opinion No. 16-10

Dear [Name redacted]:

We are writing in response to your request for an advisory opinion regarding a local health care district's proposal to cooperate with another district to jointly fund the cost of a transportation coordinator to educate patients about local transportation options and subsidize certain forms of transportation for patients with financial need (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, 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] 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. In addition, the OIG would not impose administrative sanctions on [name redacted] under section 1128A(a)(5) 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], 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

A. Background

[Name redacted] (“District A”), the requestor of this opinion, is a public agency (specifically, a local health care district), formed under [state redacted] law. District A cited to provisions of the [state code redacted] regarding the establishment of local health care districts and the rights and responsibilities of such districts. Pertinently, local health care districts have the power to “establish, maintain, and operate, or provide assistance in the operation of, one or more health facilities or health services...at any location within or without the district for the benefit of the district and the people served by the district.” [Citation redacted]. Local health care districts are statutorily permitted to levy a tax, but the primary source of revenue for District A is compensation for the provision of clinical care at its facilities.

District A owns and operates [name redacted] (the “Hospital”) and [name redacted] (“Clinic 1”), which are located across the street from each other within District A’s boundaries. District A also owns and operates [name redacted] (“Clinic 2”), which is located approximately 25 miles south of the Hospital within another local health care district, [name redacted] (“District B,” and collectively with District A, “Districts”). The Hospital, Clinic 1, and Clinic 2 are assets of District A that operate under the same taxpayer identification number and are considered a single entity. District B does not own or operate any health

care facilities, but provides some health and wellness programs and services (e.g., flu clinics, outreach and education services) to benefit its residents. Both Districts are located in [county, state redacted], (the “County”), which District A certified is underserved in terms of hospitals, physicians, and mid-level providers. Clinic 2 is located in a medically underserved area, and all of the District A facilities are in Primary Care Health Professional Shortage Areas, as designated by the U.S. Department of Health and Human Services’ Health Resources and Services Administration.

B. The Proposed Arrangement

District A, in conjunction with District B, seeks to establish a transportation program to help patients, including Federal health care program beneficiaries, who receive services at Clinic 2 get back and forth from the Hospital. According to District A, charities, private contractors, and public entities operate various types of local and regional transportation programs, ranging from public buses traveling on a set route, to curb-to-curb transportation available to certain demographic groups (e.g., seniors) or patients with certain medical needs (e.g., dialysis patients, pediatric oncology patients, or physically disabled individuals). District A certified it would hire a transportation coordinator who would build a database of available transportation services, their associated eligibility criteria and costs, and any special programs that might offset those costs. District A would pay for equipment and supply costs required by the transportation coordinator, and District B would pay for office space and related utilities for the transportation coordinator.

District A certified that the Proposed Arrangement would not be advertised, but would be offered to all patients at Clinic 2 who may need follow-up care at the Hospital. If a patient were interested in learning about transportation options, then Clinic 2 staff would put the patient in touch with the transportation coordinator, who would help the patient complete a transportation needs assessment form. This form would include information about the patient, certain of the patient’s health care providers or suppliers, frequency of appointments, and the nature of the patient’s transportation needs, all of which would help the transportation coordinator identify which transportation services would best address the needs of the patient.

The transportation coordinator would provide travel instruction programs to train patients on using the local transportation system. The programs would be tailored to each patient’s needs and could involve simply an overview of local transportation options, specific instructions on how to get from one location to another, or mobility device training for patients who must board and exit vehicles using wheelchairs or walkers. The transportation coordinator also would obtain transit maps and schedules to distribute to patients and staff

at Clinic 2 and encourage staff to share information about these transportation options with patients.

Under the Proposed Arrangement, District A and District B also would subsidize transportation costs with travel vouchers for patients who cannot afford to pay for transportation. Patients seeking such assistance would work with the transportation coordinator to complete the financial assistance portion of the transportation needs assessment form. Only transportation operated by the County's Transportation Commission would be eligible for subsidies, which would include a fixed bus route and some types of curb-to-curb transportation that would be subject to certain eligibility criteria (e.g., available only to seniors or persons who are disabled within the meaning of the Americans with Disabilities Act). The transportation coordinator would approve or deny financial assistance requests in accordance with a matrix that is approved annually and is based on a certain percentage multiple of the current year's published Federal poverty guidelines that take into account household income and size. If a patient's request for assistance is approved, the approval term would be for three months, after which an applicant would need to submit a new request. District A stated that transportation fees that would be covered for approved subsidy applicants would range from \$.50 to \$2.50 per trip. District A and District B would split evenly the cost of subsidies for District B residents, and District A would fund the subsidies for any other patient of Clinic 2 who qualifies for transportation assistance.

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 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.

Section 1128A(a)(5) of the Act (the “Beneficiary Inducements CMP”) provides for the imposition of civil monetary penalties against any person who offers or transfers remuneration 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 has interpreted “nominal in value” to mean “no more than \$10 per item, or \$50 in the aggregate on an annual basis.” 65 Fed. Reg. 24,400, 24,410—11 (Apr. 26, 2000) (preamble to the final rule on Civil Money Penalties).

B. Analysis

The Proposed Arrangement would combine the respective contributions of District A and District B to establish a program that educates patients about existing transportation options, availability, and cost, and subsidizes some of that transportation cost for patients who cannot afford it. The Proposed Arrangement would involve two possible streams of remuneration: remuneration between District A and District B, and remuneration from the Districts to patients, including Federal health care program beneficiaries. We analyze each in turn.

