We are writing in response to your request for an advisory opinion regarding an arrangement pursuant to which a medical center provides physician services to a county-owned women’s health clinic for an annual below-fair-market-value fee, along with inpatient hospital services for the county clinic’s primarily indigent and low-income, self-paying patients at no charge (the “Arrangement”). Specifically, you have inquired whether the Arrangement constitutes grounds for the imposition of sanctions under the exclusion authority at section 1128(b)(7) of the Social Security Act (the “Act”) or the civil monetary penalty provision at section 1128A(a)(7) of the Act, as those sections relate to the commission of acts described in section 1128B(b) of the Act.

You have certified that all of the information provided in your request, including all supplementary letters, 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 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 that the Office of Inspector General (“OIG”) will not impose administrative sanctions on [Entity X] 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 Arrangement, absent any undisclosed aggravating factors (including, but not limited to, overutilization or inappropriate higher costs to the federal health care programs). This opinion is limited to the Arrangement, 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 [Entity X], the requestor of this opinion, and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

1. FACTUAL BACKGROUND

[Entity X] (the “Medical Center”) and [county and state redacted] (the “County”) have entered into a two-year written agreement pursuant to which the Medical Center will be the exclusive provider of physician services at the [clinic name redacted] (the “County Clinic”), a clinic owned and operated by the County.

A. The Parties.

The County Clinic provides outpatient services, including family planning services, prenatal care, breast and cervical cancer services, and primary care, principally to low-income women. Services are provided by physicians or nurse practitioners. The physicians are independent contractors. All other personnel are County employees.

The Medical Center, a nonprofit, charitable corporation, owns and operates an acute care facility and various outpatient facilities. The Medical Center is the product of a merger of two hospitals: a public, County-owned hospital and a private hospital owned by a nonprofit, charitable corporation. As required by the merger, the Medical Center has a continuing commitment to provide care for indigent patients.

B. The Arrangement

In 2000, the County issued a request for proposals (“RFP”) to contract for the provision of physician and medical director services for the County Clinic in exchange for a fixed annual fee. In addition, the winning bidder would have to agree to provide physician coverage for any hospitalized patient of the County Clinic. The RFP complied with all relevant government contracting laws. The RFP elicited two responses, and the contract was awarded to the Medical Center.

The Medical Center offered to provide the requested services by moving its existing
The Medical Center has made the following certifications:

- The Medical Center physicians who provide services at the County Clinic will advise each patient in writing of the patient’s freedom to choose the facility at which the patient will receive inpatient hospital services and the physician who will provide physician services during the patient’s hospitalization.

- The Medical Center physicians who provide services at the County Clinic will not be restricted from referring any patient to, or otherwise generating any business for, any other entity of his or her choosing.

- All physicians providing services under the Arrangement, including all residents and all supervising physicians, are bona fide employees of the Medical Center in accordance with the Internal Revenue Service’s (“IRS’s”) definition of the term set forth at 26 U.S.C. § 3121(d)(2) and IRS interpretations of that provision as codified in its regulations and other interpretive sources.

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1The costs of the Medical Center’s existing residency program included employment of the residents; an agreement with four physicians from one of the Medical Center’s existing clinics to supervise the residents and provide medical director services; and the administrative costs of operating the residency program. The additional costs resulting from moving the residency program to the County Clinic included a fee payable to the medical director to perform medical director services at the County Clinic for at least one additional morning per week, plus a “cushion” for other costs not calculated or calculable.

2Whether an individual is a bona fide employee is a matter that is outside the scope of the advisory opinion process. See section 1128D(b)(3)(B) of the Act. Thus, for purposes of rendering this advisory opinion, we rely on the Medical Center’s certification that all physicians providing services under the Arrangement are bona fide employees of the Medical Center. If they are not bona fide employees, this opinion is without force and effect.
For all outpatient services at the County Clinic, the County bills, collects, and retains all fees, including all fees for physician services. The payor mix of the County Clinic is approximately as follows: 22% Medicaid, including Medicaid HMO; 9% the [Health Plan A]; 2% other insurance; 0.4% Medicare; and 66% self-paying patients. Most of the self-paying patients have incomes below 150% of the poverty level, and payment is on a sliding scale, based upon each patient’s income.

