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: March 3, 2017

Posted: March 10, 2017

[Name and address redacted]

Re: OIG Advisory Opinion No. 17-01

Dear [name redacted]:

We are writing in response to your request for an advisory opinion regarding a hospital system's proposal to provide free or reduced-cost lodging and meals to certain financially needy patients (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) 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. 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

[Name redacted] ("Requestor") owns and operates an academic medical center consisting of four hospitals and multiple hospital-based clinics in [state redacted] (the "State"). One of those hospitals, [name redacted] (the "Hospital"), operates a Level I trauma center and provides state-of-the-art treatment to patients, including patients who reside in rural and medically underserved areas located in the central and eastern parts of the State. Requestor certified that the Hospital provides specialized services such as organ transplants and advanced outpatient cancer treatment and has approximately 36,000 inpatient and outpatient discharges annually.

Under the Proposed Arrangement, Requestor would help certain patients who reside in rural or underserved areas, some of whom might be Federal health care program beneficiaries, access services they may not be able to obtain locally by offering them free or reduced-cost hotel lodging and Hospital cafeteria meals. Specifically, Requestor would provide qualifying patients free or reduced-cost lodging for a single room at the [name redacted] (the "Hotel")[1] for one night before and up to two nights after treatment at the Hospital[2] and free or reduced-cost Hospital cafeteria meals, not to exceed a value of $15 per overnight stay. Requestor estimates that approximately 100 to 200 of its patients would qualify annually for the Proposed Arrangement.

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[1] The Hotel is a privately owned, modest hotel located approximately two miles from the Hospital.

[2] It is possible that a patient's family member could stay with the patient in the Hotel room; however, no lodging would be provided under the Proposed Arrangement solely to family members of patients, nor would the Hospital provide lodging at the Hotel to a patient's family member during the patient's admission to the Hospital.

To qualify for free or reduced-cost lodging and meals under the Proposed Arrangement, the patient must meet all of the following criteria ("Eligible Patient"):

(A) the patient resides ninety (90) or more miles from the Hospital and lives in either:

(i) a medically underserved area of the State as designated by the Secretary of Health and Human Services under section 330(b)(3) of the Public Health Service Act;[3] or

(ii) a health professional shortage area of the State, as defined in section 332 of the Public Health Service Act;[4]

(B) the patient has a household income that does not exceed 500% of the Federal poverty level and otherwise meets Requestor's financial need criteria, as set forth in Requestor's written policy; and

(C) the patient meets one of the following qualifying circumstances:

(i) for free or reduced-cost lodging and meals prior to treatment at the Hospital, the patient must be required to be present at the Hospital for evaluation before 10:00 a.m.; or

(ii) for free or reduced-cost lodging and meals following receipt of treatment at the Hospital, the patient must have no need for on-site care at the Hospital and:

(a) must have a follow-up appointment at the Hospital within 48 hours; or

(b) must return to the Hospital for surgery within 48 hours.

Requestor would not limit the number of times an Eligible Patient could receive free or reduced-cost lodging and meals under the Proposed Arrangement. Eligible Patients would not receive cash, cash equivalents, or any other payment. Requestor would pay the Hotel directly for lodging, and would provide Hospital cafeteria meals, up to $15 per overnight stay, solely to Eligible Patients.

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[3] 42 U.S.C. § 254b.

[4] Id. § 254e.

Hospital staff would identify Eligible Patients after they have been scheduled for treatment at the Hospital.[5] Requestor certified that Hospital staff would not consider insurance status when determining a patient's eligibility for the Proposed Arrangement. Hospital staff would determine the amount of assistance an Eligible Patient could receive for each overnight stay using a financial need-based sliding scale established by Requestor under its written financial assistance policies. Requestor certified that the current nightly price per room at the Hotel is $70. Under the Proposed Arrangement, Eligible Patients with total annual household incomes between the Federal poverty level percentages set forth below would receive the following discounts:

Total Annual Household Income as a Percentage of Federal Poverty Level	Lodging Discount	Amount Owed By Eligible Patient for Overnight Stay
0-138%	100%	$0
139-300%	80%	$14
301-400%	60%	$28
401-500%	40%	$42

Hospital administrators would approve the funds the Hospital would use for the Proposed Arrangement and would audit and monitor the Proposed Arrangement under the Hospital's compliance program policies and procedures. Requestor certified that it would not advertise or market the Proposed Arrangement to patients. Requestor also certified that it would not shift costs of the Proposed Arrangement to any Federal health care program or report any costs related to the Proposed Arrangement on any of Requestor's or the Hospital's cost reports or claims.

