

EXHIBIT 4
DATE 3/23/11
SB 278

Consultant White Paper

Montana Independent Health Alliance

Ambulance Memberships Program

September 8, 2009



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Montana Independent Health Alliance Ambulance Membership Programs White Paper

Table of Contents

OVERVIEW	1
RATIONALE FOR MEMBERSHIP PROGRAMS	2
MEMBERSHIP VS. INSURANCE	4
AIR MEDICAL MEMBERSHIP PROGRAMS IN THE NORTHWEST	6
MEMBERSHIP PROGRAM ACTUARIAL ASSESSMENT	8
ACTUARIAL CALCULATIONS	10
FACTS AND ASSUMPTIONS	10
EXAMPLE OF TESTING METHODOLOGY	10
<i>Membership Price</i>	11
<i>Member Payer Mix</i>	11
<i>Number of Members</i>	11
<i>Member Utilization</i>	11
<i>Average Air Medical Charge</i>	12
<i>Existing Collection Performance</i>	12
ANALYSIS	13
<i>Test #1:</i>	13
<i>Test #2:</i>	14
<i>Test #3:</i>	14
CONCLUSION:	15
RELEVANT LEGISLATION, OPINIONS, REGULATIONS, AND DOCUMENTS	16
CONCLUSION	17
TABLE 1. ANNUAL FEES	6
TABLE 2. AIR MEDICAL MEMBERSHIP PROGRAM (AAMMP) MEMBERS	7
TABLE 3. NETWORKS HONORING EACH OTHER'S MEMBERSHIP PROGRAMS	7
TABLE 4. PROJECT MEMBER PAYER MIX	11
TABLE 5. CURRENT AIR MEDICAL UTILIZATION RATE	12
TABLE 6. PROJECTED COLLECTION AMOUNTS BY PAYER	12
TABLE 7. MEMBERSHIP FEES AND CO-PAYMENT COMPARISON	13

Exhibits

- 1) 2008 TriCare Reimbursement Manual
- 2) 2006 Texas Department of Health Services Rule
- 3) 2003 OIG Advisory Opinion No. 03-11
- 4) 1991 Connecticut Department of Health and Human Services letter
- 5) 2003 Federal Register
- 6) 2006 Senate Bill 6231

Overview

For decades, ambulance services (air and ground) have used membership programs to supplement patient fees and other revenue sources to support operations. Membership programs are also referred to as subscription programs. The 2008 TRICARE Reimbursement Manual states that "Ambulance membership programs typically charge an annual fee for a subscription to an ambulance service."¹ (Exhibit 1) This is an important description, in that it differentiates ambulance membership programs from insurance products. (In this report we will use ambulance membership programs to refer to both air and ground ambulance. Insurers and federal health programs consider air medical programs as ambulance services.)

The structure of most membership programs is such that for an annual fee the member would satisfy any cost-share and deductible requirements. The air or ground ambulance provider would submit claims for reimbursement for the transport to the patient's insurer (commercial insurance, Medicare, etc.) and accept whatever payment received as payment in full.

Prior to 2002, ambulance services were not required to take Medicare assignment. This allowed the providers to balance bill the patient. With the implementation of the Medicare ambulance fee schedule, all ambulance providers are required to take assignment which means that the provider has to accept what Medicare allows as payment in full. For example, the retail base rate charge for an air provider may be \$10,000. Medicare allows approximately \$3,300 of which Medicare will pay 80% or \$2,640. The air medical service is then obligated to invoice the patient for the 20% co-insurance amount or \$528. Prior to the rule changes on ambulance services being required to take assignment on claims for Medicare beneficiaries, the air medical service could bill the patient the full amount not paid by Medicare or \$7,360. This is referred to as balance billing.

The purpose of this example is to demonstrate a primary reason membership programs were initially implemented in numerous jurisdictions throughout the country. The potential out-of-pocket expenses for patients could be significant. Consumers had a strong financial incentive to protect themselves for the potentially high ambulance bills and for what they considered a nominal annual fee they would be assured that would not be subject to any out-of-pocket expenses for ambulance transportation. The financial exposure of Medicare beneficiaries has been significantly reduced since 2002, but seniors remain as the most active group participating in ambulance membership programs.

¹ TRICARE Reimbursement Manual 1010.58-M, February 2008

Rationale for Membership Programs

Even with less financial risk to participants, membership programs continue to thrive. There are a number of reasons an air or ground ambulance service implements a membership program. They include:

Political—as rates continue to climb for emergency medical transportation, one means of “selling” rate increases to jurisdictions that may have rate approval authority and to the public is to offer a membership program that allows constituents to eliminate out-of-pocket costs of ambulance transportations.

Competition—membership programs can be used to differentiate one provider from another by offering this additional protection to the consumer. Conversely, a service may have to offer memberships to match a competitor’s program. This is particularly true for air medical providers since the high charges and potential co-insurance amounts for which the patients are responsible may be a deciding factor for choosing one provider over another.

Financial—successfully implemented membership programs can generate a significant amount of revenue for a service. In fact, the business model used by some air and ground ambulance providers requires the revenue from membership programs in order to be financially viable.

Consumer loyalty—membership programs create a direct link with members of the community and the provider. The members perceive that they have “ownership” in their local ambulance program and gain satisfaction in personally supporting the program financially. In many situations the membership program has been described as essential to keeping this important resource (i.e. medical helicopter) based in the community.

Marketing—the offering of a membership program provides for the opportunity for an ambulance service to have a self-funding marketing campaign. Media spots, direct mail, and community presentations allow for the direct connection to community members and their participation in the membership program funds these activities.

The origin of ambulance and air medical membership programs is unclear, but they are not unique to the US. Air Evac Lifeteam indicates that they modeled its membership program on the Swiss program Rega. Air medical membership programs are prevalent in Europe and Australia. Ground ambulance membership programs are common in Asia and South America.

A common motivation for developing ambulance membership programs in the U.S. is to be able to offer ground and air ambulances in locations where volume and fee-for-service alone cannot support the deployment of ambulances or helicopters. The trend in the rotary wing air medical service is to out-place helicopters in rural areas to provide proximity to ill and injured patients and then to transport the patients to the urban tertiary care centers. The outplacement of helicopters is an expensive operation and the reimbursement from insurance payers alone does not support the staffing and operation of a medical helicopter.

In fact, many locations would have decreased availability of emergency medical resources without the additional financial support provided by membership programs. Again, Air Evac Lifeteam reports having nearly 1,000,000 enrolled, resulting in a contribution of nearly \$55 million to support operations.

Membership vs. Insurance

The insurance commissioners in a few states have ruled that ambulance membership programs should be considered insurance, but the majority of states allow membership programs without being classified as insurance programs and eliminating the need for membership program providers from meeting the capitalization, financial reserves, and other stringent requirements imposed on insurance companies.

While there is a common objective of an ambulance membership programs and insurance in eliminating financial risk to the consumer, there are significant and important differences. First, ambulance membership programs are carefully structured to represent that membership fees are for the pre-payment of co-insurance and deductible amounts remaining after primary insurance has provided reimbursement. Most membership programs also indicate that the plan only applies to medically necessary transportation which would be covered by the primary health insurer to limit the providers' exposure to denied claims.

A more important factor that differentiates membership programs from insurance is that the benefit is generally only applicable for transportation provided by the service offering the membership program. While there are areas that have reciprocity between ambulance service providers' membership programs, there is no compensation between one of the reciprocal members and the others—they simply honor each other's programs. Primarily the membership benefit only applies when the consumer uses the service offering the program. For example, if a patient needs to be transported by helicopter from one hospital to another for medically necessary care and there are two air providers in the area and if the patient is a member of one provider's program but is transported by the other service, the patient would be responsible for the co-insurance and deductibles. For this reason, the membership programs are not considered insurance paying for a particular type of medical care, but are defined as a subscription to a particular ambulance service.

There is also an argument that states do not have the right to govern air medical membership programs. The argument is that states are precluded from involvement due to the Airline Deregulation Act, 49 U.S.C. Section 41712 (ADA). The ADA preempts any "law, regulation, or other provision having the force and effect of law related to price, route, or service of an air carrier." One air operator's attorney's letter to the Texas Department of State Health Services dated December 15, 2006 outlines their argument to allow membership programs. See Exhibit 2.

The difference between membership programs and insurance is not clearly evident and is subject to interpretation. The most compelling evidence that ambulance membership programs are not considered insurance is that the vast majority of states allows ambulance membership programs and do not subject them to the same stringent requirements applied to insurance companies and products and providers offering membership programs do not compensate other providers of ambulance service for their members.

One air and ground ambulance service specifically has the following disclaimer on their website regarding their membership program.

"WARNING: This Ambulance Plan is not an insurance program. It will not compensate or reimburse another ambulance company that provides emergency transportation to you or your family. This may occur when the 911 Emergency System has independently determined that another company could provide more expeditious service or is next in the rotation to receive a call. This might also occur when the Ambulance Plan is unable to perform within a medically appropriate time frame due to a mechanical or maintenance problem or being on another call." ²

A second air medical provider includes this response to the question of the membership program being considered insurance:

"Is an Air Evac Lifeteam membership considered insurance?"

No. Air Evac Lifeteam is not an insurance company. An Air Evac Lifeteam membership is not an insurance policy and cannot be considered as secondary insurance coverage or as supplemental coverage to any insurance policy. Membership provides prepaid protection against covered Air Evac Lifeteam air ambulance transportation costs that exceed a member's health insurance or medical benefits."³

² http://www.cal-ore.com/membership_information.htm

³ <http://www.lifeteam.net/Membership/overview.aspx>

Air Medical Membership Programs in the Northwest

There is no common source for identifying all air medical programs that have implemented membership programs. We have focused our review on the Northwest United States. The following are few examples of air services with membership programs. The annual fees are either family or household amounts based on the individual organization's descriptions.

Table 1. Annual Fees

Service	Location	Annual Fee
Airlift Northwest	Seattle, WA	\$79
Northwest Medstar	Spokane, WA	\$59
Reach Air Medical Services	CA, OR, WA	\$45
Enloe Flight Care	Chico, CA	\$45
Care Flight	Reno, NV	\$55
Life Flight	Boise, ID	\$50
Wyoming Life Flight	Casper, WY	\$60
Care Flight	Aberdeen, SD	\$49
Sanford Health	Sioux Falls, SD	\$59
Air Life	Bend, OR	\$50
Cal-Ore Life Flight Air & Ground Ambulance	Crescent City, CA	\$65
FireMed	Eugene, OR	
	Ground	\$52
	Ground plus air	\$87

At least two networks have been established in the western U.S. to honor the network participants' membership programs. This reciprocity allows the members of one service to be transported by another and still receive the benefit of prepayment of co-insurance and deductibles. This establishes large areas within which a patient can be transported and still benefit from membership.

One such program has been established by The Association of Air Medical Membership Programs, AAMMP. The members include:

Table 2. Air Medical Membership Program (AAMMP) Members

Program	Location
Air Life	Bend, OR
AirLift NorthWest	Seattle, WA
Air St. Luke's	Boise, ID
CalStar	McClellan, CA
Care Flight Reno	Reno, NV
Enloe Flight Care	Chico, CA
Life Flight Network	Portland, OR
Northwest Medstar	Spokane, WA
Portneuf Life Flight	Pocatello, ID
St. Alphonsus Life Flight	Boise, ID

Another network honoring each other's membership programs include:

Table 3. Networks honoring each other's Membership Programs

Program	Location
Reach Air Medical Services	Santa Rosa, CA
Enloe Flight Care	Chico, CA
Cal-Ore Life Flight Air & Ground Ambulance	Crescent City, CA

The coverage by air medical programs with membership programs surrounds Montana except no programs were found in North Dakota. Membership programs were identified for Idaho, Wyoming, and South Dakota.

Membership Program Actuarial Assessment

The federal government has recognized ambulance membership programs as a means for the patients to pre-pay their cost-share portion of their ambulance bill. Even so, the Office of Inspector General (OIG) and Centers for Medicare and Medicaid Services (CMS) have expressed concerns that these programs may represent a routine waiver of co-insurance and deductibles which is not allowed. The Office of Inspector General has opined that the "routine waiver of Medicare Part B cost-sharing amounts"⁴ may implicate the anti-kickback statute. (Exhibit 3) The OIG further states that:

*"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."*⁵

Previously, the Department of Health & Human Services addressed ambulance subscription agreements in an August 14, 1991 letter. (Exhibit 4) This letter states that:

*"in analyzing the legality of the subscription agreements...it would be necessary to determine whether the amounts charged as "premiums" by the ambulance companies are a reasonable assessment of the actuarial risk faced by these companies. In other words, it would be necessary to determine whether the amounts charged as premiums are a reasonable approximation of the amounts that an average beneficiary would expect to spend for co-payments and deductibles over the period covered by the subscription agreement."*⁶

⁴ OIG Advisory Opinion No. 03-11, May 21, 2003

⁵ Ibid.

