

Memorandum On Air Ambulance Membership Program Legal Considerations Taken Into Account By Kalispell Regional Medical Center in Establishing It's a/L.E.R.T. Assist Membership Program

To: The Economic Affairs Interim Committee of the Montana Legislature Related to Air Ambulances under House Joint Resolution 29

When Kalispell Regional Medical Center (KRMC) began its consideration of establishing an air ambulance membership program as a part of its A.L.E.R.T. program, it looked to federal law and Montana law to determine issues that needed to be taken into account. Because there was not a Montana statute on the subject, representatives of KRMC worked with MHA and other interested parties to fashion legislation for consideration by the Montana legislature. Statutes of neighboring states were primary examples for the Montana statute that was adopted by the legislature and is now MCA 50-6-320.

The principal legal concern for establishing the membership program, since KRMC is a Medicare and Medicaid provider, was ensuring compliance with several federal statutes that restrict incentives for the referral of patients who are Medicare or Medicaid beneficiaries. The Office of Inspector General of the U.S. Department of Health and Human Services (the "OIG") has spoken to arrangements that provided support to patients, directly or indirectly, involving ambulance services, including an air ambulance membership program, on a number of occasions. The OIG is concerned about the ability of a membership program to incentivize patients to seek care at a particular hospital. Two federal health law statutes are implicated principally:

- a. The Civil Monetary Penalties Act, which prohibits a Medicare/Medicaid services provider from offering anything of value (except in a very limited dollar amount) to Medicare or Medicaid beneficiaries that may influence their selection of a particular healthcare services provider.
- b. The Medicare and Medicaid Anti-Kickback Statute, which makes it a criminal offense, and a civil law violation as well, for a person to knowingly and willfully offer, or solicit, anything of value to induce or reward referrals for, or the use of, items or services reimbursable by a federal healthcare program.

An air ambulance membership program which allows the waiver of the usual cost-sharing amount paid by the patient, could be found to violate these laws if not structured properly. The OIG has ruled favorably and unfavorably on ambulance services support arrangements in several Advisory Opinions, including a favorable opinion on an air ambulance membership program. A key factor in the favorable opinion was that the

membership fees paid by the members reasonably approximate the aggregate amount the members would expect to spend as their cost-sharing amounts in a year, or the amounts collected from members who are Medicare beneficiaries under Medicare Part B, reasonably approximate the amounts those members would expect to spend as their cost-sharing amounts in a year. This requires that the membership plan sponsor use a historical or actuarial determination with the intent to ensure that the membership fees collected in the aggregate exceed the amounts that the persons who had to use the service in the year would have been expected to pay as their cost-sharing amounts for that use.

KRMC has structured its program to satisfy the guidance of the OIG. A copy of the Advisory Opinions is attached, as well as a copy of the KRMC program brochure.



[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: May 21, 2003

Posted: May 28, 2003

[name and address redacted]

Re: OIG Advisory Opinion No. 03-11

Dear [name redacted]:

We are writing in response to your request for an advisory opinion concerning an ambulance company's collection of a fixed annual subscription fee in lieu of Medicare Part B cost-sharing amounts from its members (the "Arrangement"). Specifically, you have asked whether the Arrangement 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 penalties provision for illegal remuneration to beneficiaries at section 1128A(a)(5) 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 were present, but that the Office of Inspector General (“OIG”) would not impose administrative sanctions on [name redacted] under section 1128A(a)(5) of the Act or under section 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 other agreements or any other arrangements disclosed or referenced in your request letter or supplemental submissions.

This opinion may not be relied on by any persons other than [name redacted] (the “Requestor”), 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

The Requestor is a nonprofit corporation that provides emergency ambulance services. The Requestor has operated since 1963 on a subscription basis and has two classes of subscribers: individuals who pay an annual \$20 subscription fee and businesses that pay annual subscription fees proportionate to their size (\$30 for those with fewer than 12 employees; \$50 for those with 12 or more employees).

