[*We redact certain identifying information and certain potentially privileged, confidential, or proprietary information associated with the individual or entity, unless otherwise approved by the requester*.]

Date Issued: July 2, 2001

Date Posted: July 3, 2001

[name and address redacted]

Re: [name redacted]
OIG Advisory Opinion No. 01-7

Dear [name redacted]:

We are writing in response to your request for an advisory opinion regarding Hospital A's practice of accepting reimbursement from third-party payors plus certain payments from Hospital A Foundation as payment in full, without regard to a patient's financial need (the "Insurance Only Billing Policy"). Specifically, you have inquired whether the application of the Insurance Only Billing Policy would constitute 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, or under the civil monetary penalty provision at section 1128A(a)(5) of the Act.

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, this opinion is without force and effect.

Based on the information provided in your request and supplemental submissions, and subject to certain conditions described below, we conclude that the Insurance Only Billing Policy could potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce or reward referrals were present, but that the Office of Inspector General ("OIG") would not impose administrative sanctions on Hospital A 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) or under section 1128A(a)(5) of the Act in connection with the Insurance Only Billing Policy as applied to (i) Part A inpatient hospital services and (ii) hospital or physician services provided to patients of the Full-Time Employed Physicians (as defined below).

This opinion may not be relied on by any person other than Hospital A and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

## I. FACTUAL BACKGROUND

### A. Hospital A

Originally founded as a tuberculosis sanatorium in 1922, Hospital A ("Hospital A") is now a 161-bed specialty teaching hospital and tertiary-care facility, providing highly specialized diagnoses and treatment of heart, lung, and vascular diseases in adults and congenital and acquired heart defects in children. Hospital A, a nonprofit, tax-exempt corporation, is licensed by the State of B as a "specialty hospital" and does not maintain an emergency room or certain other ancillary care services typically provided by licensed "general hospitals". Hospital A provides substantial amounts of free care, including charity care and care provided to uninsured patients who do not meet State B Department of Health's subsidy charity care guidelines.

The Hospital A Foundation (the "Foundation"), a not-for-profit foundation, was formed in 1974 to further the activities of Hospital A's extensive grassroots movement of volunteers and to conduct other fundraising and endowment efforts. The Foundation has approximately 70,000 volunteers organized into 280 chapters located in four regions of the nation. The Boards of Directors of Hospital A and the Foundation are closely aligned, and Hospital A and the Foundation issue a joint annual report. The Foundation provides Hospital A with substantial financial support through grants to cover operating losses.

### B. Hospital A's Insurance Only Billing Policy

Initially, Hospital A funded the entire cost of care for all patients entirely through private contributions. In the 1960s, when commercial insurance became generally available, Hospital A instituted a new policy, accepting reimbursement from third-party payors, including Medicare and Medicaid, and supplemental insurers, while never billing patients or their families for deductible or copayment amounts (collectively, "coinsurance"). Hospital A continued to treat, and does treat, uninsured patients free of charge.

The Insurance Only Billing Policy applies to all patients, without regard to the patient's financial need, the reason for the patient's admission or outpatient visit, the length of the patient's hospital stay, the patient's Diagnostic Related Group ("DRG") code or outpatient procedure, or the identity of the patient's treating physician. The Insurance Only Billing Policy is not part of a price reduction agreement between Hospital A and any third-party payor. Hospital A has certified that it does not claim amounts attributable to unbilled coinsurance as bad debt on its Medicare or Medicaid cost reports, and it does not shift these costs to other third-party payors in the form of higher rates or charges.

In conjunction with the Insurance Only Billing Policy, Hospital A submits a bill to the Foundation on a quarterly basis for an amount equal to the amount of waived coinsurance. The Foundation pays the bills as part of its charitable contribution to Hospital A.

### C. Hospital A's Relationships with Physicians

Historically, virtually all inpatient and outpatient services at Hospital A have been provided by a closed medical staff of approximately sixty full-time, salaried physicians who are members of Hospital A's active medical staff and who practice exclusively at and for Hospital A (the "Full-Time Employed Physicians").[1] Hospital A pays each Full-Time Employed Physician a salary that is fixed in advance annually and that does not vary directly or indirectly based on the volume or value of tests, procedures, items, or services ordered or performed by the physician.[2] Hospital A does not allow Full-Time Employed Physicians to accept patients for routine cardiology or pulmonary care at Hospital A, and no Full-Time Employed Physician has an outside medical practice. Referrals to Hospital A have typically come from unaffiliated physicians, who refer patients for specific procedures, such as open heart surgery or diagnostic or therapeutic cardiac catheterizations, and who resume care of their patients after the patients' post-procedure care at Hospital A is complete. The Insurance Only Billing Policy has been uniformly applied to all hospital and professional services rendered by Hospital A's Full-Time Employed Physicians.