⁶ Letter from DHHS to Lawrence J. DeNardis, August 14, 1991

The OIG declines to provide specific procedures to follow in order to actuarially or historically project the amounts that members or beneficiaries would likely pay for co-payments in order to compare with membership fees. The OIG also does not provide a definition for "aggregate" used in the Advisory Opinion.

Actuarial Calculations

Interpretation of the OIG Advisory Opinion No. 03-11 and the 1991 DHHS letter lends to three potential tests for evaluating the legality of an ambulance subscription program. The OIG Opinion indicates that either of the first two tests would suffice, but in order to provide a conservative assessment, it is wise to make projections based on all three possible options. The three tests are:

1. 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.
2. 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.
3. Amounts charged as membership fees are a reasonable approximation of the amounts that an average beneficiary would expect to spend for co-payments and deductibles over the period covered by the subscription agreement.

Facts and Assumptions

Specific facts and assumptions need to be ascertained in order to accomplish the described testing. These include:

- Membership Price (includes multiple household members)
- Member Payer Mix
- Number of Members
- Member Utilization
- Average Air Medical Charge
- Existing Collection Performance

Example of Testing Methodology

The following provides an example of how these three tests can be applied to an air medical provider's membership program to ensure that it meets the OIG and CMS tests for the membership revenue to approximate the amount that would have been paid by members

through their cost-sharing requirements. The specific numbers, payer mix, and other items in this example are hypothetical, but are consistent with our experience.

Membership Price

In this example the price for each membership is \$59.00.

Member Payer Mix

The payer mix used in this example are included in the table below and reflect that Medicaid recipients' air transportation is covered by the various state Medicaid programs and that they do not need nor should they purchase memberships in the air medical program.

Table 4. Project Member Payer Mix

Payer	Percent of Members
Medicare	60%
Commercial Insurance	30%
Un-insured	10%
Medicaid	0%

Number of Members

The estimated number of potential households in the service area is 1,071,000. (Service area population divided by 2.48⁷)

An initial roll-out of the membership program is expected to result in 4,000 members. This represents a penetration of 0.4% of the households and is a realistic estimate for the first year.

Member Utilization

The estimated utilization of the population in the service area is 0.088%. This includes calculations for estimates of competitor flights in the service area and conservatively restricts the service area to account for the impact of other air medical services with overlapping coverage. The following table shows the existing utilization rate.

⁷ U.S. Census Bureau, 2000 Census population per household.

Table 5. Current Air Medical Utilization Rate

Air Medical Transports	2,331
Service Area Population	2,655,822
Utilization Rate	0.088%

Using a weighted calculation to determine the number of people per household of members, we assumed that Medicare beneficiaries had on average 2 members of their household and the commercial and uninsured had an average of 2.48 members per household. Multiplying the weighted number of individuals per household for members by the air medical utilization rate for the service area we arrived at a projected utilization rate for members of 0.19%.

For the purpose of projections, the utilization rate for members is estimated at 2.0%. This would result in the transport of 80 members per year and is more than 10 times the current air medical utilization rate in the sample service area.

Average Air Medical Charge

In this example we will use an average air medical charge of approximately \$9,300.

Existing Collection Performance

The sample service collects approximately 80% of the billed charges for patients with commercial insurance. The average amount paid by Medicare is approximately \$4,000 and the amount collected from patients who do not have insurance represents a very small percentage. Table 6 shows the average charge and the average amount collected on each transport that will be used in the membership tests.

Table 6. Projected Collection Amounts by Payer

Payer	Average Charge	Average Payment	Patient Responsibility
Commercial Ins	\$9,300	\$7,440	\$1,860
Medicare	\$9,300	\$4,000	\$1,200
Uninsured	\$9,300	\$0	\$9,300

The Medicare payments reflect actual payments from Medicare and the average co-payment amount indicated is current experience of the example program. In testing, we have opted to not include the small percentage of payments collected from uninsured patients.

Analysis

The following analyses provide the results of the three possible tests of legality inferred from the OIG Opinion and the DHHS letter. Table 7 contains the membership payer mix, the number of expected members, the projected membership fees, and the co-payments expected to be the responsibility of the patients.

Table 7. Membership Fees and Co-payment Comparison

Payer	Number of Members	Membership Payments	Total Co-payments
Medicare	2,400	\$141,600	\$57,600
Commercial Ins	1,200	\$70,800	\$44,640
Uninsured	400	\$23,600	\$74,400
Medicaid	0	\$0	\$0
Total		\$236,000	\$176,640

Test #1:

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.

Total membership payments for all members are estimated at \$236,000.

The total co-payments are the amount due after payment from primary insurance. We made no adjustments for likely collections or the payments made from co-insurance or supplemental policies. Total patient responsibility is estimated at \$176,640.

The aggregate amount collected from membership fees exceeds the amounts for which the patients are responsible by 34% and meets the test inferred by the OIG. The amount that could reasonably be expected to be collected from the patients' cost-sharing responsibilities is less than that collected from membership fees.

On average, patients should expect to pay \$44.16 per year in co-payment amounts. This amount is less than the membership fees of \$59.00 and therefore the test is met.

Test #2:

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.

Total membership payments from Medicare beneficiaries are estimated at \$141,600.

The total co-payments are the amounts due after payment from Medicare. We made no adjustments for likely collections or the payments made from co-insurance or supplemental policies. Total patient responsibility is estimated at \$57,600.

The aggregate amount collected from membership fees exceed the amounts for which the patients are responsible by 146% and meets the test inferred by the OIG. The amount that could reasonably be expected to be collected from the patients' cost-sharing responsibilities is less than that collected from membership fees.

On average, Medicare beneficiaries should expect to pay \$24.00 per year in co-payment amounts. This amount is less than the membership fees of \$59.00 and therefore the test is met.

Test #3:

Amounts charged as premiums are a reasonable approximation of the amounts that an average beneficiary would expect to spend for co-payments and deductibles over the period covered by the subscription agreement.

This test is a slight variation of Test #2 and focuses on the average rather than the aggregate.

Total membership payments from Medicare beneficiaries are estimated at \$141,600.

The total co-payments are the amounts due after payment from Medicare. We made no adjustments for likely collections or the payments made from co-insurance or supplemental policies. Total patient responsibility is estimated at \$57,600.

The aggregate amount collected from membership fees exceeds the amounts for which the patients are responsible by 146% and meets the test inferred by the OIG. The amount that could reasonably be expected to be collected from the patients' cost-sharing responsibilities is less than that collected from membership fees.

On average, Medicare beneficiaries should expect to pay \$24.00 per year in co-payment amounts. This amount is less than the membership fees of \$59.00 and therefore the test is met.

Conclusion:

The three tests of legality of membership programs have been evaluated based on the conservative and realistic assumptions defined in this report. In this example the membership program meets the intent of CMS and the OIG in that the fees collected from memberships exceed the amount that would be due from patients from their cost-sharing obligations. In fact, member utilization would have to exceed 4.9% before the average cost-sharing obligations of Medicare beneficiaries would exceed the membership fees and 2.65% before the entire group of members would have aggregate cost-sharing obligations that approach the aggregate membership fees collected.

Relevant Legislation, Opinions, Regulations, and Documents

A number of documents have been cited and referred to in this report. The most relevant documents are:

- The OIG Advisory Opinion No. 02-11 dated May 21, 2003
- The DHHS Letter dated August 14, 1991 (Exhibit 4)
- Federal Register / Vol. 68. No 56/Monday, March 24, 2003; "OIG Compliance Program Guidance for Ambulance Suppliers (Exhibit 5)

The last of the documents represents the Office of Inspector General's Compliance Program Guidance for Ambulance Suppliers. The Guidance expresses concern regarding ambulance membership programs but goes on to state that membership programs must meet the criteria of the amount of membership revenue "reasonably approximate the amounts that the subscribers or members would expect to spend for cost-sharing amounts."

A few states have state legislation which governs membership programs. At least one only allows fire services to provide memberships and mandates reciprocity. Others are less restrictive. The Washington legislation represents an override of the Insurance Commissioner's determination that membership programs are insurance products. The legislature passed specific legislation which excluded air medical membership programs from being classified as insurance. See Exhibit 6.

Conclusion

A cursory internet review revealed more than 30 states with active ambulance membership programs. These programs continue to expand and are essential in financially supporting some operations, particularly in rural areas. The membership programs develop a strong loyalty and feeling of community support among members and are valued by these constituents.

Ambulance membership programs should not be considered insurance, particularly since there is no indemnification or payment to other healthcare providers providing ambulance transportation. The benefits of the membership programs are only accrued to the members if they use the service providing the membership or with reciprocal partners.

The federal government is concerned that membership programs may be used to skirt the law and may represent a routine waiver of the co-insurance and deductibles. The OIG has stated that an ambulance membership program must meet the requirement of collecting in membership fees a close approximation of what the patients would have paid for co-insurance and deductibles. A well designed membership program should be able to fulfill these requirements as long as the membership fees are at a reasonable level. A nominal membership fee would not meet the tests required by the OIG.

Membership programs should be considered an important part of the business plan of many air medical providers—they offer value to the service's patients and offer an opportunity to generate additional funds to ensure availability of essential emergency medical services provided by air medical and ground ambulance services.

Exhibit 1

2008 TriCare Reimbursement Manual

Chapter 1

Section 14

Ambulance Services

Issue Date: August 26, 1985

Authority: 32 CFR 199.4(d)(3)(v)

1.0 APPLICABILITY

This policy is mandatory for reimbursement of services provided by either network or non-network providers. However, alternative network reimbursement methodologies are permitted when approved by the TRICARE Management Activity (TMA) and specifically included in the network provider agreement.

2.0 ISSUE

How are ambulance services to be reimbursed?

3.0 POLICY

3.1 General.

3.1.1 Allowable charge/cost methodology will be used to adjudicate ambulance claims. Information from ambulance companies in each service area is to be used in the development of prevailing base rate screens.

3.1.2 In contractor service areas where suppliers routinely bill a mileage charge for ambulance services in addition to a base rate, an additional payment based on prevailing mileage charges may be allowed. Charges for mileage must be based on loaded mileage only, i.e., from the pickup of a patient to his/her destination. It is presumed that all unloaded mileage costs are taken into account when a supplier establishes its basic charge for ambulance services and its rate for loaded mileage.

3.1.3 When there are both Basic Life Support (BLS) and Advanced Life Support (ALS) ambulances furnishing services in a state, separate prevailing profiles are to be developed for each type.

3.1.3.1 BLS vs. ALS. There are situations when an advanced life support ambulance is provided but, based on hindsight, it appears that a BLS would have sufficed. In such cases, the question is whether ALS should be billed (since it was provided) or whether BLS should be billed (since that was the minimum service that would have met the patient's needs).

3.1.3.1.1 In localities which offer only ALS ambulance service, the type of vehicle used, rather than the level of service, is normally the primary factor in determining TRICARE payments. Therefore, ALS may be billed for all transports if only ALS is offered in the locality. However, if the

TRICARE Reimbursement Manual 6010.58-M, February 1, 2008

Chapter 1, Section 14

Ambulance Services

provider has established a different pattern of billing for the level of service provided, then the contractor may recognize the difference and allow payment to be based upon the level of services rendered rather than the type of vehicle and crew. In other words, in an all ALS environment where the provider has established different billing patterns based on the level of care (e.g., emergency vs. non-emergency), the contractor may allow one amount for emergency and another for non-emergency.

3.1.3.1.2 If the company has only ALS vehicles but BLS and ALS vehicles operate in the locality, then it is the level of service required which will determine the amount allowed by TRICARE. Thus, even though the provider transported via ALS, it may be paid ALS or BLS rates, based on the following:

- If local ordinances or regulations mandate ALS as the minimum standard of patient transportation, then ALS reimbursement will be made.
- If the ALS was the only vehicle available, then the transfer may be reimbursed at the ALS level at the discretion of the contractor.
- If the company receives a call and dispatches ALS, although BLS was available, then BLS will be paid if the patient's condition was such that BLS would have sufficed. There must be justification on the claim supporting the use of the ALS ambulance in those areas where both ALS and BLS ambulances are available and no state or local ordinances are in effect mandating ALS as the minimum standard transport.

3.1.3.2 Information will be shared among the Managed Care Support Contractors (MCSCs) regarding local and state ordinances/laws affecting payment of advanced life support ambulance transfers within their respective jurisdictional areas/regions, the sharing of this information among MCSCs should allow for the accurate processing and payment of beneficiaries traveling outside their contract areas.