Requestor certified that neither Requestor nor the Hospital would condition eligibility for the Proposed Arrangement on the receipt of any particular item or service provided by the Hospital. Additionally, Requestor certified that no remuneration would be provided by Requestor or Hospital to any clinician to encourage him or her to refer Eligible Patients to the Hospital.

[5] Social workers on the Hospital's staff would determine whether an Eligible Patient requires lodging for one or more overnight stays in accordance with the Hospital's written policy. For example, an Eligible Patient could receive free or reduced-cost lodging for two nights to attend a follow-up appointment that occurs 48 hours after his or her treatment.

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 the Beneficiary Inducements CMP as including "transfers of items or services for free or for other than fair market value." Section 1128A(i)(6)(F) of the Act provides that, for purposes of the Beneficiary Inducements CMP, the term "remuneration" 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)" (the "Promotes Access to Care Exception"). We have interpreted this provision to apply to:

> [i]tems or services that improve a beneficiary's ability to obtain items and services payable by Medicare or Medicaid, and pose a low risk of harm to Medicare and Medicaid beneficiaries and the Medicare and Medicaid programs by — (i) [b]eing unlikely to interfere with, or skew, clinical decision making; (ii) [b]eing unlikely to increase costs to Federal health care programs or beneficiaries through overutilization or inappropriate utilization; and (iii) [n]ot raising patient safety or quality-of-care concerns[.]

42 C.F.R. § 1003.110 (2017) (defining "remuneration").

B. Analysis

Under the Proposed Arrangement, Requestor would provide remuneration to Eligible Patients, some of whom may be Federal health care program beneficiaries, in the form of free or reduced-cost Hotel lodging and Hospital cafeteria meals. The Proposed Arrangement implicates both the anti-kickback statute and the Beneficiary Inducements CMP, because the lodging and meals could induce a beneficiary to select the Hospital as his or her provider for federally reimbursable inpatient or outpatient services. While we would be concerned if Requestor proposed to offer luxury accommodations or expensive restaurant meals, the Proposed Arrangement would not involve these types of incentives. For the combination of reasons set forth below, we conclude that the Proposed Arrangement would not constitute grounds for sanctions under the Beneficiary Inducements CMP because the lodging and meals provided under the Proposed Arrangement would satisfy the requirements of the Promotes Access to Care Exception. In addition, we would not subject Requestor to administrative sanctions under the anti-kickback statute in connection with the free or reduced-cost lodging and meals it would provide to Federal health care program beneficiaries under the Proposed Arrangement.

Our analysis of the Proposed Arrangement under the Promotes Access to Care Exception is divided into two parts. First, we must examine whether the remuneration offered under the Proposed Arrangement improves a beneficiary's ability to obtain items and services payable by Medicare or Medicaid. Second, we must examine whether the remuneration provided under the Proposed Arrangement poses a low risk of harm to Medicare and Medicaid beneficiaries and the Medicare and Medicaid programs. We analyze each factor in turn.

1. Promotes Access to Care

As we stated in the preamble to OIG's final rule interpreting the Promotes Access to Care Exception:

> We recognize that there are socioeconomic, educational, geographic, mobility, or other barriers that could prevent patients from getting necessary care (including preventive care) or from following through with a treatment plan. Our interpretation of items or services that "promote access to care" encompasses giving patients the tools they need to remove those barriers.