Although the majority of hospital care is still provided by Full-Time Employed Physicians, Hospital A has recently begun to alter its traditional medical staff relationships by (i) permitting existing Full-Time Employed Physicians to enter into part-time employment arrangements with medical groups in private practice and (ii) extending hospital staff privileges to physicians in private practice in surrounding communities. For purposes of this advisory opinion, the physicians described in the preceding sentence are collectively defined as the "Private Practice Physicians".

For example, Hospital A has entered into an arrangement with a local cardiology group practice composed of nine general cardiologists (for purposes of this opinion, the "Community Cardiology Group"). Under the arrangement, the Community Cardiology Group has contracted with Hospital A for several of Hospital A's interventional cardiologists (formerly Full-Time Employed Physicians) to become part-time employees of the Community Cardiology Group. Thus, for

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[1]For purposes of the advisory opinion, the term "Full-Time Employed Physicians" does not include physicians employed part-time by Hospital A or physicians affiliated with private practices in the community; these physicians are included in the category of "Private Practice Physicians" (defined below). Hospital A contracts with a small number of specialists to provide services to its patients on an as-needed basis in areas, such as urology, neurology, and hematology/oncology, that are outside Hospital A's core heart, lung, and vascular disease specialties and for which Hospital A generally has a limited need. These contracted specialists generally do not refer patients to Hospital A and primarily provide consulting services. While the application of the Insurance Only Billing Policy to these courtesy staff is analytically different from its application to the full-time staff, for purposes of this advisory opinion, we will treat them as if they were Full-Time Employed Physicians.

[2]Physician salaries are based on standards relating to clinical activity (other than volume or value of items or services provided, ordered, or generated on behalf of Hospital A), on-call responsibilities, academic productivity, seniority, and administrative duties.

purposes of this advisory opinion, they have become Private Practice Physicians. As part-time employees of the Community Cardiology Group, these part-time employed physicians provide interventional cardiology and related evaluation and management services to the Community Cardiology Group's patients at Hospital A. The Community Cardiology Group bills third party payors and collects payment for such services. The Community Cardiology Group pays the part-time employed physicians a salary equal to a pro rata share of the physician's Hospital A salary.[3]

In addition to the arrangement with the Community Cardiology Group, Hospital A has granted medical staff privileges to five interventional cardiologists with private practices located in nearby counties. Hospital A's staff privileges permit these physicians to perform cardiac catheterizations and related procedures on their patients at Hospital A. Some, if not all, of these physicians regularly practice with other community-based physicians, including medical cardiologists. In addition, these physicians assist with the training of Hospital A's cardiac residents and fellows.

## II. HOSPITAL A'S WAIVER POLICY IMPLICATES FEDERAL LAW

### A. Applicable Law and Guidance

The anti-kickback statute makes it a criminal offense knowingly and wilfully to offer, pay, solicit, or receive any remuneration to induce referrals of items or services reimbursable by Federal health care programs. See section 1128B(b) of the Act. Where remuneration is paid purposefully to induce or reward referrals of items or services paid for by a Federal health care program, the anti-kickback statute is violated. By its terms, the statute ascribes 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, in cash or in-kind, directly or indirectly, covertly or overtly.

The statute has been interpreted to cover any arrangement where one purpose of the remuneration is 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 (3rd Cir.), cert. denied, 476 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.

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[3]In the two year period from 1998 to 1999, the arrangement generated more than $[number redacted] in additional net income to the Community Cardiology Group (i.e., the difference between its salary payments to the part-time employed physicians for services provided at Hospital A and the professional fees generated by such physicians and retained by the Community Cardiology Group). Referrals of patients from the Community Cardiology Group to Hospital A during that period more than doubled over the prior two year period.

Waivers of Federal health care program coinsurance amounts implicate the anti-kickback statute because such waivers may constitute an inducement to beneficiaries to use services in exchange for something of value, *i.e.*, the forgiveness of a financial obligation. Providers that routinely waive coinsurance amounts may be held liable under the anti-kickback statute. See Special Fraud Alert: Routine Waiver of Copayments or Deductibles Under Medicare Part B (issued May 1991), reprinted in 59 Fed. Reg. 65,373, 65,374 (Dec. 19, 1994).[4] When providers forgive financial obligations for reasons other than genuine financial hardship of the particular patient, they may be unlawfully inducing the patient to purchase items or services in violation of the anti-kickback statute's proscription against offering or paying something of value as an inducement to generate business payable by a Federal health care program. Waivers of coinsurance amounts may make beneficiaries less conscientious health care consumers, selecting services because they are free, rather than because they are medically necessary.[5]

