Posted: 4-14-98

[April 6, 1998]

[name redacted]

Re: Advisory Opinion 98-3

Dear [name redacted]:

We are writing in response to your request for an advisory opinion on behalf of Company A ("Company A") regarding whether a hospital system's provision of an ambulance to a municipal fire department as described in your request letter and supplemental submissions (the "Proposed Arrangement"): (i) constitutes grounds for the imposition of criminal sanctions under § 1128B(b) of the Social Security Act (the "Act"), 42 U.S.C. § 1320a-7b(b); (ii) constitutes grounds for the imposition of an exclusion under § 1128(b)(7) of the Act, 42 U.S.C. § 1320a-7(b)(7) (as it applies to kickbacks); or (iii) constitutes grounds for the imposition of civil monetary penalties within the meaning of § 1128A(a)(7) of the Act, 42 U.S.C. § 1320a-7a(a)(7).

Company A has certified that all of the information provided in the request, including all supplementary letters, is true and correct, and constitutes a complete description of the relevant facts and agreements among the parties. Company A has also certified that upon our approval, it will undertake to effectuate the Proposed Arrangement.

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 and subject to certain conditions described below, we have determined that the Proposed Arrangement may potentially generate prohibited remuneration within the meaning of the anti-kickback statute, but, for the reasons set out herein, would not constitute grounds for the imposition of criminal sanctions under § 1128B(b) of the Act, an exclusion under § 1128(b)(7) of the Act (as it applies to kickbacks), or civil monetary penalties under § 1128A(a)(7) of the Act.

This opinion may not be relied on by any person or entity other than the addressee and is further qualified as set out in Part III below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

Company A has made the following representations with respect to the Proposed Arrangement.

Company A Health System, a State W corporation, provides health care services to patients in County Y, including City X ("the City" or "City X"). Approximately 67,000 of the approximately 450,000 residents of City X are members of managed care plans that list Company A facilities as preferred providers. A portion of these 67,000 patients are enrolled in managed care plans for which Company A facilities are exclusive providers.

Prior to February 1997, Company A operated four hospitals, three of which were located in City X. In February 1997, Company A opened Health Facility B ("Health Facility B"), a new comprehensive health care facility with emergency room services in City of Z, located in County Y, approximately ten miles from City X. Subsequent to the opening of Health Facility B, Company A continued to operate two inpatient facilities in City X, each with an emergency room. As of January 31, 1998, Company A consolidated all of its inpatient operations at Health Facility B, in the process closing its two remaining inpatient facilities in City X. Company A currently maintains two free-standing outpatient surgical facilities in City X, which are permitted to provide some, but not all, emergency services.[1]

Although Health Facility B is located within County Y, it is significantly farther from City X than the only other two hospitals with emergency rooms in the county, which are located in City X. These two hospitals are not affiliated with Company A.[2]

Pursuant to § [redacted] of the State W Public Health Code ([cite redacted]), the State W Department of Public Health (now known as the State W Department of Community Health) designated the County Y Medical Control Authority ("MCA") as the responsible authority for developing protocols for providing emergency services in County Y (the

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[1]The free-standing outpatient surgical facilities may not receive patients via ambulance with certain severe conditions, including, but not limited to, multi-system trauma, blunt torso trauma, penetrating torso trauma, active labor, or high risk obstetrical conditions.

[2]The two hospitals are Hospital C, owned and operated by the City X, and Hospital D, which is privately owned.

"MCA Protocol Guidelines"). Under the statute, the Chief of the City Fire Department and every hospital in County Y are members of the MCA and are required to abide by the protocols adopted by the MCA. The MCA Protocol Guidelines adopted by the MCA apply to all providers of emergency services in County Y.

The MCA Protocol Guidelines provide that a patient needing pre-hospital care ambulance services must be transported to any facility in County Y of the patient's choice, unless the patient is medically unstable and the choice would endanger the patient's health. Emergency medical technicians are required to consider whether the patient's choice of facility would jeopardize the patient's health due to: (i) the facility's distance; (ii) the inadequacy of the facility with respect to the patient's condition; or (iii) the facility being overburdened.

In correspondence submitted by Company A in support of its advisory opinion request, the City, through its Director of Finance, acknowledged its obligations under the MCA Protocol Guidelines, but represented to Company A and its counsel that the City lacks adequate ambulance resources to comply fully. The City also stated that it cannot purchase an additional ambulance because of severe budget constraints. According to facts certified by Company A, the City believes that because of the distance to Health Facility B, ambulances going there would be out of commission for lengthy periods of time, which would decrease the Fire Department's capacity to provide adequate EMS and advanced life support to the citizens of City X, the constituency the City must serve.[3]

Notwithstanding the MCA Protocol Guidelines, from the opening of Health Facility B until February 1, 1998, the Fire Department declined to transport patients directly to Health Facility B, even upon a patient's request. Patients requesting transport to Health Facility B were taken either to one of Company A's two inpatient facilities in City X or provided initial treatment by the Fire Department and then transferred to another ambulance company which would transport the patient to Health Facility B. Initially, the City represented to Company A that it would not transport any patients to Health Facility B after January 31, 1998. However, since February 1, 1998, the City has transported some patients to Health Facility B, to the extent it has deemed its resources adequate.