The Requestor does not collect Medicare Part B cost-sharing amounts from its subscribers (other than supplemental insurance coverage of the subscriber’s obligations), but does collect such balances from non-subscribers through its contracted billing agent.

The Requestor has certified that the subscription revenues collected from its subscribers currently exceed, in the aggregate, the cost-sharing amounts waived for all subscribers, and that the subscription revenues collected from all subscribing Medicare Part B beneficiaries currently exceed, in the aggregate, the cost-sharing amounts waived for the subscribing Part B beneficiaries.

II. 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 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

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, 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 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 care programs under section 1128(b)(7) of the Act.

III. LEGAL ANALYSIS

The Arrangement may implicate the anti-kickback statute to the extent that it might be construed as a routine waiver of Medicare Part B cost-sharing amounts. In evaluating the risk, the threshold concern is whether, in the aggregate, (i) the subscription fees collected from subscribers reasonably approximate the amounts that the subscribers would expect to spend for cost-sharing amounts over the period covered by the subscription agreement, *or* (ii) the amounts collected from subscribing Medicare Part B beneficiaries reasonably approximate the amounts that the subscribing Medicare Part B beneficiaries would expect to spend for cost-sharing amounts. If the subscription amounts are not actuarially or historically reasonable in comparison to the uncollected cost-sharing amounts under one of the two alternatives noted above, then we would view the subscription plan as a potentially illegal practice to disguise the routine waiver of Medicare Part B cost-sharing amounts.

In this case, the subscription amounts collected by the Requestor from participating Medicare beneficiaries in the aggregate exceed the amounts that the Medicare Part B beneficiaries would be expected to spend for Medicare Part B cost-sharing over the period covered by the subscription agreement. Accordingly, we would not subject the Arrangement to administrative sanctions under the anti-kickback statute or section 1128A(a)(5) of the Act.

IV. 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 were present, but that the OIG would not impose administrative sanctions on [name redacted] under section 1128A(a)(5) of the Act or 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 other agreements or any other arrangements disclosed or referenced in your request letter or supplemental submissions.

V. 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, 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 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, 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,

/s/

Lewis Morris
Chief Counsel to the Inspector General



[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: August 11, 2009

Posted: August 18, 2009

[Name and address redacted]

Re: OIG Advisory Opinion No. 09-13

Ladies and Gentlemen:

We are writing in response to your request for an advisory opinion regarding a proposal for a hospital to provide subsidies to an affiliated ambulance cooperative, to enable the cooperative to provide certain ambulance services currently provided by the hospital (the "Proposed Arrangement"). Specifically, you have inquired whether the Proposed Arrangement 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, 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 while the Proposed 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”) would 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 Proposed Arrangement. This opinion is limited to the Proposed 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 [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

The requestor is [name redacted], a [state redacted] nonprofit, nonstock corporation that has been recognized by the Internal Revenue Service (the “IRS”) as an organization described in section 501(c)(3) of the Internal Revenue Code and as a public charity. It is part of the [name redacted] (the “Health System”), which is also a [state redacted] nonprofit, nonstock corporation recognized by the IRS as a section 501(c)(3) organization.

[Requestor name redacted] owns and operates a 226-bed acute care hospital in [town redacted] (the “Town”), [county redacted] (the “County”), [state redacted] (the “State”). (For purposes of this opinion, [requestor name redacted] and the acute care hospital it operates will be referenced as the “Hospital.”) The Hospital has certified that it offers a wide variety of primary, secondary, and tertiary services and is the only hospital in the County or within a radius of 35 miles that has been certified by the State Department of Health as having “comprehensive” emergency services capability. The only other hospital in the County is also a member of the Health System and has only general emergency room capability.