The Department's "safe harbor" regulations define practices that are not subject to the anti-kickback statute because such practices are unlikely to result in fraud or abuse. See section 1128B(b)(3) of the Act; 42 C.F.R. § 1001.952. The safe harbors set forth specific conditions that, if met, assure entities involved of not being prosecuted or sanctioned for the arrangement qualifying for the safe harbor. However, safe harbor protection is only afforded to those arrangements that precisely meet all of the conditions set forth in the safe harbor. Under the regulations, hospitals are permitted to waive coinsurance for inpatient services subject to certain conditions. See 42 C.F.R. § 1001.952(k).

Waivers of Medicare and Medicaid program coinsurance amounts also implicate section 1128A(a)(5) of the Act. Section 1128A(a)(5) of the Act prohibits a person from offering or transferring remuneration to a beneficiary that such person knows or should know is likely to influence the beneficiary to order items or services from a particular provider or supplier for which payment may be made under the Medicare and Medicaid programs. "Remuneration" is defined as including the waiver of coinsurance. The statute contains an exception, not applicable here, for certain waivers of coinsurance that are not advertised nor routine, and that are made on the basis of individualized determinations of financial hardship. See section 1128A(i)(6) of the Act. The statute also contains an exception for any payment practice, such as certain waivers of coinsurance obligations related to Medicare Part A hospital inpatient services, that qualify for a safe harbor under section 1128B(b)(3) of the Act. See Section 1128A(h)(i)(6)(B) of the Act.

**B. Analysis**

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[4]The Special Fraud Alert specifically addressed charge-based providers; however, the Special Fraud Alert notes that it should not be construed as endorsing, by omission, routine waivers of Medicare copayments by providers paid under prospective payment or cost-based systems.

[5]Moreover, under section 1862(a)(2) of the Act, services may not be covered services if a Medicare beneficiary is not obligated to pay for them.

Hospital A asserts that the Insurance Only Billing Policy does not result in waivers of coinsurance because the Foundation pays the uncollected coinsurance on behalf of patients. We disagree. Given the close relationship between Hospital A and the Foundation — their overlapping Boards, their joint annual statement, the Foundation's specific charitable mission — the Foundation payments simply move money from one Hospital A pocket to another, and the coinsurance is effectively waived. Moreover and most importantly, payment by the Foundation provides no meaningful check on potential overutilization. In these circumstances, we conclude that the Insurance Only Billing Policy should be analyzed as a routine waiver of coinsurance.

### 1. Hospital A's Insurance Only Billing Policy with Respect to Part A Inpatient Coinsurance Meets the Safe Harbor Requirements.

As applied to inpatient Part A services, Hospital A's Insurance Only Billing Policy fits within the safe harbor for certain waivers of inpatient coinsurance at 42 C.F.R. § 1001.952(k). Hospital A is reimbursed by Medicare under Part A based on the prospective payment system. It does not claim any of the waived coinsurance as bad debt or otherwise shift the burden of the Insurance Only Billing Policy to third parties. The waivers are not made as part of any price reduction agreement with a third-party and are made without regard to the reason for admission, the length of stay, or the DRG for which the claim for Medicare reimbursement is filed. Because 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.

### 2. Hospital A's Insurance Only Billing Policy With Respect to Part B and Non-Inpatient Part A Services Provided by the Full-Time Employed Physicians Will Not Result in OIG Sanctions.

The Insurance Only Billing Policy with respect to non-inpatient Part A services and Part B services provided by the Full-Time Employed Physicians does not fit within the safe harbors and might violate the anti-kickback statute if the requisite intent were present. Notwithstanding, for the reasons discussed below, the OIG will not seek to impose administrative sanctions related to the commission of acts under the anti-kickback statute or for providing inducements to beneficiaries in connection with the Insurance Only Billing Policy as applied to non-inpatient Part A services and Part B services provided by the Full-Time Employed Physicians.

This determination rests in large measure on a recognition that, when applied to services provided by the Full-Time Employed Physicians, Hospital A's Insurance Only Billing Policy is a singular vestige of Hospital A's charitable origin and continuing mission. In this circumstance, the Insurance Only Billing Policy and its direct antecedents predate the Medicare and Medicaid programs by decades and have at all times been applied uniformly to all patients. Hospital A, together with its volunteer network, views the Insurance Only Billing Policy as an integral component of Hospital A's continuing extra-ordinary commitment to free and charitable care. This institutional history merits deference to the Insurance Only Billing Policy that would be inappropriate for an identical policy implemented today.