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[3]The MCA Protocol Guidelines permit an emergency medical or advanced life support system to obtain approval of the central medical control physician to override the patient's decision when the facility is an "extreme distance away, [thereby] removing the EMS vehicle from availability for an extensive period of time." However, the MCA Protocol Guidelines specifically state that "extreme distance away" means "out of [County Y]." Paragraph 5, MCA Protocol Guidelines.

Under the Proposed Arrangement, Company A will donate an ambulance furnished with such equipment as is necessary to provide advanced life support services (a donation worth approximately $150,000) to City X.[4] Title will pass free and clear to the City with no conditions on the use of the ambulance. After the initial donation, Company A will not provide or furnish any personnel, supplies, equipment, salaries, or repairs for the donated ambulance. Nor will it make donations of any kind to the Fire Department for a five-year period commencing on the date of the ambulance donation, except for donations exclusively in connection with civic or community events that are funded by donations solicited from and submitted by individuals or entities in the community generally (e.g., a City-wide "Fun Run").

II. LEGAL ANALYSIS

The anti-kickback statute makes it a criminal offense knowingly and willfully to offer, pay, solicit or receive any remuneration to induce referrals of items or services reimbursable by the Federal health care programs. See 42 U.S.C. § 1320a-7b(b). Where remuneration is paid purposefully to induce referrals of items or services for which payment may be made 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 any thing 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 (3d 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. This Office may also initiate administrative proceedings to exclude persons from the Federal and State health care programs or to

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[4]Company A has suggested that it may be interested in donating a "cash equivalent" instead of an actual ambulance. This alternative was not raised in the original advisory opinion request, and is not addressed here. This opinion is without force and effect with respect to any "cash equivalent" donation. We note that we might reach a different conclusion if the donation were a "cash equivalent".

impose civil monetary penalties for fraud, kickbacks, and other prohibited activities under sections 1128(b)(7) and 1128A(a)(7) of the Act.[5]

A. The Proposed Arrangement May Be Prohibited Remuneration

This Office's concern with the provision of goods and services for free or at below-market rates to potential referral sources is longstanding and clear: such arrangements are suspect. The provision of free goods to any referral source may violate the anti-kickback statute if one purpose of the gift is to induce referrals of Federal program business. In general, the provision of free goods to referral sources gives rise to an inference that one purpose of the gift is to induce referrals. However, the strength of that inference may vary with the circumstances.

Because the Fire Department is a major provider of EMS services in City X and the sole provider of advanced life support services, the Fire Department has some ability to affect the transport of patients from City X to Health Facility B. To the extent that the donation of the ambulance will provide additional resources to the Fire Department, the gift will make it easier for the Fire Department to take patients directly to Health Facility B, potentially increasing the number of transports to Health Facility B. In other words, Company A will be giving something of value to the Fire Department, which potentially will increase the number of patients, including Medicare and Medicaid patients, that the Fire Department transports to Health Facility B.

In our preamble to the Interim Final Rule on the advisory opinion process, we stated that an advisory opinion is a "means of relating the anti-kickback statute to the particular facts of a specific arrangement." 62 Fed. Reg. 7350, 7351 (February 19, 1997). We went on to say that "[t]here are likely to be factors that make some specific arrangements appropriate for a favorable advisory opinion, even in subject matter areas where a generalized safe harbor may be impractical." Id. Thus, while the Proposed Arrangement could potentially involve a payment of remuneration to induce the referral of Federal health care program business, the advisory opinion process permits this Office to protect specific arrangements that "contain[] limitations, requirements, or controls that give adequate assurance that Federal health care programs cannot be abused." Id.

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[5]Because both the criminal and administrative sanctions related to the Proposed Arrangement are based on violations of the anti-kickback statute, the analysis for purposes of this advisory opinion is the same under all three provisions.

B. The Proposed Arrangement Presents Minimal Risk of Abuse of Federal Health Care Programs

In the specific factual context presented, we believe the Proposed Arrangement presents a minimal risk of abuse of Federal health care programs, while providing significant benefits to the City X community. For the reasons set out below, we think the Proposed Arrangement would not constitute grounds for sanction under the anti-kickback statute.

In assessing the potential risk of abuse from the Proposed Arrangement, our concerns are fourfold: increased risk of overutilization, increased program costs, patient freedom of choice, and unfair competition. In this case, the Proposed Arrangement presents little risk of overutilization or increased costs[6] to any Federal health care program. Simply put, the number of patients requiring emergency transport is unrelated to whether the Fire Department receives a new ambulance. Nor should the quantity or cost of services rendered to these patients be affected; the patients will still be treated by some health facility. Accordingly, our focus is on: (i) the Arrangement's potential impact on patient freedom of choice; and (ii) whether the Arrangement is likely to give Health Facility B an unfair competitive advantage because of possible inappropriate "steering" of patients by the Fire Department.

