



[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: January 3, 2011

Posted: January 10, 2011

[Names and addresses redacted]

Re: OIG Advisory Opinion No. 11-01

Ladies and Gentlemen:

We are writing in response to your request for an advisory opinion regarding your plan for your network of pediatric charity hospitals to: (1) begin billing third-party payers, including Federal health care programs, for services rendered, and waive all cost-sharing amounts without regard to your patients' financial need; (2) adopt a new financial need-based policy of providing lodging assistance, in limited circumstances, to patients, including Federal health care program beneficiaries, and their families; and (3) adopt a new financial need-based policy of providing transportation assistance, in limited circumstances, to patients, including Federal health care program beneficiaries, and their families. Collectively, these three provisions are referred to herein as the "Proposed Arrangements." Specifically, you have inquired whether the Proposed Arrangements 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 the Proposed Arrangements 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 that the Office of Inspector General (“OIG”) would not impose administrative sanctions on [names 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 Arrangements. In addition, the OIG would not impose administrative sanctions on [names redacted] under section 1128A(a)(5) of the Act in connection with the Proposed Arrangements. This opinion is limited to the Proposed Arrangements 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 [names 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

A. The Requestors’ Hospital Network

[Name redacted] (the “Network Parent”) and [name redacted], its wholly owned subsidiary, (collectively, the “Requestors”) are nonprofit, tax-exempt corporations with a long history of providing free, charitable, pediatric care for certain catastrophic and intractable injuries and medical conditions.

The Requestors provided the following information regarding their history. The first hospital in the Requestors’ network opened to provide free, charitable orthopedic care for children during the first quarter of the 20th century. In the decades since, the hospital network emerged and expanded across the United States, and greatly increased the scale and the scope of its activities. Since the mid-1960s, for example, the hospital network has invested in clinical research projects, through which it has been linked with advances in orthopedic and burn care and, more broadly, improved outcomes for pediatric patients.

The Requestors currently own and operate a network of [number redacted] U.S.-based specialty hospitals (each a “Hospital,” and collectively, the “Hospitals”), which provide

care to children with orthopedic disorders from congenital abnormalities, injuries, or musculoskeletal disease; spinal cord injuries; burns; and cleft lip and palate. Any child with these injuries or conditions is eligible for care if, at the time of his or her initial application, he or she was under 18 years of age¹ and a reasonable possibility existed that he or she could be medically helped. Children are referred to the Hospitals through screening clinics, primary care providers, or by word-of-mouth. More than 90 percent of initial referrals made to the Hospitals are made by physicians who have no affiliation with the Requestors. All of the network hospitals have been dedicated to the same underlying charitable mission, adhering to the same policies for providing free, charitable care to very sick and injured children.

According to the Requestors, their Hospitals possess special expertise, particularly with regard to pediatric burn and spinal cord injury care. The Hospitals are unable to accommodate all the patients who request and are qualified to receive services. For virtually every hospital in the network, the wait for services is at least seven months.

Many young patients qualified for care from the Hospitals are unable to obtain comparable care where their families reside. Consequently, the families of children undergoing the sorts of treatments in which the Hospitals specialize often incur burdensome lodging and transportation costs.

The Requestors and the hospital network were established by [name redacted] (the “Fraternity”) a separately incorporated, nonprofit, tax-exempt, fraternal organization. Although legally independent, they remain closely tied to the Fraternity through common directors and governing board members, and the Fraternity’s continuing support of, and involvement with, the Requestors and the Hospitals.

B. The Hospitals’ Medical Staffs

For the most part, physicians who treat patients at the Hospitals are employed by the Network Parent and are members of the Hospitals’ medical staffs. Of the 182 physicians employed on the active medical staffs of the Hospitals, 133 are employed on a full-time basis. The 49 remaining physician employees work only part-time for the Hospitals. The Network Parent maintains arrangements with 100 independent contractor physicians on the active medical staffs. In addition, several hundred consulting physicians (mainly specialists in areas such as anesthesia, plastic surgery and radiology) provide independent contractor services to the Hospitals.

¹ [Citation to Network Parent’s regulations redacted.]

Hospital compensation for employed physicians is fixed, and does not, directly or indirectly, take into account or vary based on the volume or value of services the physicians provide or order.² Although compensation systems for independent contractors vary from Hospital to Hospital, the Requestors have certified that none of the systems for payment of independent contractor physicians (e.g., hourly, per clinic visit, and per day payments) are based on the number of patients seen.³ The methodology for determining payments to independent contractors is set in advance and their compensation does not take into account the volume or value of referrals.⁴ Less than four percent of the physicians with whom the Requestors have employment or contractual relationships have made an initial referral to the Hospitals.