Standing alone, institutional history will not protect an otherwise improper practice from sanctions under the anti-kickback statute. In this case, however, that history is joined with certain aspects of Hospital A's relationship with the Full-Time Employed Physicians that, taken together, reduce the risk that the Insurance Only Billing Policy will result in overutilization or unnecessary services. First, Hospital A employs the Full-Time Employed Physicians on a full-time basis, precludes them from maintaining outside medical practices, and pays them a fair market value salary that is determined annually in advance and that is not based directly or indirectly on the volume or value of tests or procedures that the physicians perform or order. This compensation arrangement significantly reduces the Full-Time Employed Physicians' personal financial incentive to provide or order unnecessary services to patients.

Second, as to the Full-Time Employed Physicians, Hospital A's role as a specialty hospital further reduces the risk of unnecessary services. The Full-Time Employed Physicians -- who maintain no outside medical practices -- are not in a position to refer patients to Hospital A in the first instance. Instead, virtually all of their patients at Hospital A are initially referred by the patients' own community-based cardiologists, who cannot perform services at Hospital A and who receive no financial benefit from Hospital A. These referring cardiologists have no incentive to refer their patients to Hospital A for other than medically necessary services. Moreover, because Hospital A is a specialty hospital focused on interventional cardiology and surgery, patients are less likely to self-refer directly to Hospital A or its medical staff.

In the light of this combination of circumstances, the OIG would not impose administrative sanctions on Hospital A arising under sections 1128A(a)(7) or 1128(b)(7) of the Act (as those section relate to the commission of acts under the anti-kickback statute) or section 1128A(a)(5) of the Act in connection with the Insurance Only Billing Policy when applied to hospital or professional services provided for patients under the care of Full-Time Employed Physicians.

We cannot, however, offer similar protection to the application of the Insurance Only Billing Policy to patients under the care of Private Practice Physicians. With respect to Private Practice Physicians and their patients, Hospital A is one of several regional hospitals competing for lucrative cardiology business. Hospital A's waiver of otherwise applicable patient coinsurance amounts potentially confers a competitive advantage both on Hospital A and on the Private Practice Physicians (as well as on the medical cardiologists and other physicians in the Private Practice Physicians' affiliated medical groups).[6] In these circumstances and with respect to

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[6]Since the reorganization of the medical staff, referrals from the Private Practice Physicians, who formerly had to refer patients to Hospital A without the opportunity to benefit financially from the referrals, have increased substantially. Further, the part-time employment of Hospital A's formerly full-time physicians by the Community Cardiology Group has resulted in an additional and substantial financial benefit to the Community Cardiology Group for services performed on patients referred to Hospital A. Hospital A has not asked us to opine on that arrangement. While we express no opinion on the legality of the arrangement, the presence of this additional financial incentive heightens our concern about the potential for abuse from the application of Hospital A's Insurance Only Billing Policy to the patients of the Private Practice Physicians.

patients of the Private Practice Physicians, we see no distinction between Hospital A and competing hospitals such that we should protect Hospital A's waiving of patient coinsurance when competing hospitals cannot. Hospital A remains free to waive patient coinsurance for these patients based on good faith, individual determinations of financial need.

## III. CONCLUSION

Based on the information provided in your request and supplemental submissions, and subject to certain conditions described below, we conclude that the Insurance Only Billing Policy could potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce or reward referrals were present, but that the OIG would not impose administrative sanctions on Hospital A 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) or under section 1128A(a)(5) of the Act in connection with the Insurance Only Billing Policy as applied to (i) Part A inpatient hospital services and (ii) hospital or physician services provided to patients of the Full-Time Employed Physicians.[7]

Nothing in this opinion is intended to prohibit use of the Insurance Only Billing Policy for hospital or physician services provided to patients under the care of the Private Practice Physicians so long as the Policy is applied based on an individualized determination of the patient's financial need.

## IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to Hospital A, 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 herein expressed or implied 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 Insurance Only Billing Policy.

- This advisory opinion will not bind or obligate any agency other than the U.S. Department of Health and Human Services.

[7]We express no opinion regarding the liability of any party under the False Claims Act or other legal authorities for any improper billing, claims submission, or other related conduct.

- This advisory opinion is limited in scope to the specific arrangement described in this letter and has no applicability to other arrangements, even those that 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 requestor with respect to any action that is part of the Insurance Only Billing Policy applied to Medicare Part A inpatient items and services and Medicare Part B and non-inpatient Part A items and services provided by the Full-Time Physicians 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 Insurance Only Billing Policy as applied to such services 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 requestor 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/

D. McCarty Thornton
Chief Counsel to the Inspector General