Since 1984, pursuant to an agreement with the Town, the Hospital has provided advanced life support (“ALS”) services for the Town and surrounding areas.¹ The ALS services the

¹ The Hospital has certified that, prior to its assuming this responsibility, the Town was providing ambulance services at a loss, was having serious budget problems, and was planning to close a number of fire stations and eliminate the jobs of certain firefighters, which would have resulted in a loss of fire rescue services and inadequate ambulance services to the community. The Hospital states that the Town requested and the Hospital agreed to provide ambulance services to the Town as a subsidized service to the

Hospital currently provides include ALS ambulance services and non-transport paramedic services. The ALS ambulance services consist of two ALS ambulance units owned by the Hospital, each staffed with a paramedic and an emergency medical technician (“EMT”). The non-transport paramedic services (“Paramedic Squads”) consist of specially-equipped squad units that do not transport patients but carry paramedics. When ALS services are required and an ALS ambulance is not available, a Paramedic Squad meets an ambulance equipped for basic life support (“BLS”) that has been dispatched through the 911 emergency dispatch services. The Hospital’s ALS ambulance service and Paramedic Squads respond to approximately 7,500 calls per year.

[Name redacted] (the “Ambulance Cooperative” or the “Cooperative”) is a [state redacted] nonprofit cooperative corporation that is taxable for Federal income tax purposes. Its members are the Hospital, which has four voting representatives, and three local volunteer fire companies (the “Volunteer Fire Companies”), each of which has one voting representative. Because of its majority voting representation, the Hospital controls the Ambulance Cooperative. Like the Hospital, the Cooperative is part of the Health System.

The Ambulance Cooperative provides ambulance services in the Town and surrounding communities in the County. The Ambulance Cooperative owns one BLS ambulance, one of the Volunteer Fire Companies owns one BLS ambulance, and the other two Volunteer Fire Companies own two BLS ambulances each. These BLS ambulances are staffed by EMTs and are available when the 911 emergency dispatch service determines, using protocols established by the Regional Emergency Medical Services Council, that an ALS unit is not required, or when the Hospital’s ALS ambulances are not available because they are already in use.

Under the current arrangement, when an ALS ambulance is dispatched, the Hospital bills for the patient transport at the ALS rate. When a BLS ambulance is dispatched from one of the Volunteer Fire Company stations, the Volunteer Fire Company bills for the patient transport at the BLS rate. If a Hospital Paramedic Squad is also dispatched, the Hospital bills for the services provided by the paramedics, if non-transport services are covered separately. When the BLS ambulance owned by the Ambulance Cooperative is dispatched together with the Paramedic Squad provided by the Hospital, however, the Cooperative bills the ALS rate, and the Hospital does not bill. The Hospital has explained that the Cooperative bills the ALS rate when the ALS portion of the ambulance service actually is

community, to lessen the burdens of the Town, limit the closure of fire stations, and ensure the continued availability of necessary ambulance services.

provided by the Hospital Paramedic Squad, because the Cooperative and the Hospital are both members of the Health System and subject to the Health System's global budget.²

In addition to BLS services, the Ambulance Cooperative provides intra-hospital transports and other services that support the Volunteer Fire Company emergency medical service teams. The Ambulance Cooperative also offers specialty needs transport services such as van transports for cancer patients and wheelchair and stretcher van transports. All van transports must begin or end at a facility that offers medical services.

The Hospital recoups only about half the cost of providing ALS services through billings to Medicare and other payers. It has certified that its cost of providing these services is approximately \$1.8 million annually and that it provides them at an annual net loss of approximately \$900,000.

The Hospital cites, among the reasons for these operational losses, the fact that it must provide ALS services to a large geographic area that is sparsely populated and predominantly rural. As a result, it has a low number of patient contacts relative to the geographic area covered and the fixed costs incurred, and its costs per trip are higher than the costs per trip of ambulance suppliers that provide services to smaller, more densely populated areas with a high volume of patient contacts. By way of illustration, the Hospital represents that, according to the State Department of Health, in 2008 there were 18 ambulance calls per square mile in the County, compared to 1720 ambulance calls per square mile in one of the State's more densely populated counties.

According to the Hospital, there are no for-profit entities licensed to provide ALS service in the County, which covers an area of more than 1200 square miles. Two volunteer fire companies that are not part of the Ambulance Cooperative provide ALS service in areas of the County where they have been designated to provide those services through the State EMS System. Except in certain limited situations where they may be called upon to provide back-up service, they do not provide ALS service outside their designated areas.