C. The Insurance-Only Billing Policy

Historically, the Hospitals did not seek or accept payment from patients, their families, insurers, health plans, other third party payers, or the government. On the Requestors' receipt of a favorable OIG advisory opinion in this matter, they would direct the Hospitals to begin billing both public and private third-party payers, including Medicare, Medicaid, and Tricare, the Federal health care program which covers the families of members of the U.S. military, while not billing patients or their families for cost-sharing amounts (the "Insurance-Only Billing Policy"). Under the new policy, the Hospitals would continue to treat uninsured patients free of charge. The criteria for Hospital admission would not change, and the Requestors have certified that, as in the past, insurance coverage would not be a factor in deciding who would be offered care.

The Requestors have certified that under the Insurance-Only Billing Policy, the waiver of cost-sharing amounts would not be a part of price reduction agreements with third party payers. The Hospitals would not report unbilled cost-sharing amounts as bad debt on Medicare or Medicaid cost reports, nor would these costs be shifted to other third-party payers in the form of higher charges or rates. The Hospitals would disclose their policy to waive all cost-sharing amounts to all non-governmental third-party payers.

² The Requestors indicate that the factors used in determining salaries include salary survey data, the number of years the physician has been certified in a specialty, job performance, research activity, administrative duties, and publishing of scholarly articles.

³ No opinion has been sought, and we express no opinion, regarding the Requestors' or the Hospitals' arrangements with the employed or independent contractor physicians.

⁴ When independent contractor physicians render services to the Hospitals' patients outside of the Hospitals and insurance is available, these physicians historically have billed third-party payers.

The Requestors regard the change from free charitable care to the Insurance-Only Billing Policy to be needed to address the severe financial challenges resulting from the combined effects of significant recent losses from their endowment fund, declining membership in the Fraternity, and rising medical costs. The additional revenue obtained from third-party payers would help to close the budget deficit and preserve their endowment fund. The Requestors have certified that, if they do not implement the Insurance-Only Billing Policy, they fear that financial conditions might force them to close down some of the Hospitals.

Virtually all of the Federal health care program beneficiaries treated at the hospitals are children under the age of 18 who are eligible for Medicaid and are not subject to co-pays or deductibles.⁵ The Requestors estimate that the annual dollar amount of waivers of Medicaid co-payments under the Insurance-Only Billing Policy would be less than \$27,000. The Requestors report that at any given time during 2009, only one patient in the entire hospital network was Medicare-eligible, and they indicate that this represents a typical total. The Requestors estimate that approximately .61 percent of their patients are eligible for Tricare.

The Requestors have certified that they would not advertise or market the Insurance-Only Billing Policy. The Insurance-Only Billing Policy would be discussed with patients after they were admitted for care.

D. The Lodging Assistance Program

On receipt of a favorable OIG advisory opinion in this matter, the Requestors would adopt a new policy to aid patients and families to obtain lodging accommodations (the “Lodging Assistance Program”). The Lodging Assistance Program would assist the families of inpatients, as well as outpatients and their families.

⁵ While the Act generally permits states to impose “nominal” cost-sharing requirements on Medicaid beneficiaries, no cost-sharing amounts are allowed for individuals under age 18. See sections 1916(a)(2)(A) and (b)(2)(A) of the Act (42 U.S.C. § 1396o); 42 C.F.R. § 447.53(b)(1) (2010). The Act permits states to exercise several options concerning cost-sharing amounts. In some states, the restriction on cost-sharing could extend to age 21. See id. The relevant rules are contained in the Medicaid state plan for the state in which the Medicaid recipient resides. See 42 C.F.R. § 435.403 (2010).

1. Aid for Families of Inpatients

Some Hospitals have on-site housing available to parents or guardians of Hospital patients. Under the Lodging Assistance Program, if the patient or his or her family is in financial need, Hospitals may cover the costs of on-site lodging for persons accompanying an inpatient, or pay the costs of housing them in nearby commercial lodging. Patients' families would be considered in financial need if their annual household income were determined to be below 400 percent of the Federal Poverty Level. Lodging assistance would only be provided when the Hospital has funds available for this purpose and in the context of one or more of the following circumstances:

- (i) the inpatient's physical condition is such that the immediate presence of the parents or legal guardian is medically necessary at times other than regular visiting hours;
- (ii) the inpatient's emotional condition is such that it is medically necessary to have the immediate presence of parents or a legal guardian at times other than regular visiting hours;
- (iii) the inpatient has a recent spinal cord injury or burn injury; or
- (iv) the limited periods of time when instruction is being given to parents or a legal guardian as to the care to be furnished by the family to the inpatient after his or her discharge.