Remuneration Between District A and District B

Each District would pay for certain expenses related to the salary and overhead costs for District A to employ a transportation coordinator, and the Districts would split the cost of transportation subsidies for financially needy District B residents. Our analysis must consider whether there is remuneration under the anti-kickback statute between Districts A

and B, whether any such remuneration would flow to a referral source, and the degree of risk that any such remuneration would be offered or given to induce or reward referrals.

First, we conclude that remuneration does flow between the Districts. Both District A and District B contribute to the cost of the transportation coordinator and for transportation subsidies that would benefit both Districts. These joint contributions would fund services that help the Districts further each of their missions as local health districts under state law.

Next, we conclude that District B could be a referral source for District A. District B operates outreach and educational programs that benefit its residents, but no health care facilities. Because District A operates a clinic within District B's region, it is possible that District B could refer or recommend services offered by District A. In contrast, District B does not operate any health care facilities and offers very few health care services, so District A is not a referral source for District B.

Accordingly, we turn our focus to District A's remuneration to District B, which benefits District B's residents who are District A's patients. Although District A would be contributing funds that benefit District B's residents, as discussed further below, those residents are also District A's patients by virtue of being patients of Clinic 2, which is an asset of District A. By selecting Clinic 2, the patients are essentially selecting District A, which also owns the Hospital, as their health care provider. The remuneration under the Proposed Arrangement would be tied to transportation between District A's Clinic 2 and the Hospital for follow-up care for District A's patients. Importantly, the Districts are public agencies empowered both to provide health care directly and to provide assistance in operating facilities or services. The Proposed Arrangement would operate consistently with that mission. Thus, the risk is low that the contributions of remuneration would be for the purpose of inducing or rewarding referrals by District B to District A.

Remuneration to Patients

Under the Proposed Arrangement, the Districts potentially would provide remuneration to Federal health care beneficiaries in two forms: (i) the transportation coordinator's education services concerning transportation options; and (ii) a subsidy for public transportation for financially needy patients of Clinic 2. We do not consider the educational component of the Proposed Arrangement, wherein the transportation coordinator would explain transportation options that might be available to the patient, to be remuneration.

However, the subsidies for financially needy beneficiaries would be remuneration under both the Federal anti-kickback statute and the Beneficiary Inducements CMP.¹

Section 1128A(i)(6)(f) of the Act provides that the Beneficiary Inducements CMP does not apply to “remuneration which promotes access to care and poses a low risk of harm to patients and Federal health care programs (as defined in section 1128B(f) and designated by the Secretary under regulations).” No regulations have been finalized pursuant to this provision.² Similarly, we proposed a safe harbor³ to the Federal anti-kickback statute to protect local transportation arrangements that meet certain criteria, but that rule has not yet been finalized. Thus we must undertake an analysis of the facts and circumstances to determine whether the Proposed Arrangement presents a sufficiently low risk of fraud and abuse and, for the following reasons, we conclude that the risk is sufficiently low.

First, the Districts that would offer the transportation subsidies are public entities, supported in part by taxpayer funds. District B’s subsidies would help its residents access health care services that are not available within its own boundaries. Although District A’s subsidies would not be limited to its own residents, all patients to whom the subsidies would be offered already would be patients of District A.

Second, the subsidies would be relatively modest at \$.50 to \$2.50 per trip and, as explained above, would be available only to patients who have a financial need, and only for certain transportation operated by the County’s Transportation Commission.

Third, the Proposed Arrangement would not be advertised or marketed, nor would it be targeted to particular patients or beneficiaries. While the educational aspect of the Proposed Arrangement (which is not remuneration to beneficiaries) would be available to all patients of Clinic 2 (who are already patients of District A) who may need to access services available at the Hospital, only those patients who demonstrate financial need would receive subsidies. Financial need criteria would be set forth in a matrix to be used by the

¹ We have stated in past guidance that items or services of nominal value (\$10 per instance, up to \$50 per year) do not constitute remuneration under the Beneficiary Inducements CMP. See Special Advisory Bulletin: Offering Gifts and Other Inducements to Beneficiaries, August 2002, available at:

<http://oig.hhs.gov/fraud/docs/alertsandbulletins/SABGiftsandInducements.pdf>. Here, the subsidies could exceed those amounts. In any case, the nominal value concept does not apply to the anti-kickback statute analysis.

² Regulations have been proposed, but not finalized, to interpret this exception and incorporate it into our regulations. See 79 Fed. Reg. 59717 (Oct. 3, 2014).

³ See id.

transportation coordinator and would be based on a multiple of the Federal poverty guidelines. Further, the subsidies only would cover limited forms of public transportation to and from the Hospital. Thus the risk that the Proposed Arrangement would be used to recruit patients is low.

For the combination of reasons described above, we conclude that the Proposed Arrangement presents a low risk of fraud and abuse under the anti-kickback statute. For the same reasons, in an exercise of our discretion, we would not impose sanctions under the Beneficiary Inducements CMP as a result of the Proposed Arrangement.

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 the OIG would 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 Proposed Arrangement. In addition, the OIG would not impose administrative sanctions on [name redacted] under section 1128A(a)(5) of the Act in connection with the 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:

- 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 by a person or entity other than [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] 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] 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