



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 14, 2015

Posted: October 21, 2015

[Names and addresses redacted]

Re: OIG Advisory Opinion No. 15-13

Ladies and Gentlemen:

We are writing in response to your request for an advisory opinion about a plan to offer free van shuttle service to certain medical facilities in an integrated health system (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], [name redacted] or [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], [name redacted] or [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], [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 an integrated health system offering health care services to residents of certain areas of rural [state name redacted]. [Name redacted] (the “Medical Center”) is described in the request as the largest regional referral tertiary/quaternary care medical center in northeastern [state name redacted].¹ It is licensed for 505 beds and located in [town name redacted] (the “Town”). [Name redacted] (“Community Hospital A”) is a 72-bed hospital located about ten miles away from the Medical Center. [Name redacted] (the “Clinic”) is a 501(c)(3) corporation that operates a multispecialty group practice with more than 1,000 physicians. The Medical Center, Community Hospital A and the Clinic (collectively, the “Requestors”) are components of the System and jointly requested this advisory opinion. Two other System components affected by the Proposed Arrangement are [name redacted] (“Community Hospital B”), a 55-bed hospital located approximately 16 miles away from the Medical Center, and the [name redacted] ambulatory surgical center (the “ASC”), located just over two miles from the Medical Center.

All physicians practicing at the Medical Center, Community Hospital A and the ASC are bona fide System employees. Some physicians working at Community Hospital B are bona fide System employees, while others are private practice physicians (the “Private Physicians”) who are not compensated by the System. Services provided by the Private

¹ The Medical Center’s clinical departments include medicine, surgery, pediatrics, family practice, obstetrics and gynecology, laboratory medicine, psychiatry and radiology, with a total of 86 subspecialties. It also maintains an active Level I Regional Trauma Center with additional qualifications in pediatrics.

Physicians are billed by their local practices. Three Private Physicians lease office space from the System on Community Hospital B's campus.²

The Requestors certified that the Town and all other communities served by the facilities described in this opinion have limited access to public transportation. For instance, there is no public transportation to the Medical Center or Community Hospital A. Although two private taxi services operate locally, they do so only for limited hours. The Requestors submitted documentation suggesting that the lack of affordable transportation in the region served by the System constitutes a barrier to health care access for residents.

Under the Proposed Arrangement, the System would offer a free van shuttle service between certain medical facilities run by the System, as well as a stop at a "drop-off and pick-up" location in the center of the Town. There would be two separate shuttle circuits. One would run approximately 18 miles, with stops at the Medical Center, Community Hospital B, the ASC and the drop-off and pick-up location in the Town. The second would run approximately 10 miles, with stops at the Medical Center and Community Hospital A. The vans would complete each circuit ten times daily, from 8 a.m. to 6 p.m., Monday through Thursday. The purpose of the Proposed Arrangement is to provide transportation for patients to be seen at any of the System facilities³ along the two routes, and for individuals who accompany patients to those visits. Individuals would be transported without regard for their health insurance status or their ability to pay for medical services.

The Requestors certified that the vans would not be equipped or operated as ambulances.⁴ While on board the vans, patients would not be transported on stretchers, nor would they be furnished any medications. No physicians, nurses or paramedic personnel would travel in the vans to treat or monitor patients.

The Requestors certified that no marketing of health care items or services would occur during the course of the transportation.⁵ The Requestors further certified that the van drivers would not market to patients while driving or at other times. The Requestors

² The Requestors have not requested an opinion, and we express no opinion regarding, Community Hospital B's office space lease arrangements with the three Private Physicians.

³ The vans would not transport patients to or from any Private Physicians' offices located off Community Hospital B's campus.

⁴ The vans would be equipped to carry patients in wheelchairs.

⁵ The Requestors stated that signage would mark the vans as belonging to the System.

indicated that the drivers would be System employees with salaries and benefits⁶ and that neither the drivers nor anyone else arranging the transportation would be paid on a per-patient or per-person-transported basis.

The Requestors certified that the shuttle service would not be advertised to the general public or publicized on any System website. The availability of the shuttle service would be communicated only to people who are already patients of System physicians and, at Community Hospital B, to patients of the Private Physicians. Written notice of the availability of the shuttle service would be posted in patient waiting areas in certain System facilities. In addition, System personnel at the facilities along the two routes, including receptionists, nurses, physicians and social workers, might inform patients of the shuttle service.

The Requestors certified that the availability of the shuttle service to patients would not be determined in a manner related to the past or anticipated volume or value of Federal health care program business for the System or any of its components. The Requestors also certified that the System would bear the costs of the shuttle service and would not shift the burden of these costs onto Medicare, a State health care program, other payers or individuals.

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

⁶ The Requestors noted that, in the future, they may use an outside contractor to furnish van drivers. The Requestors certified that any contracted drivers would not be paid on a per-patient or per-person-transported basis.