3.1.4 For ambulance transportation to or from a Skilled Nursing Facility (SNF), the provisions in Chapter 8, Section 2, paragraph 4.3.13.5 will apply to determine if ambulance costs are included in the SNF Prospective Payment System (PPS) rate.

3.2 Charges made in addition to base rates and mileage charges. The following guidelines shall be used when an ambulance supplier bills for other than the base rate and a mileage charge.

3.2.1 Reusable devices and equipment such as backboards, neckboards and inflatable leg and arm splints are considered part of the general ambulance services and shall be included in the cost of, or charge for, the trip. Any additional charge for such items is to be denied.

3.2.2 A separate reasonable charge based on actual quantities used may be recognized for non-reusable items and disposable supplies such as oxygen, gauze, dressings and disposable linens required in the care of the patient during his trip.

3.2.3 When separate charges are billed for specific covered ALS services, allowable charge profiles for each such service should be developed. When a claim is filed for any one or a combination of such covered services, the maximum allowable charge for the total ambulance

TRICARE Reimbursement Manual 6010.58-M, February 1, 2008

Chapter 1, Section 14

Ambulance Services

service will be the sum of the allowable amounts for the supplier's base rate, any mileage charges, and the specific specialized service(s). When the contractor does not have a profile for the specialized service, it may use the profile for an equivalent service as a guideline for determining an appropriate allowance. For example, if an ambulance supplier submits a separate additional charge for covered EKG monitoring and the contractor does not have a prevailing profile for such charges submitted by an ambulance supplier, the contractor may use the profiles for CPT¹ procedure codes 93012 and 93270 as guidelines for determining the allowable amount.

3.2.4 Although separate charges may be allowed for specific ALS services, no separate charge can be allowed for the personnel manning the ALS, even though they are obviously more highly qualified than the personnel in a basic ambulance. Their costs are to be included in the base and mileage charges with the exception of paramedic ALS intercept services (PI) under the following conditions:

3.2.4.1 Be furnished in an area that is designated as a rural area by any law or regulation of the State or that is located in a rural census tract of a metropolitan area.

3.2.4.2 Be furnished under contract with one or more volunteer ambulance services that meet the following conditions:

- Are certified to furnish ambulance services;
- Furnish services only at the BLS level; and
- Are prohibited by State law from billing for any service.

3.2.4.3 Be furnished by a paramedic ALS intercept supplier that meets the following conditions:

- Is certified to furnish ALS services.
- Bills all the recipients who receive ALS intercept services for the entity, regardless of whether or not those recipients are Medicare beneficiaries.

3.3 The cost-sharing of ambulance services and supplies will be in accordance with the status of the patient at the time the covered services and supplies are rendered (32 CFR 199.4(a)(4)).

3.3.1 Ambulance transfers from a beneficiary's place of residence, accident scene, or other location to a civilian hospital, Military Treatment Facility (MTF), Veterans Affairs (VA) hospital, or SNF will be cost-shared on an outpatient basis. Transfers from a hospital or SNF to a patient's residence will also be considered an outpatient service for reimbursement under the program. A separate cost-share does not apply to ambulance transfers to or from a SNF, if the costs for ambulance transfer are included in the SNF PPS rate (see Chapter 8, Section 2, paragraph 4.3.13.5).

3.3.2 Ambulance transfers between hospitals (acute care, general, and special hospitals; psychiatric hospitals; and long-term hospitals) and SNFs will be cost-shared on an inpatient basis.

3.3.3 Under the above provisions, for ambulance transfers between hospitals, a nonparticipating provider may bill the beneficiary the lower of the provider's billed charge or 115% of the TRICARE allowable charge.

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TRICARE Reimbursement Manual 6010.58-M, February 1, 2008

Chapter 1, Section 14

Ambulance Services

3.3.4 Transfers to a MTF, VA hospital, or SNF after treatment at, or admission to, an emergency room or civilian hospital will be cost-shared on an inpatient basis, if ordered by either civilian or military personnel.

3.3.5 Medically necessary ambulance transfers from an Emergency Room (ER) to a hospital more capable of providing the required level of care will also be cost-shared on an inpatient basis. This is consistent with current policy of cost-sharing ER services as inpatient when an immediate inpatient admission for acute care follows the outpatient ER treatment.

3.3.6 Cost-share amounts for ambulance services are included in Chapter 2, Section 1.

4.0 POLICY CONSIDERATIONS

4.1 Ambulance Membership Programs.

4.1.1 Ambulance membership programs typically charge an annual fee for a subscription to an ambulance service. The ambulance provider agrees to accept assignment on all benefits from third party payers for medically necessary services. By paying the annual fee, the covered family members pay no additional fees (including third party cost-shares and deductibles) to the ambulance service.

4.1.2 When a beneficiary pays premiums to a pre-paid ambulance plan, the premiums are considered to fulfill the beneficiary's cost-share and deductible requirements. Under this arrangement, the ambulance membership program becomes analogous to a limited supplemental plan.

4.2 When an ambulance company bills a flat fee for ambulance transport within its service area, reimbursement will be at the lesser of the billed amount (flat fee) or the statewide prevailing for Healthcare Common Procedure Coding System (HCPCS) codes A0426 through A0429 subject to applicable beneficiary cost-sharing.

4.3 The TRICARE national allowable charge system used to reimburse professional services does not apply to ambulance claims. The above reimbursement guidelines are to be used by the contractors.

4.4 Itemization requirements are dictated by the particular HCPCS codes used in filing an ambulance claim.

- END -

Exhibit 2

**2006 Texas Department of Health
Services Rule**

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December 15, 2006

VIA FEDERAL EXPRESS
VIA FACSIMILE

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CLIENT/MATTER NUMBER
999999-9999

Mr. Donald Jansky
Assistant General Counsel
Office of General Counsel
Texas Department of State Health Services
1100 W. 49th Street
Austin, TX 78756-3199

Re: EMS Subscription Rule

Dear Mr. Jansky:

This firm represents PHI Air Medical Group ("PHI"), a national FAA-certificated air ambulance carrier with operations in Texas. PHI representatives were present during the Governor's EMS and Trauma Advisory Council meetings in Dallas on November 18 and 19 and listened with great interest to your preliminary comment that the State may not be able to regulate air ambulance subscription programs based upon federal preemption. PHI wishes to initiate a subscription program in some of the local Texas jurisdictions in which it operates, and has sought our advice on this matter.

We have reviewed the Texas regulation governing subscription programs, 25 TX. ADC Section 157.11 (the "Regulation"), and are aware of the pending amendments. We agree with your preliminary analysis and respectfully submit that the Regulation, both in its current form and with the proposed amendments, is preempted as applied to air ambulance carriers by Section 105 of the Airline Deregulation Act, 49 U.S.C. Section 41713 (the "ADA"). Therefore, we do not believe that PHI or other air ambulance carriers should be obligated to comply with it. PHI has requested, however, that we seek your concurrence with our views prior to expanding its subscription program into Texas. We will summarize the basis for our conclusion and then provide a detailed analysis. We would greatly appreciate a response within 30 days indicating whether you concur.

SUMMARY

The ADA preempts any "law, regulation or other provision having the force and effect of law related to a price, route, or service of an air carrier." Its purpose is to promote competition and efficiency among air carriers for the benefit of consumers, through lower prices and enhanced service.

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Mr. Donald Jansky

December 15, 2006

Page 2

As you know, in a typical subscription program, an air carrier offers an alternative (discounted) rate structure to its prospective passengers pursuant to which they essentially prepay that part of the carrier's fare that is not covered by insurance. In exchange, the carrier agrees to accept what the passenger's insurer pays as payment in full at the time of transport. In addition to the savings achieved by members, carriers who establish effective membership programs may be able to reduce their overall rate structure to all their passengers, and/or provide a higher level of service.

Any state regulation that limits or burdens a carrier's ability to implement such a program would, on its face, be "related to a price, route, or service of an air carrier," and would therefore fall squarely within the purview of the ADA's preemption. Such regulation would also frustrate the intent of the ADA by precluding the discounts and potentially enhanced level of service inherent in subscription programs. For these reasons, the Regulation as a whole is expressly preempted by the ADA as applied to air ambulance carriers. When looked at individually, the various parts of the Regulation also fail to survive preemption under the ADA.

A more detailed analysis follows:

DISCUSSION

1. The Preemption Provision of the ADA.

As you are aware, air ambulance carriers are extensively regulated by the Federal Aviation Administration ("FAA") under the Federal Aviation Act, which was amended by the ADA in 1978. Congress enacted the ADA after "determining that 'maximum reliance on competitive market forces' would best further 'efficiency, innovation and low prices' as well as 'variety and quality' . . . of air transportation services." Morales v. Trans World Airlines, Inc., 504 U.S. 374, 378 (1992). To achieve this goal, Congress included a broad preemption provision in the ADA intended to protect air carriers from state regulation that might hinder competition. That section provides, in relevant part, as follows:

a state, political subdivision of a state, or political authority of at least two states may not enact or enforce a law, regulation or other provision having the force and effect of law related to a price, route, or service of an air carrier that may provide air transportation under this subpart.

49 U.S.C. Section 41713(b).

The seminal Supreme Court case interpreting this provision, Morales v. Trans World Airlines, supra, construed it expansively. In that case, several airlines sued to enjoin State Attorneys General in Texas and other states from enforcing state deceptive practices laws against airline advertising and related conduct. The Attorneys General, acting through the National Association of



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Mr. Donald Jansky
December 15, 2006
Page 3

Attorneys General ("NAAG"), had adopted guidelines that contained detailed standards governing, among other things, the content and format of airline fare advertising, the awarding of premiums to regular customers (i.e., "frequent flyers"), and the payment of compensation to passengers who voluntarily yield their seats on overbooked flights. In striking down the NAAG guidelines, the Supreme Court stated, in relevant part, as follows:

[The ADA] expressly preempts the states from enacting or enforcing any law, rule, regulation, standard or other provision having the force and effect of law relating to rates, routes, or services of any air carrier. For purposes of the present case, the key phrase, obviously, is "relating to." The ordinary meaning of these words is a broad one - "to stand in some relation; to have bearing or concern; to pertain; refer; to bring into association with or connection with," Black's Law Dictionary 1158 (5th ed. 1979) - and the words thus express a broad pre-emptive purpose. . . . State enforcement actions having a connection with or reference to airline "rates, routes or services" are preempted under [the ADA].

Morales, 504 U.S. 374, 383.

The Court made it clear that preemption under the ADA can be either express or implied. Implied preemption can occur if a state regulation has a "forbidden significant effect upon fares." Restrictions on advertising have such an effect because "[a]dvertising serves to inform the public of the . . . prices of products and services, and thus performs an indispensable role in the allocation of resources. [citations] Restrictions on advertising serve to increase the difficulty of discovering the lowest cost seller. . . and reduce the incentive to price competitively." Morales, 504 U.S. 374, 389.

The Morales court further observed that a state law need not be one specifically addressed to the airline industry to be preempted by the ADA as a law "relating to rates, routes, or services" of an air carrier; the ADA expressly preempts all laws "relating to" rates, routes or services, including laws of general applicability that fall within its sphere, even if those laws are consistent with the ADA's substantive requirements. Morales, 504 U.S. 374, 389; see also, Lawal v. British Airways PLC, 812 F.Supp. 713 (S.D. Tex. 1992)

Numerous subsequent decisions have followed the Supreme Court's lead in broadly construing the preemptive effect of the ADA. Any state law or rule that could cause rates in one jurisdiction to differ from those in other jurisdictions is preempted. Illinois Corporate Travel, Inc. v. American Airlines, Inc., 682 F.Supp. 378 (N.D. Ill. 1988), affirmed, 889 F.2d 751 (7th Cir. 1989). Preemption has been deemed to apply in numerous cases in which states have attempted to impose unfair or deceptive business practices prohibitions and similar statutory regimes of general application upon air carriers. See, e.g., American Airlines, Inc. v. Wolens, 513 U.S. 219 (1995); Sam L. Majors Jewelers v. ADX, Inc., 117 F.3d 922 (5th Cir. 1997); Trujillo v. American Airlines,

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Mr. Donald Jansky
December 15, 2006
Page 4

Inc., 938 F.Supp. 392 (N.D. Tex. 1995), affirmed without op., 98 F.3d 1338 (5th Cir. 1996). Similarly, several courts have followed Morales in finding that advertising by carriers is out of bounds for state regulators. For example, in Musson Theatrical, Inc. v. Federal Express Corporation, 89 F.3d 1244, amended on denial of rehearing on other grounds, 1998 W.L. 117980 (6th Cir. 1998), rehearing en banc denied (January 15, 1998), the court held that Congress intended the Federal Department of Transportation to be the sole legal control on possible advertising fraud by air carriers.