2. Aid for Outpatients and Their Families

A Hospital would provide overnight accommodations of limited duration for an outpatient and persons accompanying an outpatient when the Hospital has funds available for this purpose and such expenditures are approved. The patient or the patient's family member must be in financial need, as defined above, and the lodging must be necessary:

- (i) to allow a patient to be discharged and to complete his or her initial postoperative rehabilitation in an ambulatory setting as an outpatient;
- (ii) to allow a patient to complete all preoperative processing, testing and evaluations prior to being admitted as an inpatient or accepted and processed for ambulatory surgery;
- (iii) to allow a patient to be evaluated, tested and treated in an ambulatory setting as an outpatient; or

(iv) to allow a Hospital to react appropriately to a patient's management situation beyond its control (e.g., a patient is stranded due to his or her clinic appointment being delayed beyond the time of scheduled commercial flights or bus rides).

Under the Lodging Assistance Program, only a small number of patients and families would be granted assistance. Approximately 4.8% of total patients served by the Hospitals received similar lodging aid from Hospital budgets in the recent past and these numbers are unlikely to change significantly in the future. Aid recipients would only be helped on a first-come, first-served basis.

Help under the Lodging Assistance Program would be offered after the patient has already selected a network Hospital and has been accepted. The Requestors have certified that under the Proposed Arrangements they would not advertise or market their Lodging Assistance Program.

The Requestors have certified that under the Lodging Assistance Program, neither they nor the Hospitals would claim any of the costs of these additional services, directly or indirectly on any report, or claim or otherwise shift such costs to Medicare or Medicaid. The Requestors would not offer any discounts for covered services in connection with, or otherwise promote Hospital programs in connection with the Lodging Assistance Program.

E. The Transportation Assistance Program

On receipt of a favorable OIG advisory opinion in this matter, the Requestors would adopt a policy of providing patients, their family members, or guardians, with free local and long-distance transportation in the form of paid tickets for commercial air or land conveyance, in limited circumstances (the "Transportation Assistance Program").

Hospitals would pay the travel fares for patients and their families out of their own budgets. The Transportation Assistance Program would only be available to patients with financial need, as defined above. The following additional criteria would also be considered in determining whether to approve such assistance:

- (i) the exigent circumstances of a case, and
- (ii) the availability of hospital funds.

The Requestors certify that the costs associated with the provision of free transportation would not be claimed directly on any Federal health care program cost report or claim,

nor would they be otherwise shifted to any Federal health care programs. The Hospitals would not advertise or market the availability of any of these additional services.

Under the Transportation Assistance Program, aid would be granted to only a small number of patients and families. Approximately 3.4% of total patients served by the Hospitals received similar transportation aid from Hospital budgets in the recent past and this number is unlikely to change significantly in the future. Aid recipients would only be helped on a first-come, first-served basis. The Requestors would not offer any discounts for covered services, or otherwise promote Hospital programs in connection with the Transportation Assistance Program.

II. LEGAL ANALYSIS

A. Law

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. 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 “CMP”) 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. (This provision does not apply to Tricare.) 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 value to be no more than \$10 per item, or \$50 in the aggregate on an annual basis.” 65 Fed. Reg. 24400, 24410-24411 (Apr. 26, 2000) (preamble to the final rule on the CMP).

Section 6402(d)(2)(B) of the Patient Protection and Affordable Care Act (P.L. 111-148, 124 Stat. 119), as amended by the Health Care and Education Reconciliation Act of 2010 (P.L. 111–152, 124 Stat. 1029) (collectively, the “ACA”), amends the Act’s statutory definition of “remuneration” by adding a new exception as subsection (F), for “any other 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 relating to this provision have been promulgated.

B. Analysis

1. The Insurance-Only Billing Policy

The Insurance-Only Billing Policy might implicate the anti-kickback statute to the extent that it would constitute a waiver of Federal health care program cost-sharing amounts. Our concern about potentially abusive waivers of cost-sharing amounts under the anti-kickback statute and (for Medicare and Medicaid beneficiaries) the civil monetary penalty prohibition on inducements to beneficiaries is longstanding. We have previously stated that providers who routinely waive Medicare cost-sharing amounts for reasons unrelated to individualized, good faith assessments of financial hardship may be held liable under the anti-kickback statute. *See, e.g.,* Special Fraud Alert, 59 Fed. Reg. 65374 (Dec. 19, 1994). Such waivers may constitute prohibited remuneration to induce referrals under the anti-kickback statute, as well as a prohibited inducement to select a particular provider, practitioner, or supplier under section 1128A(a)(5) of the Act.