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 “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 the CMP 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). In addition, in the Conference Committee report accompanying the enactment of the CMP, Congress expressed its intent that, with respect to allowable remuneration, the statute should not preclude the provision of items and services of nominal value, including complimentary local transportation services. (See H. R. Conf. Rep. No. 104-736, at 255 (1996)).

B. Analysis

The Proposed Arrangement potentially implicates the anti-kickback statute and the CMP, because the transportation could be offered to induce Federal health care program beneficiaries to obtain federally payable items or services from the Requestors, Community Hospital B, the ASC or the System generally.⁷ The value of the transportation could exceed

⁷ In October 2014, the OIG published a proposed rule that would establish a new safe harbor under the anti-kickback statute to protect free or discounted local transportation services provided to Federal health care program beneficiaries, if certain conditions are met. See Medicare and State Health Care Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements and Gainsharing, 79 Fed. Reg. 59,717, 59,732 (Oct. 3, 2014). Any practice permissible under the anti-kickback statute through the regulatory safe harbor,

\$10 per transport or \$50 on an annual basis, and therefore could be of more than nominal value. However, for the combination of reasons set out below, we conclude that the Proposed Arrangement presents a minimal risk of fraud and abuse under the anti-kickback statute or the CMP.

First, the Requestors certified that the availability of the shuttle service to patients would not be determined in a manner related to the past or anticipated volume or value of Federal health care program business for the System or any of its components. Although the vans would provide transportation only to certain system facilities, these facilities offer a broad range of services. Availability would not be conditioned on patients' use of specific items or services from the System or their selection of any other particular provider, practitioner or supplier. Individuals would be transported without regard for their health insurance status or their ability to pay for medical services. The Proposed Arrangement is therefore distinguishable from suspect arrangements in which free transportation is selectively offered to patients based on their diagnoses, conditions, treatments or type of insurance coverage.

Second, the free transportation made available under the Proposed Arrangement would not include air, luxury or ambulance-level transportation. These types of transportation are more valuable to the patient and therefore more likely to be an improper inducement.

Third, the van drivers would not be paid on a per-person or per-patient-transported basis. The OIG has stated its long-standing concern with drivers offering Federal health care program beneficiaries free transportation to health care providers, and receiving compensation from those providers on a per-person or per-patient-transported basis. The compensation under the Proposed Arrangement does not involve these problematic pay structures.

Fourth, the Proposed Arrangement would be offered only locally, with the longest circuit being approximately 18 miles. The Proposed Arrangement is therefore distinguishable from arrangements in which facilities offer free transportation to beneficiaries residing outside the facilities' primary service areas in order to leapfrog competitor facilities and recruit beneficiaries from beyond the offerors' primary service areas.

Fifth, the Requestors would not market or advertise the Proposed Arrangement to the general public. We have noted that when a free transportation arrangement is marketed or

if finalized, would also be excepted from the CMP. See section 1128A(i)(6)(B) of the Act. As of the date this opinion is issued, the proposed local transportation safe harbor has not been finalized. Because this proposed rule has not been finalized (and thus cannot be relied upon as a safe harbor), we do not consider whether the Proposed Arrangement meets each of its proposed requirements. Instead, we consider whether the Proposed Arrangement, taken as a whole, poses more than a minimal risk of fraud and abuse.

advertised, there is greater risk that the arrangement is being offered as an inducement for referrals. In addition, the Requestors certified that no marketing of health care items and services to patients would occur during the course of the transportation or be undertaken at any other time by the drivers.⁸ Marketing health care items and services to patients in connection with free transportation can induce overutilization and medically unnecessary services.

Sixth, the System would bear the costs of the shuttle service under the Proposed Arrangement. The System would not shift the burden of these costs onto Medicare, a State health care program, other payers, or individuals.

Seventh, the Proposed Arrangement would be unlikely to subsidize the practices of the Private Physicians. The routes would serve only the Medical Center, Community Hospital A, Community Hospital B, the ASC and the drop-off and pick-up location in the Town. Although three Private Physicians have offices on Community Hospital B's campus, any benefits derived from the Proposed Arrangement by these physicians would likely be incidental. It does not appear that a purpose of the Proposed Arrangement is to induce referrals to System facilities by these physicians, or that the effect of the Proposed Arrangement would be to influence patients to choose the Private Physicians over other practitioners.

Finally, the Requestors certified that the availability of local public transportation is limited and no public transportation is available to the Medical Center or Community Hospital B. The shuttle service would offer patients alternative means of transport to the System facilities on the two routes, thus facilitating access to health care services.

For the combination of these reasons, we would not subject the Requestors to sanctions for the Proposed Arrangement under the anti-kickback statute or the CMP.

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], [name redacted] or [name redacted] under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to

⁸ We note that the vans would bear signage indicating they belong to the System. While signage can be a type of marketing, we believe that the identifying signage would be important for passenger safety and would be unlikely to unduly influence beneficiaries to receive Federally payable items and services from the Requestors or other particular providers, practitioners or suppliers.

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], [name redacted] or [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.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [name redacted], [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], [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], [name redacted] or [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], [name redacted] or [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