We are writing in response to your request for an advisory opinion regarding a Training Affiliation Agreement between a military medical group and a public community hospital pursuant to which certain military physician specialists provide free services to patients at the hospital as part of a proficiency training program, and the hospital provides free clinical space and related facilities and supplies needed for the training program to the military medical group (the “Arrangement”). Specifically, you have inquired whether the Arrangement constitutes 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 Arrangement does not constitute grounds for the imposition of civil monetary penalties under section 1128A(a)(5) of the Act; and (ii) while 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, the Office of Inspector General (“OIG”) will 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 Arrangement. 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 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” or the “Hospital”) is a not-for-profit, public, community hospital owned by the [city and state redacted] and the [county redacted] Hospital District. The Hospital operates a 445-bed main campus facility, maintains a medical staff of over 275 physicians representing more than 40 specialties, and is a certified provider in the Medicare and Medicaid programs. The [name of Air Force medical group redacted] of [name redacted] Air Force Base (the “Air Force Medical Group”) operates the [name redacted] Medical Center (the “Air Force Medical Center”). The Air Force Medical Center is one of the largest medical centers in the Air Force and is also a teaching facility.

When Hurricane Katrina devastated the [state redacted] Gulf Coast in 2005, the Air Force Medical Center’s teaching mission was impaired. In addition, a shift in population demographics occurred in the region. For example, some military personnel were displaced, and there was an influx of younger, single service members. Although the medical and surgical residency programs have resumed at the Air Force Medical Center, one effect of the population shift is that the number of children and expectant mothers in the region is insufficient to sustain the pediatric and obstetrics/gynecology residency programs.

In an effort to ensure that the Air Force Medical Group’s specialists gain access to necessary proficiency training and maintain their clinical experience, the Air Force Medical Group entered into a Training Affiliation Agreement (the “Agreement”) with the
Hospital. The Hospital certified that the Agreement is consistent with and in furtherance of Air Force Instruction 41-108 (January 1, 2005), which sets forth standards and requirements for establishing Training Affiliation Agreements between Air Force medical treatment facilities and non-Federal healthcare institutions. According to Air Force requirements, such agreements should be entered into for proficiency training purposes, must be in the best interests of the Air Force, and must be approved by designated Air Force officials. The Hospital has certified that the Agreement is in compliance with these requirements. Pursuant to the Agreement, the Air Force Medical Group physicians remain full-time military personnel and receive full wages, salaries, and benefits from the Air Force Medical Group, but are members of the Hospital’s medical staff. Under the Arrangement, the physicians provide professional services to civilians, including Medicare and Medicaid beneficiaries, who are inpatients and outpatients of facilities operated by the Hospital. In addition to pediatrics and obstetrics/gynecology, the Agreement includes general surgery and internal medicine in the proficiency training program. The Air Force Medical Group physicians have access to the Hospital’s clinics, wards, intensive care units, and related equipment and facilities needed for training. The Air Force Medical Group physicians are covered under the Hospital’s professional liability policy. The Hospital also provides office, storage, dressing and locker room space, and all other administrative privileges typically enjoyed by the Hospital’s professional staff.

The Air Force Medical Group physicians do not bill any patients or third-party payors, including Medicare and Medicaid, for professional services provided under the Arrangement, but the Hospital bills patients and payors for any services the Hospital provides itself for the inpatients and outpatients treated by the physicians (e.g., facility fees, or any ancillary service fees). Although the Air Force Medical Group physicians may refer patients to the Hospital and to civilian physicians on the Hospital’s medical staff, they are not obligated to do so, and neither party tracks these types of referrals. The Hospital introduces the Air Force Medical Group physicians to other local physicians, but does not market the Air Force Medical Group physicians’ services. Similarly, the Hospital does not advertise that the Air Force Medical Group physicians do not bill for their services.

The Hospital has certified that there is a community need for the professional services the Air Force Medical Group physicians provide, and that many of the subspecialist services that the Air Force Medical Group provides are not otherwise available in the region. Further, the Agreement permits Air Force Medical Group physicians to participate in the program only to the extent that the Hospital has a need for that specialty. For example, because the Hospital already offers pediatric endocrinology services, no Air Force Medical Group pediatric endocrinologist would participate in the program. Because of the shortage of physician specialists in the region, the Hospital has certified that the
projected costs associated with implementing and continuing the Arrangement will be offset by the Hospital’s avoidance of the expenditures it would otherwise make to recruit needed specialists.

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). 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 F.R. 24400, 24410 – 24411 (April 26, 2000) (preamble to the final rule on the CMP).

B. Analysis

Under the Arrangement, the Hospital provides Air Force physicians in designated specialties with a setting for training that is not sufficiently available at the Air Force Medical Center, and the Air Force Medical Group physicians provide services to the Hospital’s patients. The Hospital and the Air Force Medical Group may be in a position to generate Federal health care program business for one another. Accordingly, we must examine the implications of the Arrangement under the anti-kickback statute. Moreover, because some Medicare or Medicaid patients might receive free professional services under the Arrangement, we must examine it in light of the CMP as well.

For a combination of the following reasons, we conclude that the Arrangement presents a minimal risk of fraud or abuse, and we will not seek to impose administrative sanctions.