The Hospital has certified that, when an ALS or BLS ambulance unit transports a patient in response to an emergency call, it is required by state regulations and protocols to transport the patient to the hospital of his or her choice, if the patient is able to express a choice, and otherwise to the nearest hospital with appropriate facilities. It has also certified that, when a patient is transported in situations other than emergencies, the medical facility is always selected by the patient or patient representative.

² No opinion has been sought, and we express no opinion, regarding this existing billing arrangement.

Under the Proposed Arrangement, responsibility for providing the ALS services now provided by the Hospital and the BLS services provided by the Ambulance Cooperative would be consolidated in the Cooperative. The Hospital believes that this would result in improved service delivery, create various efficiencies, and reduce operational costs. In addition, the Cooperative would apply to the IRS for 501(c)(3) status, which would make it eligible for certain funding for ALS services earmarked for tax-exempt entities. Until the Cooperative obtains such funding, however, the Hospital expects it to incur losses in providing the ALS services now provided by the Hospital. Under the Proposed Arrangement, the Hospital and the Cooperative would enter an agreement whereby (1) the Cooperative would assume responsibility for providing the ALS services currently provided by the Hospital; and (2) the Hospital would provide a subsidy to the Cooperative, in the form of cash, equipment, and services, to be used exclusively for the provision of ALS services that would qualify as Section 501(c)(3) charitable health care activities if conducted by a Section 501(c)(3) organization. The Hospital has certified that its donations to the Cooperative would not vary with the number of transports of patients to the Hospital, relative to transports to other facilities.

The Hospital represents that the purpose of the Proposed Arrangement is to provide ALS ambulance service to the community more efficiently and at less cost to the Hospital. The Hospital further represents that there are no alternatives to the Proposed Arrangement that do not involve a subsidy provided by the Hospital. According to the Hospital, the Town has no legal requirement to provide ALS ambulance services and is not financially in a position to do so.

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 care programs under section 1128(b)(7) of the Act.

B. Analysis

The Proposed Arrangement would continue an essential service to the community—ALS ambulance services—currently provided by the Hospital at a financial loss. The services would be provided just as now, by the same personnel and using the same equipment. Changes would be made in the entity that would be directly responsible for the services and that would bill for the services. Currently, the services are directly provided and billed either solely by the Hospital or by the Hospital in cooperation with the Ambulance Cooperative and its other members. Under the Proposed Arrangement, the services would be provided by the Cooperative, using equipment and other forms of assistance donated by the Hospital.

In assessing the potential risk of kickback abuse from the Proposed Arrangement, we examine the possibility that the Hospital's donation of cash, equipment, and services—things necessary for the Ambulance Cooperative to provide ALS ambulance services—could be remuneration to the Cooperative (and possibly its other members, the Volunteer Fire Companies) to refer or influence referrals of patients to the Hospital. In conducting this analysis, we look not only to whether the ALS-related donations would encourage the referral of ALS patients, but also to whether these contributions might result in the referral to the Hospital of other patients who receive services from the Ambulance Cooperative and its members, including those who receive BLS ambulance services or van transportation to medical appointments.

We conclude that the risk of abuse is sufficiently low, for a combination of the following reasons. First, the Ambulance Cooperative and its members would receive no net benefit from the Proposed Arrangement. The Cooperative would assume from the Hospital, which is its affiliate and majority member, direct responsibility for providing ALS ambulance services; it would receive from the Hospital no more than the means to carry out this responsibility. The individual Volunteer Fire Companies would continue to provide BLS transport service and to bill for it as before. They would receive no direct benefit from the Proposed Arrangement as individual ambulance providers, and no indirect benefit as members of the Cooperative.

Second, the Hospital's donations to the Ambulance Cooperative would not vary with the volume or value of referrals to the Hospital by the Cooperative. The donations might vary with the number of transports of patients (because of variation in costs); however, they would not vary with the number of transports of patients to the Hospital, relative to transports to other facilities.