In addition to striking down regulations that implicate advertising and rates directly, the courts have also struck down regulatory provisions purporting to control the entry of air carriers, including air ambulance carriers, into state or local jurisdictions. For example, in Hiawatha Aviation of Rochester, Inc. v. Minnesota Dept. of Health, 389 N.W.2d 507 (Minn. 1986), the court held that the state of Minnesota was preempted from controlling entry into the field of air ambulance service by the ADA. In a more recent case, a federal district court in Missouri found that the ADA preempted that portion of Missouri's ambulance licensing law that mandated a determination that the "public convenience and necessity" required a proposed ambulance service, as a condition of granting licensure. Rocky Mountain Holdings vs. Ronald W. Cates, Director, Missouri Department of Health, No. 97-4165-CV-C-9 (W.D. Mo. Central Division 1997). The court held that "in making the determination of public convenience required by the Missouri provision, the state is making decisions having a connection with or reference to the rates, routes or services of an air carrier." Slip Op., pages 13 and 14.

As the touchstone for finding a wide range of regulatory constraints to be invalid, the courts routinely note that the ADA's preemption clause serves the statute's goal of promoting maximum reliance on competitive market forces, as opposed to state regulation, in shaping the contours of the air carrier industry. See, e.g., Branche v. Air Tran Airways, Inc., 342 F.3d 1248 (11th Cir. 2003). In other words, any regulation that hinders competition among air carriers is suspect and must fall if it relates to rates, routes or services. See generally, 149 ALR Fed. 229 ("Construction and application of Section 105 Airline Deregulation Act, pertaining to preemption of authority over prices, routes and services.")

Notably, the FAA itself has been active in opposing state regulation of air ambulance carriers that intrudes upon its authority under the ADA and other provisions of the Federal Aviation Act. In a case currently pending in Tennessee, the Department of Justice very recently filed a "Statement of Interest of the United States of America" on behalf of the FAA in which it urged the court to strike down Tennessee regulations purporting to regulate safety and related equipment of air ambulance carriers. See "Statement of Interest of the United States of American" in Air-Evac EMS, Inc. v. Kenneth S. Robinson, M.D., Commissioner of Health, and Tennessee Board of Emergency Medical Services, No. 3:06-0239 (M.D. of Tenn.). As one of its reasons for opposing the Tennessee regulations, the Department of Justice states:

In 1978 Congress included a provision within the ADA expressly prohibiting a state from enacting any regulation "relating to rates,

Mr. Donald Jansky
December 15, 2006
Page 5

routes or services of any air carrier." [citing Morales and the ADA]. This express preemption provision is interpreted broadly, applying even to those state laws that have only an indirect effect on rates, routes or services. See Morales, 504 U.S. at 383-384, 386 . . . Accordingly, the preemption provision applies to any state regulation having a connection with or reference to a price, route or service. *Id.* at 384.

Statement of Interest of the United States of America, *supra*, at 9-10.

Finally, Texas state courts have also expansively interpreted the ADA's preemption provision. See Delta Airlines, Inc. v. Black, 116 S.W.3d 745 (Tex. 2003) (finding that an airline's boarding procedures and seating policies relate to "services" provided to customers for purposes of the preemption provision) and Shupe v. American Airlines, Inc., 893 S.W.2d 305 (Tex. App. Ft. Worth 1995), writ granted (August 1, 1995) and judgment aff'd on other grounds, 920 S.W. 2d 274 (Tex. 1996) (finding that claims under the Texas Deceptive Practices Act against an airline were preempted by the ADA).

2. The Texas Subscription Regulation.

As noted above, a subscription program is essentially an alternative rate structure adopted by an air ambulance carrier. In such programs, carriers agree that they will discount their rates by accepting what the passengers' insurers pay as payment in full in exchange for an advance payment of a membership fee. In addition to reduced rates for members, the carrier's overall rate structure for all of its passengers may be favorably affected, and the carrier may have the resources to purchase better equipment or to pay more highly trained staff. In restricting such programs undertaken by air carriers, the Regulation falls clearly and squarely within the purview of the ADA's preemption provision invalidating any state or local law that "relates to" rates and services.

Although we do not believe it is necessary to parse the various provisions of the Regulation to reach the conclusion that preemption applies, a closer examination of its specific provisions demonstrates that each is expressly or impliedly preempted by the ADA under the precedents discussed above.

First, the requirement for a written authorization from the bureau chief elected official of the governmental entity in which the carrier proposes to operate provides unfettered and absolute authority to that official to preclude the carrier from offering an alternative membership rate structure within its jurisdiction. As noted above, the ADA has been construed as prohibiting regulatory schemes which require different rates and rate structures within different jurisdictions. Illinois Corporate Travel, Inc. v. American Airlines, Inc., 682 F.Supp. 378 (N.D. Ill. 1988), affirmed, 889 F.2d 751 (7th Cir. 1989). This provision of the Regulation not only provides elected officials in each local jurisdiction with unfettered authority over an air carrier's rate structure, it also creates the



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Mr. Donald Jansky
December 15, 2006
Page 6

possibility that the carrier may be required to use a different rate structure in each jurisdiction to satisfy the requirements of such officials. It is therefore preempted on those grounds.

This part of the Regulation must also fall under the rationale of the court decisions in Minnesota and Missouri, in which regulations permitting state or local officials to serve as gatekeepers of the air ambulance marketplace based on economic considerations were found preempted. Hiawatha Aviation of Rochester, Inc. v. Minnesota Dept. of Health, 389 N.W.2d 507 (Minn. 1986); Rocky Mountain Holdings vs. Ronald W. Cates, Director, Missouri Department of Health, No. 97-4165-CV-C-9 (W.D. Mo. Central Division 1997). This part of the regulation has a similar impact, since it may not be feasible for a carrier to enter some jurisdictions without a membership program.

Second, the requirement for air carriers to submit a sample of their subscription contract and application is similarly preempted. The Morales court and its progeny struck down regulations that purported to restrict discounts, frequent flyer miles and other aspects of the economic relationship between carriers and their passengers. In attempting to regulate membership agreements establishing those relationships, including the rates payable and services provided thereunder, the Regulation encroaches on preempted ground.

Third, the requirement to submit a copy of all advertising used to promote the subscription program runs afoul of the preemption provisions as interpreted by Morales and other courts. One of the central holdings of Morales is that states may not regulate advertising by air carriers, since this goes to the heart of competition.

Fourth, the requirement for carriers to provide evidence of financial responsibility is preempted. Bond and insurance undertakings securing performance of financial obligations by air carriers have a direct and substantial impact on the carriers' rates, and therefore relate directly to those rates. The courts have been clear that such nexus is sufficient to trigger preemption.

Finally, the provisions of the Regulation providing for periodic review of the program also impinge upon exclusive federal authority as set out in the ADA. Because the essence of a subscription program relates to rates and services of a carrier, neither the state nor any local jurisdiction has the authority to review that program on a periodic or any other basis, nor may the state or local jurisdiction require the provider to furnish the names and addresses of its customers.

CONCLUSION

For the foregoing reasons, we believe that the ADA clearly preempts the Regulation as applied to air ambulance carriers. Viewed as a whole, the thrust of the Regulation is to restrict programs that enhance competition by providing passengers with reduced rates and potentially enhanced service. When the various parts of the Regulation are viewed in isolation, each addresses an area that is out of bounds under the ADA—market entry, advertising, financial undertakings and other areas which directly and significantly relate to rates and services. We therefore believe our

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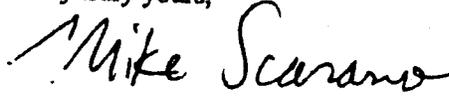
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Mr. Donald Jansky
December 15, 2006
Page 7

client should be able to proceed with its membership program without complying with the Regulation.

We are hopeful you will agree with our analysis and respectfully request a response with your views on this issue within 30 days. We appreciate your consideration of this request and would be happy to answer any questions you may have or to discuss these issues further.

Very truly yours,



R. Michael Scarano, Jr.

cc: Howard Ragsdale

Exhibit 3

2003 OIG Advisory Opinion No. 03-11



DEPARTMENT OF HEALTH & HUMAN SERVICES

[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

Exhibit 4

**1991 Connecticut Department of
Health and Human Services Letter**



AUG 14 1991

The Honorable Lawrence J. DeNardis
President-Designate
University of New Haven
300 Orange Avenue
West Haven, CT 06516

Dear Larry,

This letter is in response to your recent call and Mr. Werfel's June 14, 1991 letter concerning ambulance subscription agreements. You state that it is common for ambulance companies to offer subscription agreements (also known as membership plans) to Medicare beneficiaries. Under such an agreement, the ambulance company charges an annual fee (typically \$40-\$50 per household) and agrees to accept assignment of all claims for medically necessary services. The ambulance company does not bill the beneficiary for the coinsurance or deductible. You state that the annual membership fee is treated as the amount that would have been paid for coinsurance and deductibles. You suggest that the subscription fees are, in effect, premiums for coverage by the ambulance company of coinsurance and deductible fees. You question whether this practice is legal in light of the Office of Inspector General's (OIG's) Special Fraud Alert on Waiver of Copayments and Deductibles Under Medicare Part B.

As explained in the Special Fraud Alert, Medicare patients are generally responsible for paying an annual Medicare deductible and then a copayment for each item or service paid for by Medicare. There are several purposes to this requirement, including sharing costs between Medicare and beneficiaries, and encouraging patients to be better health care consumers by giving them a financial stake in their health care decisions. Unfortunately, however, some providers routinely waive collection of coinsurance and deductibles. Providers often waive these fees as a marketing technique, to encourage Medicare beneficiaries to use a particular provider, and to order items and services on the theory that they are "free" because the beneficiaries incur no-out-of-pocket expense. This, unfortunately, leads to the ordering of many unnecessary items or services for which the Medicare Part B program must pay. In our view, this practice is unlawful under the anti-kickback statute, 42 U.S.C. § 1320a-7b(b) and the Civil Monetary Penalties statute, 42 U.S.C. § 1320a-7a.

Page 2 - The Honorable Lawrence J. DeNardis

The OIG has found that, in order to be less obvious about routinely waiving coinsurance and deductible fees, some providers have established phony "insurance programs." Under these programs, providers charge nominal premiums to cover the copayments and deductibles so long as the items or services are ordered from that provider. These "premiums" are often very small and are not based on a good faith assessment of actuarial risk. Rather, these insurance programs are simply a disguise for illegal routine waiver of coinsurance and deductibles.

Therefore, in analyzing the legality of the subscription agreements discussed in your letter, it would be necessary to determine whether the amounts charged as "premiums" by the ambulance companies are a reasonable assessment of the actuarial risk faced by these companies. In other words, it would be necessary to determine whether the amounts charged as premiums are a reasonable approximation of the amounts that an average beneficiary would expect to spend for copayments and deductibles over the period covered by the subscription agreement. If the answer to this question is no, then we would likely view the membership plans as an illegal practice designed to disguise routine waiver of Medicare Part B coinsurance and deductibles.

You attached to your inquiry a June 3, 1986 letter from Elmer W. Smith, Director, Office of Eligibility Policy, Health Care Financing Administration, and a copy of section 2306(E) of the Medicare Carriers Manual. As you know, Mr. Smith's letter states that he is not in a position to render an answer on whether these subscription agreements violate the anti-kickback statute nor, as you point out, does section 2306(E) of the Medicare Carriers Manual discuss that issue.

Thank you for your interest in exploring this issue.

Sincerely,



Michael J. Astrue
General Counsel

cc: David Werfel

Exhibit 5

2003 Federal Register

forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For medical devices, the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(3)(B).

FDA recently approved for marketing the medical device GENESIS NEUROSTIMULATION SYSTEM. GENESIS NEUROSTIMULATION SYSTEM is indicated as an aid in the management of chronic, intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with failed back surgery syndrome, intractable low back pain, and leg pain. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for GENESIS NEUROSTIMULATION SYSTEM (U.S. Patent No. 4,793,353) from Advanced Neuromodulation Systems, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated October 31, 2002, FDA advised the Patent and Trademark Office that this medical device had undergone a regulatory review period and that the approval of GENESIS NEUROSTIMULATION SYSTEM represented the first permitted commercial marketing or use of the product. Thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for GENESIS NEUROSTIMULATION SYSTEM is 469 days. Of this time, 292 days occurred during the testing phase of the regulatory review period, while 177 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date a clinical investigation involving this device was begun:* August

11, 2000. The applicant claims that the investigational device exemption (IDE) required under section 520(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360(g)) for human tests to begin became effective on June 16, 1999. However, FDA records indicate that the IDE was determined substantially complete for clinical studies to have begun on August 11, 2000, which represents the IDE effective date.

2. *The date the application was initially submitted with respect to the device under section 515 of the act (21 U.S.C. 360e):* May 29, 2001. The applicant claims April 3, 2001, as the date the premarket approval application (PMA) for GENESIS NEUROSTIMULATION SYSTEM (PMA P010032) was initially submitted. However, FDA records indicate that PMA P010032 was submitted on May 29, 2001.