81 Fed. Reg. 88388, 88393 (Dec. 7, 2016). For the following reasons, we believe that the lodging and meals[6] would promote access to care, meaning they would improve a beneficiary's ability to obtain items and services payable by Medicare or Medicaid.[7]

The lodging and meals would both remove certain socioeconomic and geographic barriers that could prevent Eligible Patients from getting necessary Hospital services, and facilitate Eligible Patients' attendance at treatment appointments to obtain medically necessary care. Access to lodging near the Hospital the night before treatment would remove potential geographic or mobility barriers for Eligible Patients by enabling them to attend early morning treatments or evaluations required prior to treatment. Given that travel may be painful or exhausting after treatment, post-treatment lodging would make follow-up care more accessible for Eligible Patients by eliminating round-trip travel of at least 180 miles to and from the Hospital to receive treatment. We also conclude that free or reduced-cost meals would reduce economic barriers to Eligible Patients receiving care at the Hospital by ensuring they can afford Hospital cafeteria meals before, during, or after treatment. The combination of free or reduced-cost lodging and meals offered under the Proposed Arrangement therefore would promote a beneficiary's access to care.

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[6] To be excepted from the Beneficiary Inducements CMP, remuneration under the Promotes Access to Care Exception must be in the form of items or services. We consider both the lodging and the meals to be items and services that fit within this definition, as the Hospital provides the items or services directly or via its designated vendor.

[7] Because the Hospital determines patient eligibility regardless of patient insurance status, the proposal also could increase access to medically necessary services for uninsured patients.

2. Low Risk of Harm

To meet the Promotes Access to Care Exception's requirement that the items or services pose a low risk of harm to Medicare and Medicaid beneficiaries and the Medicare and Medicaid programs, the lodging and meals offered under the Proposed Arrangement must: (i) be unlikely to interfere with, or skew, clinical decision making; (ii) be unlikely to increase costs to Federal health care programs or beneficiaries through overutilization or inappropriate utilization; and (iii) not raise patient safety or quality-of-care concerns. For the following reasons, we conclude that the remuneration Requestor would provide under the Proposed Arrangement would meet these elements and therefore satisfy the conditions of this prong of the Promotes Access to Care Exception.

First, the Proposed Arrangement is unlikely to interfere with clinical decision-making, both because Requestor would not condition eligibility for the Proposed Arrangement on the receipt of any particular service provided by the Hospital and because neither Requestor nor the Hospital would provide remuneration to any clinician to encourage him or her to refer Eligible Patients to the Hospital.

Second, the Proposed Arrangement is unlikely to increase costs to Federal health care programs, because Requestor certified that it would neither shift any of the Proposed Arrangement's costs to any Federal health care program nor report any of the Proposed Arrangement's costs on Requestor's or the Hospital's cost reports or claims. Additionally, the fact that the Hospital would identify Eligible Patients only after they have scheduled services at the Hospital and would not advertise or market the Proposed Arrangement to patients makes it unlikely that the Proposed Arrangement will lead to overutilization or inappropriate utilization. Moreover, only a small fraction of the Hospital's patients would receive lodging and meals under the Proposed Arrangement, which also makes it unlikely that its purpose is to facilitate medically unnecessary or inappropriate care. Rather, the purpose of the Proposed Arrangement appears to be to facilitate access to care at the hospital of the patient's choice and to reduce risks (including the risk of missed appointments) inherent in long-distance travel immediately before and after a hospital treatment.

Finally, the Proposed Arrangement would not raise patient safety or quality-of-care concerns. Nothing in the Proposed Arrangement appears to encourage Eligible Patients to seek out unnecessary or poor quality care. To the contrary, the Proposed Arrangement would remove logistical and financial obstacles for Eligible Patients to obtain necessary treatment at the Hospital. For example, access to follow-up care could promote patient safety by preventing and detecting post-treatment health conditions.

For the combination of reasons described above, we conclude that the free or reduced-cost lodging and meals the Hospital would provide under the Proposed Arrangement would satisfy the requirements of the Promotes Access to Care Exception and would not

constitute remuneration under the Beneficiary Inducements CMP. The Promotes Access to Care Exception to the Beneficiary Inducements CMP does not apply to the anti-kickback statute. Although the lodging and meals would constitute remuneration provided to Federal health care beneficiaries under the anti-kickback statute, for the same reasons described above, we also conclude that we would not subject Requestor to administrative sanctions under the anti-kickback statute in connection with the Proposed Arrangement.

III. CONCLUSION

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) 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] 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:

- 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