Notwithstanding these concerns, for the reasons discussed below, the OIG would not seek to impose administrative sanctions related to the commission of acts under the anti-kickback statute or for providing inducements for beneficiaries in connection with the Insurance-Only Billing Policy.

This determination rests in part on recognition that the Requestors' plan to routinely waive cost-sharing under the Insurance-Only Billing Policy represents a singular vestige of the Requestors' founding and continuing charitable care mission. Here, a policy of providing free care predates the Medicare and Medicaid program by decades and has at all times been applied uniformly to all patients. The Requestors' Hospitals have never charged patients or their families, insurers, government health care programs, or any other third-party payer for any of the care provided during their long history.

Because of a combination of diminution of the Requestors' ability to raise funds and increases in the cost of providing care, the Requestors must choose to either begin billing third-party payers for services or take actions that are counter to their mission, such as closing facilities. The Requestors view the Insurance-Only Billing Policy as an integral component of their continuing commitment to charitable care after the Hospitals become Medicare and Medicaid participating providers. The question of cost-sharing waivers would not be relevant to the Requestors, but for their desire to continue providing cost-free services to pediatric patients in need of the Hospitals' specialized care and the Requestors' need to seek alternate funding sources to continue their mission. This institutional history merits deference to the Insurance-Only Billing Policy that would be inappropriate for an identical proposal to provide routine cost-sharing waivers implemented by other institutions today.

Standing alone, institutional history would not protect an otherwise improper practice from sanctions under the anti-kickback statute or the beneficiary inducement provision. In this case, however, that history is joined with certain aspects of the Requestors' operations and relationships with physicians that, taken together, reduce the risk that the Insurance-Only Billing Policy would result in overutilization or unnecessary services. Given that typically, very few, if any, of Requestors' patients are Medicare-eligible,⁶ a very small percentage are Tricare-eligible, and Medicaid beneficiaries under 18 generally have no cost-sharing obligations, the Federal cost-sharing amounts waived would be

⁶ To the extent that the Insurance-Only Billing Policy would apply to inpatient Medicare Part A services, the policy would fit within the safe harbor for certain waivers of waiver of beneficiary coinsurance and deductible amounts at 42 C.F.R. § 1001.952(k) because: (1) the Hospitals would not claim any of the waived amounts as bad debt or otherwise shift the burden of the waiver to third parties; and (2) the cost-sharing waivers would not be made as part of any price reduction agreement with a third-party and would be made without regard to the reason for admission, the length of stay, or the DRG for which the claim for Medicare reimbursement is filed. Since the Insurance-Only Billing Policy as applied to Part A inpatient services is protected by a safe harbor under section 1128B(b) of the Act, it also qualifies for protection from section 1128A(a)(5) of the Act. As noted, however, the Hospital network typically serves only a single Medicare-eligible patient at a given time, therefore this safe harbor would likely have extremely limited applicability in the Requestors' situation.

insubstantial, with an estimated figure of less than \$27,000 of Medicaid co-pays waived annually by the entire Hospital network.

Within this context, the following factors and safeguards, in combination, sufficiently reduce the risk that the Insurance-Only Billing Policy would result in overutilization or unnecessary billing of services payable by Federal health care programs:

First, the highly specialized nature of the services offered at the Hospitals reduces the risk of unnecessary services. The Hospitals limit their care to severe pediatric illness, injury, and disability, which do not represent services that are typically susceptible to overutilization. Patients and their families would consequently be unlikely to self-refer to the Hospitals for unnecessary services.

Second, the Insurance-Only Billing Policy would be discussed with patients after they were already admitted for care. Patients who select one of the Requestors' Hospitals would more likely be influenced in their choice of provider by factors such as the Hospitals' unique specializations in pediatric orthopedic, spinal injury, burns, and cleft palate and lip care, and the Hospitals' reputation for treatment of catastrophic medical conditions in children.

Third, Hospital compensation for employed physicians is fixed, and does not, directly or indirectly, take into account or vary based on the volume or value of services the physicians provide or order. While compensation systems for independent contractors vary from Hospital to Hospital, the Requestors have certified that none of the systems for payment of independent contractor physicians (e.g., hourly, per clinic visit, and per day payments), are adjusted based on the number of patients seen. The methodology for determining payments to independent contractors is set in advance and their compensation does not take into account the volume or value of referrals. Thus, physicians on the Hospitals' staff have no financial incentive to order unnecessary care.