3. *The date the application was approved:* November 21, 2001. FDA has verified the applicant's claim that PMA P010032 was approved on November 21, 2001.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 840 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Dockets Management Branch (see ADDRESSES) written or electronic comments and ask for a redetermination by May 23, 2003. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by September 22, 2003. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30

Comments and petitions should be submitted to the Dockets Management Branch. Three copies of any information are to be submitted, except that individuals may submit one copy identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 7, 2003.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. 03-6692 Filed 3-21-03; 8:45 am]

BILLING CODE 4160-01-5

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice of Filing of Annual Report of Federal Advisory Committee

Notice is hereby given that pursuant to section 13 of Public Law 92-463, the fiscal year 2002 annual report for the following Health Resources and Services Administration's Federal advisory committee has been filed with the Library of Congress: Maternal and Child Health Research Grants Review Committee.

Copies are available to the public for inspection at the Library of Congress, Newspaper and Current Periodical Reading Room in the James Madison Memorial Building, Room LM-133 (entrance on Independence Avenue, between First and Second Streets, SE, Washington, DC).

Copies may be obtained from: Kishena C. Wadhvani, Ph.D., Executive Secretary, Maternal and Child Health Research Grants Review Committee, Parklawn Building, Room 18A-55, 5600 Fishers Lane, Rockville, Maryland 20857. Telephone 301-443-2340.

Dated: March 17, 2003

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 03-6858 Filed 3-21-03; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

OIG Compliance Program Guidance for Ambulance Suppliers

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Notice.

SUMMARY: This Federal Register notice sets forth the recently issued Compliance Program Guidance for Ambulance Suppliers developed by the Office of Inspector General (OIG). The OIG has previously developed and published voluntary compliance program guidance focused on several different areas of the health care

industry. This voluntary compliance program guidance should assist ambulance suppliers and other health care providers in developing their own strategies for complying with federal health care program requirements.

FOR FURTHER INFORMATION CONTACT:

Sonya Castro, (202) 619-2078, or Joel Schaefer, (202) 619-1306, Office of Counsel to the Inspector General.

SUPPLEMENTARY INFORMATION:

Background

The creation of compliance program guidances (CPGs) is a major initiative of the OIG in its effort to engage the private health care community in preventing the submission of erroneous claims and in combating fraudulent and abusive conduct. In the past several years, the OIG has developed and issued CPGs directed at a variety of segments in the health care industry. The development of these CPGs is based on our belief that a health care provider can use internal controls to more efficiently monitor adherence to applicable statutes, regulations, and program requirements. Copies of these CPGs can be found on the OIG Web site at <http://oig.hhs.gov>.

Developing Compliance Program Guidance for Ambulance Suppliers

Having experienced a number of instances of ambulance provider and supplier fraud and abuse, the ambulance industry has expressed interest in protecting against such conduct through increased guidance to the industry. To date, the OIG has issued several advisory opinions on a variety of ambulance-related issues (see endnote 13 in this compliance program guidance) and has published final rulemaking concerning a safe harbor for ambulance restocking arrangements (66 FR 62979; December 4, 2001).

To provide further guidance, the OIG published a **Federal Register** notice (65 FR 50204, August 17, 2000) that solicited general comments, recommendations, and other suggestions from concerned parties and organizations on how best to develop compliance guidance for ambulance suppliers to reduce the potential for fraud and abuse. On June 6, 2002, the OIG published a Draft Compliance Program Guidance to afford all interested parties a further opportunity to provide specific comments in the development of this final CPG (67 FR 39015; June 6, 2002). In response to that notice, the OIG received three public comments, collectively representing a variety of outside sources. We have carefully considered those comments, as well as previous OIG publications, and

have consulted with the Centers for Medicare and Medicaid Services (CMS) and the Department of Justice in developing final guidance for ambulance suppliers. This final guidance outlines some of the most common and prevalent fraud and abuse risk areas for the ambulance industry and provides direction on how to: (1) Address various risk areas; (2) prevent the occurrence of instances of fraud and abuse; and (3) develop corrective actions when those risks or instances of fraud and abuse are identified.

This CPG is divided into the following five separate sections, with an appendix:

- Section I is a brief introduction.
- Section II provides information about the basic elements of a compliance program for ambulance suppliers.
- Section III discusses various fraud and abuse and compliance risks associated with ambulance services covered under the Medicare program.
- Section IV briefly summarizes compliance risks related to Medicaid coverage for transportation services.
- Section V discusses various risks under the anti-kickback statute.
- The appendix provides relevant statutory and regulatory citations, as well as brief discussions of additional potential risk areas to consider when developing a compliance program.

Under the Social Security Act (the Act), ambulance "providers" are Medicare participating institutional providers that submit claims for Medicare ambulance services (e.g., hospitals, including critical access hospitals (CAHs) and skilled nursing facilities (SNFs); the term "supplier" means an entity that is other than a provider. For purposes of this document, we will refer to both ambulance suppliers and providers as ambulance "suppliers."

Compliance Program Guidance for Ambulance Suppliers

I. Introduction

The OIG recognizes that the ambulance industry is comprised of entities of enormous variation: some ambulance companies are large, many are small; some are for-profit, many are not-for-profit; some are affiliated with hospitals, many are independent, and some are operated by municipalities or counties, while others are commercially owned. Consequently, this guidance is not intended to be a one-size-fits-all guide. Rather, like the previous CPGs, this guidance is intended as a helpful tool for those entities that are considering establishing a voluntary

compliance program and for those that have already done so and are seeking to analyze, improve or expand existing programs. As with the OIG's previous guidance, the guidelines discussed in this CPG are not mandatory, nor is the CPG an all-inclusive document containing all the components of a compliance program. Other OIG outreach efforts, as well as other federal agency efforts to promote compliance, can and should also be used in developing a compliance program tailored to an entity's particular structure and operations.

This guidance focuses on compliance measures related to services furnished primarily under the Medicare program and, to a limited extent, other federal health care programs. (See, e.g., section IV for a brief discussion of Medicaid ambulance coverage.) Suppliers are free to address private payor claims and services in their compliance programs.

As in other sectors of the health care industry, most ambulance suppliers are honest suppliers trying to deliver quality services. However, like other health care industry sectors, the ambulance industry has seen its share of fraudulent and abusive practices. The OIG has reported and pursued a number of different fraudulent and abusive practices in the ambulance transport field. Examples include

- Improper transport of individuals with other acceptable means of transportation;
- Medically unnecessary trips;
- Trips claimed but not rendered;
- Misrepresentation of the transport destination to make it appear as if the transport was covered;
- False documentation;
- Billing for each patient transported in a group as if he/she was transported separately;
- Upcoding from basic life support to advanced life support services; and
- Payment of kickbacks.

To help reduce the incidence and prevalence of fraudulent or abusive conduct, an ambulance supplier should consider the recommendations in this guidance.

This final CPG has been modified from the draft CPG to take into further consideration CMS's adoption of a new fee schedule for payment of ambulance services. The CMS's ambulance fee schedule is the product of a negotiated rulemaking process and will replace (over a five-year transition period) the retrospective, reasonable cost reimbursement system for providers, and the reasonable charge system for suppliers of ambulance services. As the government and the industry gain more experience under the new fee schedule,

the OIG may update or supplement this CPC to address newly identified risk areas, as appropriate.

II. Elements of a Compliance Program for Ambulance Suppliers

A. Basic Elements of a Compliance Program

The following basic components have become accepted as the building blocks of an effective compliance program:

1. Development of Compliance Policies and Procedures

The ambulance supplier should develop and distribute written standards of conduct, as well as written policies and procedures, that reflect the ambulance supplier's commitment to compliance and address specific areas of potential fraud or abuse. These written policies and procedures should be reviewed periodically (e.g., annually) and revised as appropriate to ensure they are current and relevant.

2. Designation of a Compliance Officer

The ambulance supplier should designate a compliance officer and other appropriate bodies (e.g., a compliance committee) charged with the responsibility for operating and monitoring the organization's compliance program. The compliance officer should be a high-level individual in the organization who reports directly to the organization's upper management, such as the chief executive officer or board of directors. The OIG recognizes that an ambulance supplier may tailor the job functions of the compliance officer position by taking into account the size and structure of the organization, existing reporting lines, and other appropriate factors.

3. Education and Training Programs

A key element of a compliance program should be regular training and education of employees and other appropriate individuals. Training content should be tailored appropriately and should be delivered in a way that will maximize the chances that the information will be understood by the target audience.

4. Internal Monitoring and Reviews

Appropriate monitoring methods are essential to detect and identify problems and to help reduce the future likelihood of problems.

5. Responding Appropriately to Detected Misconduct

Ambulance suppliers should develop policies and procedures directed at ensuring that the organization responds

appropriately to detected offenses, including the initiation of appropriate corrective action. An organization's response to detected misconduct will vary based on the facts and circumstances of the offense. However, the response should always be appropriate to resolve and correct the situation in a timely manner. The organization's compliance officer, and legal counsel in some circumstances, should be involved in situations when serious misconduct is identified.

6. Developing Open Lines of Communication

Ambulance suppliers should create and maintain a process, such as a hotline or other reporting system, to receive and process complaints and to ensure effective lines of communication between the compliance officer and all employees. Further, procedures should be adopted to protect the anonymity of complainants, where the complainants desire to remain anonymous, and to protect whistleblowers from retaliation.

7. Enforcing Disciplinary Standards Through Well-Publicized Guidelines

Ambulance suppliers should develop policies and procedures to ensure that there are appropriate disciplinary mechanisms and standards that are applied in an appropriate and consistent manner. These policies and standards should address situations in which employees or contractors violate, whether intentionally or negligently, internal compliance policies, applicable statutes, regulations, or other federal health care program requirements.

Developing and implementing a compliance program may require significant resources and time. An individual ambulance supplier is best situated to tailor compliance measures to its own organizational structure and financial capabilities. In addition, compliance programs should be reviewed periodically to account for changes in the health care industry, federal health care statutes and regulations, relevant payment policies and procedures, and identified risks.

B. Evaluation and Risk Analysis

It is prudent for ambulance suppliers conducting a risk analysis to begin by performing an evaluation of internal and external factors that affect their operations. These may include internal systems and management issues, as well as the federal health care program requirements that govern their business operations. In many cases, such evaluation will result in the creation and adoption or revision of written policies and procedures. The evaluation

process may be simple and straightforward or it may be fairly complex and involved. For example, an evaluation of whether an ambulance supplier's existing written policies and procedures accurately reflect current federal health care program requirements is straightforward. However, an evaluation of whether an ambulance supplier's actual practices conform to its policies and procedures may be more complex and require several analytical evaluations to determine whether system weaknesses are present. Even more complex is an evaluation of an ambulance supplier's practices in light of applicable statutes, regulations, and other program requirements, when there are no pre-existing written policies and procedures.

The evaluation process should furnish ambulance suppliers with a snapshot of their strengths and weaknesses and assist providers in recognizing areas of potential risk. We suggest that ambulance suppliers evaluate a variety of practices and factors, including their policies and procedures, employee training and education, employee knowledge and understanding, claims submission process, coding and billing, accounts receivable management, documentation practices, management structure, employee turnover, contractual arrangements, changes in reimbursement policies, and payor expectations.

1. Policies and Procedures

Because policies and procedures represent the written standard for daily operations, an ambulance supplier's policies and procedures should describe the normal operations of the ambulance supplier and the applicable rules and regulations. Further, written policies and procedures should go through a formal approval process within the organization and should be evaluated on a routine basis, and updated as needed, to reflect current ambulance practices (assuming these practices are appropriate and comport with the relevant statutes, regulations, and program requirements). In addition, ambulance suppliers should review policies and procedures to ensure that they are representative of actual practices. For example, an ambulance supplier's policy for reviewing ambulance call reports (ACRs) should not state that it will review 100 percent of its ACRs, unless the ambulance supplier is capable of performing and enforcing such comprehensive reviews.

2. Training and Education

Ensuring that a supplier's employees and agents receive adequate education and training is essential to minimizing risk. Employees should clearly understand what is expected of them and for what they will be held accountable. Suppliers should also document and track the training they provide to employees and others.

An ambulance supplier should consider offering two types of compliance training: compliance program training and job-specific training. If an ambulance supplier is implementing a formal compliance program, employees should be trained on the elements of the program, the importance of the program to the organization, the purpose and goals of the program, what the program means for each individual, and the key individuals responsible for ensuring that the program is operating successfully. Compliance program education should be available to all employees, even those whose job functions are not directly related to billing or patient care.