Third, the Ambulance Cooperative and the Volunteer Fire Companies are not in a position to affect referrals to the Requestor in a significant way. The requestor is the only hospital in the County or within 35 miles that has been certified by the State Department of Health as having "comprehensive" emergency services capability. The only other hospital in the County has only general emergency room capability and is, in any event, a member of the same Health System as the requestor and the Cooperative. In addition, the ambulances are required to transport emergency patients to the hospital of the patient's choice, if the patient is able to express a choice, and otherwise to the nearest hospital with appropriate facilities, as defined in State protocols. When a patient is transported in other than emergency situations (such as van transports of wheelchair patients to medical appointments), the medical facility is selected by the patient or patient representative.³

Finally, any risk posed by the Proposed Arrangement is offset by the particular conditions in which the Proposed Arrangement is to be implemented. The Hospital has certified that, due to the expense of operating an ambulance service in a sparsely-populated area, there are no for-profit ambulance services in the County.⁴ The Hospital itself has been unable to provide ALS ambulance services on a break-even basis. The Hospital has certified that such services cannot be provided unless subsidized by the Hospital.

For all of these reasons, we conclude that the risk of anti-kickback fraud and abuse posed by the Proposed Agreement is relatively low and offset by the benefit to the local community of the services to be subsidized.

³ We would not necessarily be persuaded by these points in other circumstances. We are aware that ambulance suppliers may be able to steer patients notwithstanding applicable protocols, and the fact that a hospital is the single provider of a particular type in an area does not mean that it is the best or only appropriate choice for a particular patient. Thus, the risk of patient steering is reduced but not eliminated in the circumstances described here. In reaching our conclusion that the Proposed Arrangement poses minimal risk, we considered this factor along with other factors cited herein.

⁴ Two volunteer fire departments in the County that are not members of the Cooperative are licensed to provide ALS services. They do not present an alternative to the Proposed Arrangement for ALS services outside their designated service areas.

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that while the Proposed 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 would 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 Proposed Arrangement. This opinion is limited to the Proposed 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 [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 Proposed 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 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 Proposed 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



[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: March 7, 2007

Posted: March 14, 2007

[Name and address redacted]

Negative Opinion

Re: OIG Advisory Opinion No. 07-02

Ladies and Gentlemen:

We are writing in response to your request for an advisory opinion regarding a hospital's proposal to subsidize the cost of ambulance transportation for patients transported to the hospital from outside the hospital's local area (the "Proposed Arrangement"). Specifically, you have inquired whether the Proposed Arrangement would constitute grounds for 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 anti-kickback statute.

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 Proposed Arrangement could constitute grounds for the imposition of civil monetary penalties under section 1128A(a)(5) of the Act. We also conclude that the Proposed Arrangement could potentially generate prohibited remuneration

under the anti-kickback statute, and that the Office of Inspector General ("OIG") could potentially impose administrative sanctions 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 Arrangement. Any definitive conclusion regarding the existence of an anti-kickback violation requires a determination of the parties' intent, which determination is beyond the scope of the advisory opinion process.

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.

1. FACTUAL BACKGROUND

[Name redacted] ("Requestor") is an integrated nonprofit health care system that includes [name redacted] (the "Hospital") as one of its subsidiaries. The Hospital is a [number redacted]-bed acute care hospital that employs almost 3,000 full-time employees and has more than 1,000 physicians on its medical staff. Requestor has certified that the Hospital is recognized as a leader in cardiovascular services.

From time to time, patients are transferred by ambulance to the Hospital from hospitals outside the Hospital's local area. Requestor has certified that, historically, claims for such transportation services were generally paid by the local Medicare carrier. However, the Medicare carrier began refusing to pay the full amount of these claims, citing Medicare requirements that provide for local ambulance transportation only, except where

non-local transportation is necessary to take the patient to the “nearest institution with appropriate facilities.”¹

¹The Medicare Benefit Policy Manual (CMS-Pub. 100-02) provides, at Chapter 10, section 10.3, in relevant part:

The Destination.— . . . As a general rule, only local transportation by ambulance is covered, and therefore, only mileage to the nearest appropriate facility equipped to treat the patient is covered. However, if two or more facilities that meet the destination requirements can treat the patient appropriately and the locality (see Section 10.3.6 below) of each facility encompasses the place where the ambulance transportation of the patient began, then the full mileage to any one of the facilities to which the beneficiary is taken is covered. Because all duly licensed hospitals and SNFs [skilled nursing facilities] are presumed to be appropriate sources of health care, only in exceptional situations where the ambulance transportation originates beyond the locality of the institution to which the beneficiary was transported, may full payment for mileage be considered, and then, only if the evidence clearly establishes that the destination institution was the nearest one with appropriate facilities under the particular circumstance (see Section 10.3.6 below).

* * * * *

10.3.5. Locality.— The term “locality” with respect to ambulance service means the service area surrounding the institution from which the individuals normally come or are expected to come for hospital or skilled nursing services.

EXAMPLE: Mr. A becomes ill at home and requires ambulance service to the hospital. The small community in which he lives has a 35-bed hospital. Two large metropolitan hospitals are located some distance from Mr. A’s community but they regularly provide hospital services to the community’s residents. The community is within the “locality” of the metropolitan hospitals and direct ambulance service to either of these (as well as the local community hospital) is covered.

10.3.6. Appropriate Facilities.— The term “appropriate facilities” means that the institution is generally equipped to provide the needed hospital or skilled nursing care for the illness or injury involved. . . . The fact that a more distant institution is better equipped, either qualitatively or quantitatively, to care for the patient does not warrant a finding that a closer institution does not have “appropriate facilities.” Such a finding is warranted, however, if the beneficiary’s condition requires a higher level of trauma care or other specialized service available only at the more distant hospital.

As a result, Requestor reports that patients have been receiving bills from their ambulance suppliers for the uncovered portion of non-local ambulance trips to the Hospital (the "excess mileage"). According to Requestor, this has prompted patient complaints and a disinclination on the part of physicians to order or recommend the transfer of patients to the Hospital if excess mileage charges may result.

The Hospital is exploring the Proposed Arrangement, under which it would contract with various air and ground ambulance suppliers to transport patients to the Hospital from hospitals located outside its locality. The Hospital would pay the ambulance suppliers a negotiated fee for the ambulance services² and submit claims for reimbursement directly to third-party payors, including Medicare and Medicaid. Under the Proposed Arrangement, the Hospital would absorb any costs beyond those reimbursed by Medicare and other payors.³ The Hospital anticipates that most of the patients affected would have cardiac-related conditions, but the Proposed Arrangement would not be limited to cardiac patients, nor would it be based on individual determinations of financial need. The Hospital would not advertise the availability of the subsidized ambulance services to patients.

II. LEGAL ANALYSIS

A. Law

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 Medicaid program 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 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 the section 1128A(a)(5) as including "the waiver of coinsurance and deductible amounts (or any part thereof) and transfers of items or services for free or for other than fair market value."

²We have not been asked about, and express no opinion regarding, any agreement between the Hospital and an ambulance supplier entered into to effectuate the Proposed Arrangement.

³Thus, in addition to absorbing any differential between the cost of local transportation and the cost of transportation to the Hospital, the Hospital would also absorb the cost-sharing portion of the ambulance expense that the patient would owe if the transportation were billed by the ambulance supplier.

The statute contains several specific exceptions, none of which are potentially applicable here.

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 care programs under section 1128(b)(7) of the Act.

B. Analysis

For the following reasons, we conclude that the Proposed Arrangement would potentially violate the anti-kickback statute and the CMP.

First, the payment or subsidy of an expense that would ordinarily be borne by a patient constitutes remuneration to the patient. This is true whether the expense is the additional cost of non-local transportation (e.g., excess mileage charges) or the patient's cost-sharing obligation.