Fourth, the Requestors have certified that they would bear the costs of the forgone cost-sharing waivers and would not claim the waived amount as bad debt or otherwise shift the burden to the Medicare or Medicaid programs, other payers, or individuals.

Fifth, the Hospitals would offer the cost-sharing waivers to all patients, regardless of which facility in the network would perform treatment, or the nature of the individual patient's condition. The Insurance-Only Billing Policy could not be used as an inducement to draw patients to particular facilities in the network or to draw to the Hospitals only certain types of patients who receive services that draw lucrative third-party payments.

Sixth, the Requestors have certified that the cost-sharing waiver offered in conjunction with Hospitals' services would neither be advertised nor marketed.

Seventh, although we cannot determine a party's intent, we think it is implausible that the Requestors, already faced with more qualified patient applicants than they can accommodate, would waive the small aggregate cost-sharing amounts at issue here in order to generate additional referrals. Even after implementing the Insurance-Only Billing Policy, the Hospitals would need to rely on charitable donations and their endowment fund for much of their income.

Finally, we also take into account the public benefits obtained from the specialized care provided at the Hospitals in aiding very sick and injured children. Although we have not investigated the matter, based on the Requestors' statements, it appears that the Insurance-Only Billing Policy would permit the fullest possible preservation of those benefits.

For all of these reasons, we conclude that the OIG would not seek to impose administrative sanctions related to the commission of acts under the anti-kickback statute or for providing inducements for beneficiaries in connection with the Insurance-Only Billing Policy.

2. The Lodging and Transportation Assistance Programs

Under the Lodging Assistance Program and the Transportation Assistance Program (together, the "Programs"), the Requestors' Hospitals would provide free lodging and transportation for certain financially needy patients and their families. Many of the patients would be Medicaid beneficiaries. Thus, both proposed Programs implicate section 1128A(a)(5) of the Act. However, a recent amendment to section 1128A provides that the beneficiary inducement prohibition 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 promulgated pursuant to this provision. Nevertheless, we apply the general standards described in this provision to determine whether we would seek sanctions in connection with the Programs, or exercise our discretion to decline to do so.

Under the Lodging Assistance Program, aid would be offered to the families of inpatients only in the context of recent spinal cord or burn injuries; during hospital instruction of family members on the patient's particular home care needs; and in situations when the patient's condition requires family accompaniment. Aid would only be offered to outpatients and their families to enable the patient to complete initial postoperative

rehabilitation in an ambulatory setting; to allow a patient to complete all preoperative processing, testing and evaluations; to allow a patient to be evaluated, tested and treated in an ambulatory setting as an outpatient; or to allow a hospital to react appropriately to a patient's management situation beyond its control. Under the Transportation Assistance Program, the proffered transportation aid would reflect the exigent circumstances of the patient's case. For these reasons, we conclude that the Programs would promote access to care.

We also conclude that these Programs would pose a low risk of harm to Federal health care programs. Services would only be provided under the proposed Programs in the context of a financial need determination and when the Hospitals deem they are merited by the patient's medical situation. The services would not be advertised or marketed, and, in the case of the Lodging Assistance Program, the patient would be informed by Hospital staff of its availability after his or her acceptance for treatment. The Hospitals would not promote Hospital programs in connection with the Lodging Assistance Program or the Transportation Assistance Program. Although the Programs would only be available to patients of the Hospital, the Requestors would not condition eligibility for the Programs on the receipt of any particularly lucrative services. Finally, the costs related to the Programs would not appear on any cost report or claim, and would not be otherwise shifted to any Federal health care program.

For the combination of reasons listed above, we conclude that we would not subject the Requestors to administrative sanctions under section 1128A(a)(5) of the Act or the anti-kickback statute in connection with the remuneration provided to patients under the Lodging Assistance Program or the Transportation Assistance Program.

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that the Proposed Arrangements 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 that the OIG would not impose administrative sanctions on [names 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 Arrangements. In addition, the OIG would not impose administrative sanctions on [names redacted] under section 1128A(a)(5) of the Act in connection with the Proposed Arrangements. This opinion is limited to the Proposed Arrangements 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 [names 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 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 Arrangements, 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 Requestors with respect to any action that is part of the Proposed Arrangements 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 Arrangements 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 Requestors 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