Ambulance suppliers should also train employees on specific areas with regard to their particular job positions and responsibilities, whether or not as part of a formal compliance plan. The intensity and the nature of the specific training will vary by employee type. Training employees on the job functions of other people in the organization may also be an effective training tool. Appropriate cross-training can improve employees' overall awareness of compliance and job functions, thereby increasing the likelihood that an individual employee will recognize non-compliance. Training should be provided on a periodic basis to keep employees current on ambulance supplier requirements, including, for example, the latest payor requirements. Ambulance suppliers should conduct or make available training for employees at least yearly, and more often if needed.

Generally, employees who attend interactive training better comprehend the material presented. Interactive training offers employees the chance to ask questions and receive feedback. When possible, ambulance suppliers should use "real" examples of compliance pitfalls provided by personnel with "real life" experience such as emergency medical technicians and paramedics.

The OIG is cognizant that offering interactive, live training often requires significant personnel and time commitments. As appropriate, ambulance suppliers may wish to

consider seeking, developing, or using other innovative training methods.

Computer or internet modules may be an effective means of training if employees have access to such technology and if a system is developed to allow employees to ask questions.

The OIG cannot endorse any commercial training product; it is up to each ambulance supplier to determine if the training methods and products are effective and appropriate.

Whatever form of training ambulance suppliers provide, the OIG also recommends that employees complete a post-compliance training test or questionnaire to verify comprehension of the material presented. This will allow a supplier to assess the effectiveness and quality of its training materials and techniques. Additionally, training materials should be updated as appropriate and presented in a manner that is understandable by the average trainee. Finally, the OIG suggests that the employees' attendance at, and completion of, training be tracked and appropriate documentation maintained.

3. Assessment of Claims Submission Process

Ambulance suppliers should conduct periodic claims reviews to verify that a claim ready for submission, or one that has been submitted and paid, contains the required, accurate, and truthful information required by the payor. An ambulance claims review should focus, at a minimum, on the information and documentation present in the ACR, the medical necessity of the transport as determined by payor requirements, the coding of the claim, the co-payment collection process, and the subsequent payor reimbursement. The claims reviews should be conducted by individuals with experience in coding and billing and familiar with the different payors' coverage and reimbursement requirements for ambulance services. The reviewers should be independent and objective in their approach. Claims reviewers who analyze claims that they themselves prepared or supervised often lack sufficient independence to accurately evaluate the claims submissions process and the accuracy of individual claims. The appearance of a lack of independence may hinder the effectiveness of a claims review.

Depending on the purpose and scope of a claims review, there are a variety of ways to conduct the review. The claims review may focus on particular areas of interest (e.g., coding accuracy), or it may include all aspects of the claims submission and payment process. The universe from which the claims are

selected will comprise the area of focus for the review. Once the universe of claims has been identified, an acceptable number of claims should be randomly selected. Because the universe of claims and the variability of items in the universe will vary, the OIG cannot specify a generally acceptable number of claims for purposes of a claims review. However, the number of claims sampled and reviewed should be sufficient to ensure that the results are representative of the universe of claims from which the sample was pulled.

Ambulance suppliers should not only monitor identified errors, but also evaluate the source or cause of the errors. For example, an ambulance supplier may identify through a review a certain claims error rate. Upon further evaluation, the ambulance supplier may determine that the errors were a result of inadequate documentation. Further evaluation may reveal that the documentation deficiencies involve a limited number of individuals who work on a specific shift. It is the ambulance supplier's responsibility to identify such weaknesses and to correct them promptly. In this example, at a minimum, additional employee training should be required and any identified overpayment repaid. A detailed and logical analysis will make claims reviews useful tools for identifying risks, correcting weaknesses, and preventing future errors.

Ambulance suppliers should consider using a baseline audit to develop a benchmark against which to measure performance. This audit will establish a consistent methodology for selecting and examining records in future audits. Comparing audit results from different audits will generally yield useful results only when the audits analyze the same or similar information and when matching methodologies are used.

As part of its compliance efforts, an ambulance supplier should document how often audits or reviews are conducted and the information reviewed for each audit. The ambulance supplier should not only use internal benchmarks, but should utilize external information, if available, to establish benchmarks (e.g., data from other ambulance suppliers, associations, or from payors). Additionally, risk areas may be identified from the results of the audits.

If a material deficiency is identified that could be a potential criminal, civil, or administrative violation, the ambulance supplier may disclose the matter to the OIG via the Provider Self-Disclosure Protocol. The Provider Self-Disclosure Protocol was designed to allow providers/suppliers to disclose

voluntarily potential violations in their dealings with the federal health care programs. In all cases, identified overpayments should be reported to the appropriate payor.

a. Pre-Billing Review of Claims

As a general matter, ambulance suppliers should review claims on a pre-billing basis to identify errors before claims are submitted. If there is insufficient documentation to support the claim, the claim should not be submitted. Pre-billing reviews also allow suppliers to review the medical necessity of their claims. If, as a result of the pre-billing claims review process, a pattern of claim submission or coding errors is identified, the ambulance supplier should develop a responsive action plan to ensure that overpayments are identified and repaid.

b. Paid Claims

In addition to a pre-billing review, a review of paid claims may be necessary to determine error rates and quantify overpayments and/or underpayments. The post-payment review may help ambulance suppliers in identifying billing or coding software system problems. Any overpayments identified from the review should be promptly returned to the appropriate payor in accordance with payor policies.

c. Claims Denials

Ambulance suppliers should review their claims denials periodically to determine if denial patterns exist. If a pattern of claims denials is detected, the pattern should be evaluated to determine the cause and appropriate course of action. Employee education regarding proper documentation, coding, or medical necessity may be appropriate. If an ambulance supplier believes its payor is not adequately explaining the basis for its denials, the ambulance supplier should seek clarification in writing.

4. System Reviews and Safeguards

Periodic review and testing of a supplier's coding and billing systems are also essential to detect system weaknesses. One reliable systems review method is to analyze in detail the entire process by which a claim is generated, including how a transport is documented and by whom, how that information is entered into the supplier's automated system (if any), coding and medical necessity determination protocols, billing system processes and controls, including any edits or data entry limitations, and finally the claims generation, submission, and subsequent payment

tracking processes. A weakness or deficiency in any part of the supplier's system can lead to improper claims, undetected overpayments, or failure to detect system defects.

Each ambulance supplier should have computer or other system edits to ensure that minimum data requirements are met. For example, under CMS's new fee schedule, each transport claim that does not have an originating zip code listed should be "flagged" by the system. Other edits should be established to detect potentially improper claims submissions. A systems review is especially important when documentation or billing requirements are modified or when an ambulance supplier changes its billing software or claims vendors. As appropriate, ambulance suppliers should communicate with their payor when they are implementing significant changes to their system to alert the payor to any unexpected delays, or increases or decreases in claims submissions.

Ambulance suppliers should ensure that their electronic or computer billing systems do not automatically insert information that is not supported by the documentation of the medical or trip sheets. For example, billing systems targeting optimum efficiency may be set with defaults to indicate that a physician's signature was obtained following an emergency room transport. If information is automatically inserted onto a claim submitted for reimbursement, and that information is false, the ambulance supplier's claims will be false. If a required field on a claim form is missing information, the system should flag the claim prior to its submission.

5. Sanctioned Suppliers

Federal law prohibits Medicare payment for services furnished by an excluded individual, such as an excluded ambulance crew member. Accordingly, ambulance suppliers should query the OIG and General Services Administration (GSA) exclusion and debarments lists before they employ or contract with new employees or new contractors. Additionally, ambulance suppliers should periodically (at least yearly) check the OIG and GSA web sites to ensure that they are not employing or contracting with individuals or entities that have been recently convicted of a criminal offense related to health care or who are listed as debarred, suspended, excluded, or otherwise ineligible for participation in federal health care programs. The OIG and GSA Web sites are listed at

<http://oig.hhs.gov> and <http://www.arnet.gov/epls>, respectively, and contain specific instructions for searching the exclusion and debarment databases.

C. Identification of Risks

This ambulance CPC discusses many of the areas that the ambulance industry, the OIG, or CMS have identified as common risks for many ambulance suppliers. However, this CPC does not identify or discuss all risks that an ambulance supplier may itself identify. Moreover, the CPC may ascribe more or less risk to a particular practice area than an ambulance supplier would encounter based on its own internal findings and circumstances. Because there are many different types of risk areas, ambulance suppliers should prioritize their identified risks to ensure that the various areas are addressed appropriately. Apart from the risks identified in this CPC, ambulance suppliers of all types (e.g., small, large, rural, emergency, non-emergency) should evaluate whether they have any unique risks attendant to their business relationships or processes. For example, a small, rural not-for-profit ambulance supplier may identify risk areas different from those of a large, for-profit ambulance chain that serves a primarily urban area. To stay abreast of risks affecting the ambulance and other health care industries, the OIG recommends that ambulance suppliers review OIG publications regarding ambulance services, including OIG advisory opinions, OIG fraud alerts and bulletins, Office of Evaluation and Inspections (OEI) reports, and Office of Audit Services reports, all located on the OIG's Web site at <http://oig.hhs.gov>. A review of industry-specific trade publications will also help ambulance suppliers remain current on industry changes.

D. Response to Identified Risks

An ambulance supplier should develop a reasonable response to address identified risk areas, including written protocols and reasonable time frames for specific situations. Developing timely and appropriate responsive actions demonstrates the supplier's commitment to address problems and concerns. Determining whether identified problems respond to corrective actions may require continual oversight.

III. Specific Fraud and Abuse Risks Associated With Medicare Ambulance Coverage and Reimbursement Requirements

Ambulance suppliers should review and understand applicable ambulance coverage requirements. Ambulance suppliers that are not complying with applicable requirements should take appropriate, prompt corrective action to follow the relevant requirements. The new fee schedule covers seven levels of service, including Basic Life Support (BLS), Advanced Life Support, Level 1 (ALS1), Advanced Life Support, Level 2 (ALS2), Specialty Care Transport, Paramedic ALS Intercept, Fixed Wing Air Ambulance, and Rotary Wing Air Ambulance. Generally, Medicare Part B covers ambulance transports if applicable vehicle and staff requirements, medical necessity requirements, billing and reporting requirements, and origin and destination requirements are met. Medicare Part B will not pay for ambulance services if Part A has paid directly or indirectly for the same services.

A. Medical Necessity

Medically unnecessary transports have formed the basis for a number of Medicare and Medicaid fraud cases. Consequently, medical necessity is a risk area that should be addressed in an ambulance supplier's compliance program. Medicare Part B covers ambulance services only if the beneficiary's medical condition contraindicates another means of transportation. The medical necessity requirements vary depending on the status of the ambulance transport (*i.e.*, emergency transport vs. non-emergency transport). If the medical necessity requirement is met, Medicare Part B covers ambulance services when a beneficiary is transported:

- To a hospital, a critical access hospital (CAH), or a skilled nursing facility (SNF), from anywhere, including another acute care facility, or SNF;
- To his or her home from a hospital, CAH, or SNF;
- Round trip from a hospital, CAH, or SNF to an outside supplier to receive medically necessary therapeutic or diagnostic services; or
- To the nearest appropriate renal dialysis facility from his or her home.

I. Upcoding

Ambulance suppliers should be careful to bill at the appropriate level for services actually provided. The federal government has prosecuted a number of ambulance cases involving upcoding

from BLS to ALS related to both emergency and non-emergency transports. In 1999, for example, an OIG investigation determined that an ambulance supplier was not only billing for ALS services when BLS services were provided, but the ambulance supplier did not employ an ALS certified individual to perform the necessary ALS services. This supplier paid civil penalties and signed a five-year corporate integrity agreement (CIA).

2. Non-Emergency Transports

There have also been a number of Medicare fraud cases involving non-emergency transports (i) to non-covered destinations and (ii) that were not medically necessary. An OIG OEL report, issued in December 1998, found that a high number of non-emergency transports for which Medicare claims were submitted were medically unnecessary as defined by Medicare's criteria. Medicare's ambulance fee schedule identifies non-emergency transport as appropriate if (i) the beneficiary is bed-confined and his or her medical condition is such that other methods of transportation are contraindicated, or (ii) the beneficiary's medical condition, regardless of bed-confinement, is such that transportation by ambulance is medically required. The beneficiary's medical condition and the necessity for ambulance transportation must be documented. In determining whether a beneficiary is bed-confined, the following criteria must be met: (i) The beneficiary must be unable to get up from bed without assistance; (ii) the beneficiary must be unable to ambulate; and (iii) the beneficiary must be unable to sit in a chair or wheelchair (42 CFR 410.40 (d)). The fact that other modes of transportation may not be as readily available or as convenient does not justify coverage for ambulance transport for a beneficiary who does not meet Medicare's medical necessity requirements.