1. The Training Affiliation Agreement

The risk that the Air Force Medical Group entered into the Training Affiliation Agreement and is providing free care to Hospital patients to induce Medicare and Medicaid referrals from the Hospital is low. The Air Force Medical Group physicians do not bill the Medicare or Medicaid programs, and patients covered by the military’s health care program (which is also a Federal health care program) are likely to seek care directly from a military medical group or facility rather than from the Hospital. Although the Hospital could be a referral source for the Air Force Medical Group in certain limited circumstances in which a patient covered by the military’s health care program receives treatment at the Hospital, it is likely that such a referral would be based on the patient’s insurance and would not be induced by the free services provided by the Air Force Medical Group physicians under the Arrangement.

Moreover, the Training Affiliation Agreement furthers a vital public interest in ensuring that members of the armed services and their families receive high quality medical care from well-trained specialists. The Air Force Medical Center is unable to provide the necessary training for its specialists because of damage and displacement caused by Hurricane Katrina.

The risk that the Training Affiliation Agreement is a vehicle to disguise payments from the Hospital to the Air Force Medical Group or its physicians for referrals to the Hospital is similarly low. Under the Arrangement, the Hospital provides the proficiency training
opportunity regardless of the volume or value of business generated by the Air Force Medical Group physicians and without regard to the payor status of any referrals. The Air Force Medical Group physicians are not required to make any referrals to the Hospital, and any referrals made are not tracked. Moreover, the Hospital has certified that the Arrangement is roughly equivalent in value to both the Hospital and the Air Force Medical Group. Although the Hospital does not charge the Air Force Medical Group for the use of Hospital facilities and equipment for training purposes, the Hospital’s costs are offset by savings on expenditures it would otherwise make to recruit needed specialists. Only Air Force Medical Group physicians who fill gaps in specialty service areas (i.e., those who do not compete with local physicians) are eligible to participate in the proficiency training program.

Finally, the Training Affiliation Agreement is based directly on a model agreement developed by the United States Air Force. Such agreements must benefit the United States Air Force and must be approved by Air Force officials. Further, because neither the Hospital nor the Air Force Medical Group physicians bill for professional services provided by the Air Force Medical Group’s physicians at the Hospital, the Medicare and Medicaid programs are not at risk for increased costs and likely realize a savings from the Arrangement.

2. Free Services for Medicare and Medicaid Beneficiaries

Under the Arrangement, Air Force Medical Group physicians provide free services to patients, including Medicare and Medicaid beneficiaries. In many circumstances, the provision of free services to Medicare and Medicaid beneficiaries raises concerns under the Act’s beneficiary inducement prohibitions. As set forth in the OIG August 2002 Special Advisory Bulletin: “[o]ffering valuable gifts to beneficiaries to influence their choice of a Medicare or Medicaid provider raises quality and cost concerns. Providers may have an economic incentive to offset the additional costs attributable to the giveaway by providing unnecessary services or by substituting cheaper or lower quality services.” Special Advisory Bulletin: Offering Gifts and Other Inducements to Beneficiaries, August 2002, available at: http://oig.hhs.gov/fraud/docs/alertsandbulletins/SABGiftsandInducements.pdf.

The free services offered under the Arrangement could be viewed as implicating the CMP or the anti-kickback statute in two ways. First, the Air Force Medical Group’s provision of free services to patients at the Hospital could influence those patients to order additional services from the Air Force Medical Group. However, because the Air Force Medical Group physicians do not bill the Medicare or Medicaid programs for any of the services that they provide, it follows that beneficiaries cannot be influenced to order services payable by these programs from the Air Force Medical Group. Second,
the free services could influence the Federal health care program beneficiaries who receive them to order additional services from the Hospital. Unlike the Air Force Medical Group physicians, the Hospital bills the Medicare and Medicaid programs. However, for the following reasons, we conclude that the free services provided by the Air Force Medical Group physicians are unlikely to influence beneficiaries to order services payable by the Medicare or Medicaid programs from the Hospital, and that section 1128A(a)(5) is therefore not implicated.

First, the Air Force Medical Group physicians’ free services are not advertised; most of the patients who will be treated by the Air Force Medical Group physicians will already have selected the Hospital as their provider before receiving the free services (e.g., by seeking treatment in one of the Hospital’s clinics). Second, no other free services are provided under the Arrangement; the Hospital bills patients who are treated by the Air Force Medical Group physicians for the copayments associated with any items or services that the Hospital provides (e.g., facility fees, or any ancillary service fees). Third, the Medicare and Medicaid beneficiaries who seek treatment at the Hospital do so with the expectation that they will pay their usual cost-sharing amounts; unexpected relief from cost-sharing for portions of their services seems unlikely to serve as an inducement to order other services from the Hospital. For these same reasons, we also conclude that the free professional services provided by the Air Force Medical Group physicians would not be subject to administrative sanctions arising in connection with the anti-kickback statute.

In sum, the Arrangement significantly benefits the military and our nation’s service members and their families, as well as patients in a community still recovering from the aftereffects of Hurricane Katrina. Through the Arrangement, the Air Force is able to provide its specialist physicians with access to proficiency training at a facility with a documented need for the services these specialists can provide. By allowing the military physicians to be members of its medical staff, the Hospital is able to provide needed services to patients in the local community. The patients in the community who receive services from the Air Force Medical Group specialists receive the services at no cost, regardless of whether the patients are uninsured, privately insured, or covered by Medicare or Medicaid. Finally, because the Air Force Medical Group physicians do not bill Medicare or Medicaid for any of their professional services, the programs also benefit from the Arrangement.

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) the Arrangement would not constitute grounds for the imposition of civil monetary penalties under section 1128A(a)(5) of the Act; and (ii)
while 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, the OIG will 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 Arrangement.

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 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 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 [name redacted] 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 [name redacted] 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