Second, the Proposed Arrangement is likely to influence patients to order or receive items or services reimbursable by Medicare or Medicaid. The Proposed Arrangement may influence the initial and subsequent choice of the Hospital for hospital services. For example, many of the patients who benefit from the Proposed Arrangement will be cardiac patients, who are likely to develop ongoing relationships with a hospital provider. The Proposed Arrangement may also influence patients to choose the Hospital's ambulance suppliers over other suppliers, whether for initial or future ambulance transports. The fact that the subsidized

ambulance services are not advertised directly to patients is not a meaningful safeguard; the availability of the reduced cost services will be known to patients' physicians, who may serve as indirect channels of information dissemination in these circumstances. Moreover, the Proposed Arrangement may operate in conjunction with advertising of the Hospital's inpatient and outpatient services to influence the choice of provider. The Requestor acknowledges that subsidizing patients' costs of ambulance transportation is likely to generate business for the Hospital, including Federal health care program business; indeed, that is the point of the Proposed Arrangement.

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that the Proposed Arrangement may constitute grounds for the imposition of civil monetary penalties under section 1128A(a)(5) of the Act. We also conclude that the Proposed Arrangement could potentially generate prohibited remuneration under the anti-kickback statute and that the OIG could potentially impose administrative sanctions on the Requestor or the Hospital 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 Arrangement. Any definitive conclusion regarding the existence of an anti-kickback violation requires a determination of the parties' intent, which determination is beyond the scope of the advisory opinion process.

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 Proposed 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 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.

Sincerely,

/s/

Lewis Morris
Chief Counsel to the Inspector General

A.L.E.R.T. is one of the only hospital-operated emergency air transports in Northwest Montana. From search and rescue missions to emergency retrievals in remote areas, A.L.E.R.T. is committed to its mission to assist the community and its visitors.



**Kalispell Regional
Medical Center**

KALISPELL REGIONAL HEALTHCARE



For more than three decades, the Kalispell Regional Healthcare Advanced Life-support and Emergency Rescue Team (A.L.E.R.T.) has provided a vital means to respond to a diverse range of emergency missions.

With more than 15,000 flights under its belt, the A.L.E.R.T. program serves the state of Montana from Cut Bank to Libby and Eureka to Ronan.

A.L.E.R.T. I features a Bell 407 helicopter with pilot, nurse, and medic. A.L.E.R.T. I has a 350-mile range, handling approximately 345 emergency transports per year.

A.L.E.R.T. is one of the only hospital-operated emergency air transports in Northwest Montana. From search and rescue missions to emergency retrievals in remote areas, A.L.E.R.T. is committed to its mission to assist the community and its visitors.

**Kalispell Regional Medical Center
A.L.E.R.T. Access**

310 Sunnyview Lane
Kalispell, Montana 59901

Phone (406) 751-4167

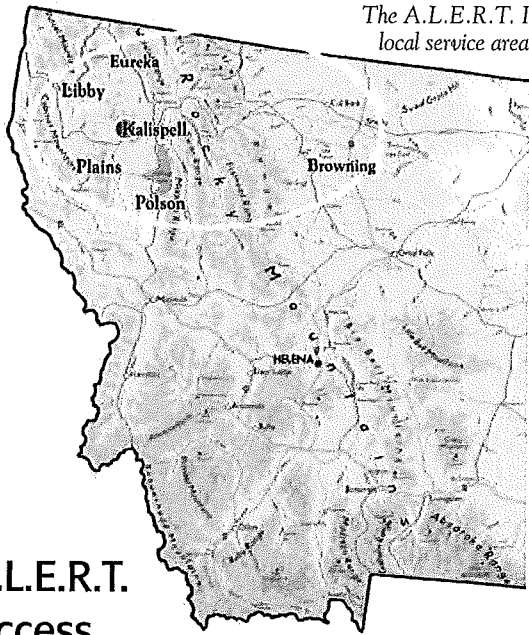
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KALISPELL REGIONAL HEALTHCARE

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The A.L.E.R.T. I
local service area

A.L.E.R.T. Access

A.L.E.R.T. Access is a membership program that provides members with helicopter emergency air transport. While Medicare and some insurance policies may provide partial coverage for emergency air transport, many do not.