Under no circumstances should ambulance suppliers mischaracterize the condition of the patient at the time of transport in an effort to claim that the transport was medically necessary under Medicare coverage requirements. If it is unclear whether the service will be covered by Medicare, the ambulance supplier should nonetheless appropriately document the condition of the patient and maintain records of the transport.

3. Scheduled and Unscheduled Transports

Because of the potential for abuse in the area of non-emergency transports, Medicare has criteria for the coverage of non-emergency scheduled and unscheduled ambulance transports. For example, physician certification statements (PCS) should be obtained by an ambulance supplier to verify that the transport was medically necessary. The PCSs should provide adequate information on the transport provided for each individual beneficiary, and each PCS must be signed by an appropriate physician or other appropriate health care professional. Except for pre-signed PCSs for scheduled, repetitive ambulance transports, which can be valid for up to 60 days of transport service, pre-signed and/or mass produced PCSs are not acceptable because they increase the opportunity for abuse.

Medicare does not cover transports for routine doctor and dialysis appointments when beneficiaries do not meet the Medicare medical necessity requirements. Similarly, ambulance services that are rendered for convenience or because other methods of more appropriate transportation are not available do not meet Medicare's medical necessity requirements and claims for such services should not be submitted to Medicare for payment. For example, an ambulance supplier was required to pay over \$1 million to the federal government and enter into a CIA with the OIG for billing for medically unnecessary ambulance trips and for non-covered ambulance trips to doctors' offices.

B. Documentation, Billing, and Reporting Risks

Currently, the HCFA 1491 or 1500 forms are the approved forms for requesting Medicare payment for ambulance services. Inadequate or faulty documentation is a key risk area for ambulance suppliers. The compilation of correct and accurate documentation (whether electronic or hard copy) is generally the responsibility of all the ambulance personnel, including the dispatcher who receives a request for transportation, the personnel transporting the patient, and the coders and billers submitting claims for reimbursement. When documenting a service, ambulance personnel should not make assumptions or inferences to compensate for a lack of information or contradictory information on a trip sheet, ACR, or other medical source documents.

To ensure that adequate and appropriate information is documented, an ambulance supplier should gather and record, at a minimum, the following:

- Dispatch instructions, if any;
- Reasons why transportation by other means was contraindicated;
- Reasons for selecting the level of service
- Information on the status of the individual;
- Who ordered the trip;
- Time spent on the trip;
- Dispatch, arrival at scene, and destination times;
- Mileage traveled;
- Pickup and destination codes;
- Appropriate zip codes; and
- Services provided, including drugs or supplies.

1. Healthcare Common Procedure Coding System (HCPCS)

The appropriate HCPCS codes should be used when submitting claims for reimbursement. The HCPCS codes reported on the ambulance trip sheets or claim forms should be selected to describe most accurately the type of transport provided based on the patient's illness, injury, signs, or symptoms at the time of the ambulance transport. HCPCS codes should not be selected based on information relating to the patient's past medical history or prior conditions, unless such information also specifically relates to the patient's condition at the time of transport. Ambulance suppliers should use caution not to submit incorrect HCPCS codes on trip sheets or claims to justify reimbursement.

2. Origin/Destination Requirements—Loaded Miles

Medicare only covers transports for the time that the patient is physically in the ambulance. Effective January 1, 2001, ambulance suppliers must furnish the "point of pickup" zip code on each ambulance claim form. Under the new Medicare ambulance fee schedule, the point of pickup will determine the mileage payment rate. The ambulance supplier should document the address of the point of pickup to verify that the zip code is accurate.

The ambulance crew should accurately report the mileage traveled from the point of pickup to the destination. Medicare covers ambulance transports to the nearest available treatment facility. If the nearest facility is not appropriate (e.g., because of traffic patterns or an inability to address the patient's condition), the beneficiary should be taken to the next closest appropriate facility. If a beneficiary

requests a transport to a facility other than the nearest appropriate facility, the ambulance supplier should inform the patient that he or she may be responsible for payment of the additional mileage incurred.

3. Multiple Payors—Coordination of Benefits

Ambulance suppliers should make every attempt to determine whether Medicare, Medicaid, or other federal health care programs should be billed as the primary or as the secondary insurer. Claims for payment should not be submitted to more than one payor, except for purposes of coordinating benefits (e.g., Medicare as secondary payor). Section 1862(b)(6) of the Act (42 U.S.C. 1395y(b)(6)) states that an entity that knowingly, willfully, and repeatedly fails to provide accurate information relating to the availability of other health benefit plans shall be subject to a civil money penalty (CMP).

The OIG recognizes that there are instances when the secondary payor is not known or cannot be determined before the ambulance transportation claim is submitted. This may be particularly true for ambulance suppliers that have incomplete insurance information from a transported patient. In such situations, if an ambulance supplier receives an inappropriate or duplicate payment, the payment should be refunded to the appropriate payor in a timely manner. Accordingly, ambulance suppliers should develop a system to track and quantify credit balances to return overpayments when they occur.

C. Medicare Part A Payment for "Under Arrangements" Services

In certain instances, SNFs, hospitals, or CAHs, may provide ambulance services "under arrangements" with an ambulance supplier. In such cases, the SNF, hospital, or CAH is the entity furnishing the transport. Accordingly, Medicare pays the SNF, hospital, or CAH for the service. The SNF, hospital, or CAH pays the ambulance supplier a contractually agreed amount. Ambulance suppliers that provide such transports "under arrangements" with a SNF, hospital, or CAH should not bill Medicare for these transports. All such arrangements should be carefully reviewed to ensure that there is no violation of the anti-kickback statute, as more fully described in section V.

IV. Medicaid Ambulance Coverage

The Medicaid program, a joint federal and state health insurance program, provides funds for health care providers and suppliers that perform or deliver

medically necessary services for eligible Medicaid recipients. Each state establishes its own Medicaid regulations, which vary depending on the state plan. However, two federal regulations form the basis for all Medicaid reimbursement for transportation services and ensure a minimum level of coverage for transportation services. First, all states that receive federal Medicaid funds are required to assure transportation for Medicaid recipients to and from medical appointments (42 CFR 431.53). Second, federal regulations further define medical transportation and describe costs that can be reimbursed with Medicaid funds (42 CFR 440.170(a)).

In short, Medicaid often covers transports that are not typically covered by Medicare, such as transports in wheelchair vans, cabs, and ambulettes. However, the transports are subject to strict coverage and payment rules. The state Medicaid Fraud Control Units and federal law enforcement have pursued many fraud cases related to transportation services billed to Medicaid programs. Ambulance suppliers should review the Medicaid regulations governing their state or service territories to ensure that any billed services meet applicable Medicaid requirements.

V. Kickbacks and Inducements

A. What Is the Anti-Kickback Statute?

The anti-kickback statute prohibits the purposeful payment of anything of value (*i.e.*, remuneration) in order to induce or reward referrals of federal health care program business, including Medicare and Medicaid business.¹² (See section 1128B(b) of the Act (42 U.S.C. 1320a-7b).) It is a criminal prohibition that subjects violators to possible imprisonment and criminal fines. In addition, violations of the anti-kickback statute may give rise to CMPs and exclusion from the federal health care programs. Both parties to an impermissible kickback transaction may be liable: the party offering or paying the kickback, as well as the party soliciting or receiving it. The key inquiry under the statute is whether the parties intend to pay, or be paid, for referrals. Paying for referrals need not be the only or primary purpose of a payment; as courts have found, if any one purpose of the payment is to induce or reward referrals, the statute is violated. (See, e.g., *United States v. Kats*, 371 F.2d 105 (9th Cir. 1989); *United States v. Gebel*, 760 F.2d 68 (3d Cir.) cert. denied, 474 U.S. 988 (1985).) In short, an ambulance supplier should

neither make nor accept payments intended, in whole or in part, to generate federal health care program business.

B. What Are "Safe Harbors"?

The department has promulgated "safe harbor" regulations that describe payment practices that do not violate the anti-kickback statute, provided the payment practice fits squarely within a safe harbor. The safe harbor regulations can be found at 42 CFR 1001.952 and on the OIG Web page at <http://oig.hhs.gov/fraud/safeharborregulations.html#1>. Compliance with the safe harbor regulations is voluntary. Thus, failure to comply with a safe harbor does not mean that an arrangement is illegal. Rather, arrangements that do not fit in a safe harbor must be analyzed under the anti-kickback statute on a case-by-case basis to determine if there is a violation. To minimize the risk under the anti-kickback statute, ambulance suppliers should structure arrangements to take advantage of the protection offered by the safe harbors whenever possible. Safe harbors that may be useful for ambulance suppliers include those for space rentals, equipment rentals, personal services and management contracts, discounts, employees, price reductions offered to health plans, shared risk arrangements, and ambulance restocking arrangements. (42 CFR 1001.952(b), (c), (d), (h), (i), (l), (u), and (v), respectively.)

C. What Is "Remuneration" for Purposes of the Statute?

Under the anti-kickback statute, "remuneration" means virtually anything of value. A prohibited kickback payment may be paid in cash or in kind, directly or indirectly, covertly or overtly. Almost anything of value can be a kickback, including, but not limited to, money, goods, services, free or reduced rent, meals, travel, gifts, and investment interests.

D. Who Are Referral Sources for Ambulance Suppliers?

Any person or entity in a position to generate federal health care program business for an ambulance supplier directly or indirectly, is a potential referral source. Potential referral sources include, but are not limited to, governmental "9-1-1" or comparable emergency medical dispatch systems, private dispatch systems, first responders, hospitals, nursing facilities, assisted living facilities, home health agencies, physician offices, staff of any of the foregoing entities, and patients.

E. For Whom Are Ambulance Suppliers Sources of Referrals?

In some circumstances, ambulance suppliers furnishing ambulance services may be sources of referrals (i.e., patients) for hospitals, other receiving facilities, and second responders. Ambulance suppliers that furnish other types of transportation—such as ambulette or van transportation, also may be sources of referrals for other providers of federal health care program services, such as physician offices, diagnostic facilities, and certain senior centers. In general, ambulance suppliers—particularly those furnishing emergency services—have relatively limited abilities to generate business for other providers or to inappropriately steer patients to particular emergency providers.

F. How Can Ambulance Suppliers Avoid Risk Under the Anti-Kickback Statute?

Because of the gravity of the penalties under the anti-kickback statute, ambulance suppliers are strongly encouraged to consult with experienced legal counsel about any financial relationships involving potential referral sources. In addition, ambulance suppliers should review OIG guidance related to the anti-kickback statute, including advisory opinions, fraud alerts, and special advisory bulletins. Ambulance suppliers concerned about their existing or proposed arrangements may obtain binding advisory opinions from the OIG.

Ambulance suppliers should exercise common sense when evaluating existing or prospective arrangements under the anti-kickback statute. One good rule of thumb is that all arrangements for items or services should be at fair market value in an arms-length transaction not taking into account the volume or value of existing or potential referrals. For each arrangement, an ambulance supplier should carefully and accurately document how it has determined fair market value. As discussed further in appendix A.4, an ambulance supplier may not charge Medicare or Medicaid substantially more than its usual charge to other payors.

Ambulance suppliers should consult the safe harbor for discounts (42 CFR 1001.952(h)) when entering into arrangements involving discounted pricing. In most circumstances, ambulance suppliers who offer discounts to purchasers who bill federal programs must fully and accurately disclose the discounts on the invoice, coupon, or statement sent to purchasers and inform purchasers of the

purchasers' obligations to report the discounts to the federal programs. Accurate and complete records should be kept of all discount arrangements.

Ambulance suppliers should exercise caution when selling services to purchasers who are also in a position to generate federal health care program business for ambulance suppliers (e.g., SNEs or hospitals that purchase ambulance services for private pay and Part A patients, but refer Part B and Medicaid patients to ambulance suppliers). Any link or connection, whether explicit or implicit, between the price offered for business paid out of the purchaser's pocket and referrals by the ambulance supplier will implicate the anti-kickback statute.

An ambulance supplier should not offer or provide gifts, free items or services, or other incentives of greater than nominal value to referral sources, including patients, and should not accept such gifts and benefits from parties soliciting referrals from the ambulance supplier. In general, token gifts used on an occasional basis to demonstrate good will or appreciation (e.g., logo key chains, mugs, or pens) will be considered to be nominal in value.

G. Are There Particular Arrangements to Which Ambulance Suppliers Should Be Alert?

Ambulance suppliers should review the following arrangements with particular care. (This section is intended to be illustrative, not exhaustive, of potential areas of risk under the anti-kickback and beneficiary inducement statutes.)