With respect to the effect on patient freedom of choice, we conclude that the Proposed Arrangement is likely to improve freedom of choice for patients who wish to go to Health Facility B. Currently, a significant number of those patients may endure unnecessary delays and vehicular transfers in order to secure transport. To the extent that some patients go elsewhere for care that they would prefer to receive at Health Facility B, such patients are being denied access to their hospital of choice. Thus, the Proposed Arrangement may have a demonstrable and positive impact on patient freedom of choice in County Y.

For the same reasons, we conclude that the Proposed Arrangement is likely to result in fairer competition among the hospitals serving the City X area. The keystone of our analysis is the recognition that continuation of the status quo places Health Facility B at an unfair competitive disadvantage. Under the MCA Protocol Guidelines, patients who wish to go to Health Facility B should receive the same treatment as patients wishing to go to any other County facility. However, depending on the Fire Department's assessment of its resources at a given moment in time, such patients may be: (1) transported directly to

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[6]There may be some additional mileage charges depending on the ambulance reimbursement methodology used by the regional carrier.

Health Facility B; (2) stabilized by the Fire Department and then transferred to another ambulance company for transport to Health Facility B; or (3) transported to Company A's City X emergency room for transport to be arranged by Health Facility B.[7] Thus, the Proposed Arrangement will both increase patient freedom of choice and promote fairer competition among the area hospitals.

Notwithstanding the potential community benefits, the Proposed Arrangement could potentially induce the Fire Department to steer patients who do not have a preferred destination facility to Health Facility B. In assessing that risk, we must first evaluate the Department's ability to determine patients' choice of hospital. Under the MCA Protocol, the Fire Department must take any patient in exigent circumstances to the nearest hospital. Of the three hospitals in the area, Health Facility B is the furthest hospital from City X. The Fire Department only picks up patients in the City. With respect to non-exigent patients, the Protocol requires the Fire Department to take the patients to their hospital of choice. In some cases, a patient's insurance plan will dictate the choice of hospital; other patients will have a preferred choice based on past experience or other reasons. In other words, the MCA Protocol Guidelines limit the number of patients that the Fire Department could potentially "steer" to Health Facility B.

Finally, the Proposed Arrangement is not structured to provide any financial incentive or reward to the Fire Department for referrals to Health Facility B.[8] Unlike many suspect arrangements, the amount of remuneration is fixed and will not vary in any way based on the volume or value of referrals. Indeed, Health Facility B's location outside the City may be a disincentive for the Fire Department to transport patients to Health Facility B, because traveling the extended distance would drain City resources through higher operational costs (e.g., gasoline, maintenance, time expended). Finally, Company A has agreed that Company A will not make donations of any kind to the Fire Department for the next five years, except for donations exclusively in connection with civic or

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[7]Pursuant to representations from the City, the City Fire Department's inability to fulfill its obligations under the MCA Protocol Guidelines is due in large part to its limited financial resources. City X has severe budgetary constraints resulting in part from several major plant closings.

[8]In advisory opinion 97-6, we stated that a protocol similar to the MCA Protocol Guidelines was not sufficient to deter abuses addressed by the anti-kickback statute where the payments offered to the ambulance service related directly to the delivery of individual patients.

community events that are funded by donations solicited from and submitted by individuals or entities in the community generally (e.g., a City-wide "Fun Run").[9]

D. Conclusion

Given the specific circumstances of the Proposed Arrangement, we are persuaded that the Proposed Arrangement does not pose a significant risk of fraud or abuse to the Federal health care programs. Therefore, for the reasons set forth above, we conclude that the Proposed Arrangement does not constitute grounds for the imposition of criminal sanctions under section 1128B(b) of the Act, an exclusion under section 1128(b)(7) of the Act (as it applies to kickbacks), or civil monetary penalties under section 1128A(a)(7) of the Act.

III. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to Company A, which is the Requestor of this opinion. This advisory opinion has no application, 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 to this opinion.

- This advisory opinion is applicable only to the statutory provisions specifically noted in the first paragraph of this advisory opinion. 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 Proposed Arrangement.

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

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[9]While we note that the donation of the ambulance is unconditional and the City retains absolute discretion over use of the ambulance, we place little weight on potentially self-serving contractual provisions. Many abusive schemes contain no written obligations to make referrals. Similarly, written agreements that preclude payments for referrals are not determinative of non-abusive relationships.

- 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.

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 Proposed Arrangement taken in good faith reliance upon this advisory opinion as long as all of the material facts have been fully, completely, and accurately presented, and the 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, 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.

Sincerely,

/s/

D. McCarty Thornton
Chief Counsel to the Inspector General