When A.L.E.R.T. is requested by 911 or direct dispatch to fly a critically ill or injured patient to appropriate medical care, the portion of the A.L.E.R.T. bill that isn't covered by insurance or Medicare is paid through the A.L.E.R.T. Access membership.

How much does the membership cost?

A one-year membership in the A.L.E.R.T. Access program is \$59 per person or \$100 for a family.



expiration date. If you pay by check you will need to pay your membership fee before the membership will be renewed; it will not renew automatically. You will be notified of any changes in the membership fee or in any other terms and conditions of membership. No membership fee refunds are made.

I understand that the A.L.E.R.T. Access membership program may be cancelled at any time by Kalispell Regional Medical Center. A.L.E.R.T. will notify the Primary Member of any cancellation.

Signature _____ Date _____

Signature

Or you
Kalispell
A.L.E.R.T.
310 Su

Membership Agreement

I have read and agree to the benefits, terms, and conditions of the A.L.E.R.T. Access membership program as follows:

The A.L.E.R.T. Access membership covers only emergency transportation by the A.L.E.R.T. helicopter. A.L.E.R.T. helicopter emergency transports are based on medical necessity, not membership status. Standard A.L.E.R.T. protocols for emergency transportation of patients apply, including that transportation is to the closest medically appropriate facility. The pick-up site must be located in the A.L.E.R.T. I local service area, as shown in this membership brochure.

You must have insurance, health benefit plan, or Medicare coverage to become an A.L.E.R.T. Access member. The A.L.E.R.T. Access membership program is not an insurance policy. Its benefit is that you will not be billed for any costs of one qualifying emergency air transportation flight by A.L.E.R.T. during your membership year. If you have Medicare, insurance, or other benefit plan coverage for emergency air transportation, A.L.E.R.T. will accept payment from that payer as payment in full. If you have that coverage you may complete an insurance information form, now or if it is needed in the future. By signing this A.L.E.R.T. Access membership application you transfer to Kalispell Regional Medical Center the right to bill for and receive any payments under that coverage.

Member benefits take effect three business days after our receipt of a complete membership application form with full payment. Household members include the A.L.E.R.T. Access primary member, his or her spouse or domestic partner, and dependents claimed on the most recent year's income tax. The first person listed on the application form is designated as the "Primary Member." Anyone who joins a household and can be claimed as a dependent after the membership goes into effect can be included under the membership. Membership becomes effective three business days from the date the Primary Member notifies membership services of the addition.

If you have an emergency, call 911 immediately. The 911 service center will determine if an A.L.E.R.T. helicopter emergency dispatch will be made, using the A.L.E.R.T. protocols. Availability of the A.L.E.R.T. emergency service cannot always be guaranteed, due to conditions such as severe weather, geographic restraints or commitment to another patient transport. The A.L.E.R.T. Access Membership Program covers A.L.E.R.T. I helicopter emergency air medical transport services only. Charges or fees for ground ambulance and other forms of air transport are not included.

The membership benefit may not fully apply if a member is transported by an air ambulance company other than A.L.E.R.T. If reciprocal emergency transportation arrangements with other air emergency transportation programs are available in the future, you will be notified of the terms of those programs and how it will relate to your A.L.E.R.T. Access membership.

Your A.L.E.R.T. Access membership will not renew automatically. To ensure that there is no lapse in your benefits, please contact us prior to your membership expiration date. If you pay by check you will need to pay your membership fee before the membership will be renewed; it will not renew automatically. You will be notified of any changes in the membership fee or in any other terms and conditions of membership. No membership fee refunds are made.

I understand that the A.L.E.R.T. Access membership program may be cancelled at any time by Kalispell Regional Medical Center. A.L.E.R.T. will notify the Primary Member of any cancellation.

Signature _____ Date _____

Member

Mailing:

City, State

Phone

Email address

Date of

Single

Family information

Please list coverage for her spouse recent year

First and

Relation

First and

Relation

(use address)

Please check

Visa

Name and

Billing Address

Account

Security

Signature

Or you
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