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.), 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

[Entity Y], which is partially sponsored by the Medical Center, owns and operates the [Health Plan A] (the “Health Plan”), a program that provides benefits for outpatient physician services, laboratory services, and pharmacy services rendered to under-insured and uninsured residents of the County. Funding for the Health Plan is derived from a combination of state funds, federal matching funds, and a transfer to the State of [state redacted] of disproportionate share adjustments afforded to the Medical Center and [Entity Z], the only other acute care facility within the service area. The Health Plan does not provide benefits for inpatient services.
care programs under section 1128(b)(7) of the Act.

B. Analysis

The Arrangement raises potential issues under the anti-kickback statute. In particular, the Medical Center may have offered a below-fair-market-value fee for physician services at the County Clinic in order to gain access to, or control over, referrals of federal health care program business -- in particular, inpatient obstetrical services payable by Medicaid. Therefore, we must carefully scrutinize the Arrangement in its entirety to determine whether, based upon a totality of the facts and circumstances presented, we would impose sanctions.

First, while the annual fee for the physician services may be less than the fair market value of purchasing the services from a staffing or other physician services company, the fee is not unreasonable in the circumstances presented. In particular, the fee is sufficient to cover the Medical Center’s additional costs, and the Arrangement gives the Medical Center an opportunity to strengthen its residency program by exposing residents to a broader range of medical conditions.

Second, while the Arrangement may give the Medical Center an opportunity to generate referrals of federal health care program patients to its hospital, any benefit derived from such referrals is offset, at least in part, by the Medical Center’s commitment to provide inpatient hospital and physician services for County Clinic patients (including the substantial numbers of indigent and low-income, self-paying patients), without regard to the patients’ ability to pay.

Third, the putative prohibited remuneration in the form of physician services (i.e., the County’s avoided costs for the physician coverage at the County Clinic) inures to the public, not private, benefit. One of the core evils addressed by kickback or bribery statutes, whether involving public or private business, is the abuse of a position of trust, such as the ability to award contracts or business on behalf of a principal for personal financial gain. Here, the public receives the financial benefit of the Arrangement by getting the best possible price for the County Clinic’s physician coverage. If the Arrangement were prohibited, the County would have to pay additional revenues for services provided to uninsured, under-insured, and indigent patients.

Fourth, the Arrangement will not have an adverse impact on competition. The County employed an open competitive bidding process consistent with the relevant government contracting laws. The contract is limited to a two-year period. Public policy favors open and legitimate price competition.

Fifth, in the circumstances presented, the Arrangement appears unlikely to result in
overutilization or increased costs to the federal health care programs. The primary inpatient hospital business generated by the County Clinic is labor and delivery services, and those admissions are reimbursed by the relevant state’s Medicaid program on a prospective fixed fee basis. The County Clinic’s Medicare business is, in the circumstances presented, negligible.

Accordingly, based on the totality of these factors and absent any undisclosed aggravating factors (including, but not limited to, overutilization or inappropriate higher costs to the federal health care programs), we conclude that we will not subject the Medical Center to administrative sanctions for violation of the anti-kickback statute in connection with the Arrangement.

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that the 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 that the OIG will not impose administrative sanctions on [Entity X] 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 Arrangement, absent any undisclosed aggravating factors (including, but not limited to, overutilization or inappropriate higher costs to the federal health care programs). This opinion is limited to the Arrangement, 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 [Entity X], 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 in any matter involving an entity or individual that is not a requestor of this opinion.

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*We express no opinion regarding the appropriate billing of any particular claims or the liability of any party under the False Claims Act or any other legal authorities for improper billing, claims submission, cost reporting, or related conduct.*
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 Arrangement, 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 Medical Center with respect to any action that is part of the 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 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 the Medical Center 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,

/s/

Lewis Morris
Chief Counsel to the Inspector General