1. Arrangements for Emergency Medical Services (EMS)

a. Municipal Contracts

Contracts with cities or other EMS sponsors for the provision of emergency medical services may raise anti-kickback concerns. Ambulance suppliers should not offer anything of value to cities or other EMS sponsors in order to secure an EMS contract. (In general, ambulance suppliers may provide cities or other municipal entities with free or reduced cost EMS for uninsured, indigent patients.) In addition, arrangements that cover both EMS and non-EMS ambulance business should be carefully scrutinized, conditioning EMS services on obtaining non-EMS business potentially implicates the anti-kickback statute. Absent a state or local law requiring a tie between EMS and non-EMS business, ambulance suppliers

contemplating such arrangements should consider obtaining an OIG advisory opinion. While cities and other EMS sponsors may charge ambulance suppliers amounts to cover the costs of services provided to the suppliers, they should not solicit inflated payments in exchange for access to EMS patients, including access to dispatch services under "9-1-1" or comparable systems.

A city or other political subdivision of a state (e.g., fire district, county, or parish) may not require a contracting ambulance supplier to waive copayments for its residents, but it may pay uncollected, out-of-pocket copayments on behalf of its residents. Such payments may be made through lump sum or periodic payments, if the aggregate payments reasonably approximate the otherwise uncollected cost-sharing amounts. However, a city or other political subdivision that *owns and operates* its own ambulance service is permitted to waive cost-sharing amounts for its residents under a special CMS rule. (See *CMS Carrier Manual*, section 2309.4; *CMS Intermediary Manual*, section 3153.3A; see also, e.g., OIG Advisory Opinion No. 01-10 and 01-11.)

b. Ambulance Restocking

Another common EMS arrangement involves the restocking of supplies and drugs used in connection with patients transported to hospitals or other emergency receiving facilities. These arrangements typically do not raise anti-kickback concerns. However, ambulance suppliers participating in such arrangements can eliminate risk altogether by complying with the ambulance restocking safe harbor at 42 CFR 1001.952(v). In general, the safe harbor requires that EMS restocking arrangements involving free or reduced price supplies or drugs be conducted in an open, public, and uniform manner, although hospitals may elect to restock only certain categories of ambulance supplies (e.g., nonprofits or volunteers). Restocking must be accurately documented using trip sheets, patient care reports, patient encounter reports, or other documentation that records the specific type and amount of supplies or drugs used on the transported EMS patient and subsequently restocked. The documentation must be maintained for 5 years. The safe harbor also covers fair market value restocking arrangements and government mandated restocking arrangements. The safe harbor conditions are set forth with specificity in the regulations.

Wholly apart from anti-kickback concerns, ambulance restocking

arrangements raise issues with respect to proper billing for restocked supplies and drugs. Payment and coverage rules are set by the health care program that covers the patient (e.g., Medicare or Medicaid). To determine proper billing for restocked supplies or drugs, ambulance suppliers should consult the relevant program payment rules or contact the relevant payment entity. Under the Medicare program, in almost all circumstances the ambulance supplier—not the hospital—will be the party entitled to bill for the restocked supplies or drugs used in connection with an ambulance transport, even if they are obtained through a restocking program. However, under the ambulance fee schedule, supplies and drugs are included in the bill for the base rate and are not separately billable. Ambulance suppliers should consult with their payor to confirm appropriate billing during the new ambulance fee schedule transition period.

2. Arrangements With Other Responders

In many situations, it is common practice for a paramedic intercept or other first responder to treat a patient in the field, with a second responder transporting the patient to the hospital. In some cases, the first responder is in a position to influence the selection of the transporting entity. While fair market value payments for services actually provided by the first responder are appropriate, inflated payments by ambulance suppliers to generate business are prohibited, and the government will scrutinize such payments to ensure that they are not disguised payments to generate calls to the transporting entity.

3. Arrangements With Hospitals and Nursing Facilities

Because hospitals and nursing facilities are key sources of non-emergency ambulance business, ambulance suppliers need to take particular care when entering into arrangements with such institutions. (See section F above.)

4. Arrangements With Patients

Arrangements that offer patients incentives to select particular ambulance suppliers may violate the anti-kickback statute, as well as the CMP law that prohibits giving inducements to Medicare and Medicaid beneficiaries that the giver knows, or should know, are likely to influence the beneficiary to choose a particular practitioner, provider, or supplier of items or services payable by Medicare or Medicaid (See section 1128A(a)(5) of the Act (42 U.S.C. 1320a-7a)(a)(5)).

Prohibited incentives include, without limitation, free goods and services and copayment waivers. The statute contains several narrow exceptions, including financial hardship copayment waivers and incentives to promote the delivery of preventive care services as defined in regulations. In addition, items or services of nominal value (less than \$10 per item or service or \$50 in the aggregate annually) and any payment that fits into an anti-kickback safe harbor are permitted.

An ambulance supplier should not routinely waive federal health care program copayments (e.g., no "insurance only" billing), although the supplier may waive a patient's copayment if it makes a good faith, individualized assessment of the patient's financial need (16) Financial hardship waivers may not be routine or advertised. As discussed in section C above, cities and other political subdivisions are permitted to waive copayments for services provided directly to their residents.

Subscription or membership programs that offer patients purported coverage only for the ambulance supplier's services are also problematic because such programs can be used to disguise the routine waiver of cost-sharing amounts. To reduce their risk under the anti-kickback statute, ambulance suppliers offering subscription programs should carefully review them to ensure that the subscription or membership fees collected from subscribers or members, in the aggregate, reasonably approximate—from an actuarial or historical perspective—the amounts that the subscribers or members would expect to spend for cost-sharing amounts over the period covered by the subscription or membership agreement.

VI Conclusion

This ambulance compliance program guidance is intended as a resource for ambulance suppliers to decrease the incidence of fraud and abuse as well as errors that might occur due to inadequate training or inadvertent noncompliance. We encourage ambulance suppliers to scrutinize their internal practices to ensure the development of a comprehensive compliance program.

Compliance programs should reflect each ambulance supplier's individual and unique circumstances. It has been the OIG's experience that those health care providers and suppliers that have developed compliance programs not only better understand applicable federal health care program requirements, but also their own internal operations. We are hopeful that

this guidance will be a valuable tool in the development and continuation of ambulance suppliers' compliance programs.

Appendix A—Additional Risk Areas

1. "No Transport" Calls and Pronouncement of Death

If an ambulance supplier responds to an emergency call, but a patient is not transported due to death, three Medicare rules apply. If an individual is pronounced dead prior to the time the ambulance was requested, there is no payment. If the individual is pronounced dead after the ambulance has been requested, but before any services are rendered, a BLS payment will be made and no mileage will be paid. If the individual is pronounced dead after being loaded into the ambulance, the same payment rules apply as if the beneficiary were alive. Ambulance suppliers should accurately represent the time of death and request payment based on the aforementioned criteria.

2. Multiple Patient Transports

On occasion, it may be necessary for an ambulance to transport multiple patients concurrently. If more than one patient is transported concurrently in one ambulance, the amount billed should be consistent with the multiple transport guidelines established by the payer in that region. Under CMS's new fee schedule rules for multiple transports, Medicare will pay a percentage of the payment allowance for the base rate applicable to the level of care furnished to the Medicare beneficiary (e.g., if two patients are transported simultaneously, 75 percent of the applicable base rate will be reimbursed for each of the Medicare beneficiaries). Coinsurance and deductible amounts will apply to the prorated amounts.

3. Multiple Ambulances Called to Respond to Emergency Call

On occasion, more than one ambulance supplier responds to an emergency call and is present to transport a beneficiary. These are often referred to as "dual transports." In such cases, only the transporting ambulance supplier may bill Medicare for the service provided. If payment is desired for services provided to a patient, the non-transporting ambulance company should receive it directly from the transporting supplier based on a negotiated arrangement. These payments should be fair market value for services actually rendered by the non-transporting supplier, and the parties should review these payment arrangements for compliance with the anti-kickback statute. On occasion, when multiple ambulance crews respond to a call, a BLS ambulance may provide the transport, but the level of services provided may be at the ALS level. If a BLS supplier is billing at the ALS level because of services furnished by an additional ALS crew member, appropriate documentation should accompany the claim to indicate to the payer that dual transportation was provided. In any event, only one supplier may submit the claim for payment.

4. Billing Medicare "Substantially in Excess" of Usual Charges

Ambulance suppliers generally may not charge Medicare or Medicaid patients substantially more than they usually charge everyone else. If they do, they are subject to exclusion by the OIG. This exclusion authority is not implicated unless the supplier's charge for Medicare or Medicaid patients is substantially more than its Medicare/non-Medicare/Medicaid charge. In other words, the supplier need not worry unless it is discounting close to half of its non-Medicare/Medicaid business. Ambulance suppliers should review charging practices with respect to Medicare and Medicaid billing to ensure that they are not charging Medicare or Medicaid substantially more than they usually charge other customers for comparable services. It is appropriate for an ambulance supplier to determine its usual charge with reference to its total charges to non-Medicare/Medicaid customers for an ambulance transport (whether or not the charges are structured as base rate plus mileage or otherwise) and then to compare the resulting "usual charge" to its total charge to Medicare (i.e., base rate plus mileage) or Medicaid for comparable transport.

Appendix B—OIG/HHS Information

The OIG's web site (<http://oig.hhs.gov>) contains various links describing the following: (1) Authorities and Federal Register Notices, (2) Publications, (3) Reports, (4) Hearing Testimony, (5) Fraud Prevention and Detection, (6) Reading Room, (7) OIG Organization and (8) Employment Opportunities. Such information is frequently updated and is a useful tool for ambulance providers seeking additional OIG resources.

Also listed on the OIG's web site is the OIG Hotline Number. One method for providers to report potential fraud, waste and abuse is to contact the OIG Hotline number. All HHS and contractor employees have a responsibility to assist in combating fraud, waste, and abuse in all departmental programs. As such, providers are encouraged to report matters involving fraud, waste and mismanagement in any departmental program to the OIG. The OIG maintains a hotline that offers a confidential means for reporting these matters.

Contacting the OIG Hotline

By Phone: 1-800-HHS-TIPS (1-800-447-8477).

By Fax: 1-800-223-8164.

By E-Mail: <https://oig.hhs.gov>

By TTY: 1-800-377-4950.

By Mail: Office of Inspector General, Department of Health and Human Services, Attn: HOTLINE, 30 Independence Ave SW, Washington, DC 20204.

When contacting the hotline, please provide the following information to the best of your ability:

- Type of Complaint: Medicare Part A, Medicare Part B, Indian Health Service, TRICARE, Other (please specify)

—HHS department or program being affected by your allegation of fraud, waste, abuse, mismanagement: Centers for Medicare and Medicaid Services (formerly Health Care Financing Administration), Indian Health Service, Other (please specify).

—Please provide the following information (however, if you would like your referral to be submitted anonymously, please indicate such in your correspondence or phone call): Your Name, Your Street Address, Your City/County, Your State, Your Zip Code, Your E-mail Address.

—Subject Person/Business/Department that allegation is against: Name of Subject, Title of Subject, Subject's Street Address, Subject's City/County, Subject's State, Subject's Zip Code.

—Please provide a brief summary of your allegation and the relevant facts.

Appendix C—Carrier Contact Information

1. Medicare

A complete list of contact information (address, phone number, e-mail address) for Medicare Part A Fiscal Intermediaries, Medicare Part B Carriers, Regional Home Health Intermediaries, and Durable Medical Equipment Regional Carriers can be found on the CMS Web site at <http://cms.hhs.gov/contacts/inccardit.asp>.

2. Medicaid

Contact information (address, phone number, e-mail address) for each state Medicaid director can be found on the CMS Web site at <http://cms.hhs.gov/medicaid/mcontact.asp>. In addition to a list of state Medicaid directors, the Web site includes contact information for each state survey agency and the CMS Regional Offices.

3. Ambulance Fee Schedule

Information related to the development of the ambulance fee schedule is located at <http://cms.hhs.gov/suppliers/ajfd/default.asp>.

Appendix D—Internet Resources

1. Centers for Medicare and Medicaid Services

The CMS Web site (<http://cms.hhs.gov/>) includes information on a wide array of topics, including Medicare's National Coverage Database, National Coverage Policies, Laws and Regulations and State Waiver and Demonstration Programs. In addition, this Web site contains information related to Medicaid, including a General Medicaid Overview, State and Federal Health Program Contacts, State Medicaid Manual, State Medicaid Plans, State Waivers and Demonstration Programs, Letters to State Officials, and CMS Publications.

2. CMS Medicare Training

This CMS Web site (<http://www.cms.hhs.gov/medlearn/ehis.asp>) provides computer-based training related to CMS's purpose and history. The three types

of Medicare coverage, the roles agencies and contractors play, and the claims handling process.

3. Government Printing Office (GPO)

The GPO Web site (<http://www.access.gpo.gov>) provides access to federal statutes and regulations pertaining to federal health care programs.

4. The U.S. House of Representatives Internet Library

The U.S. House of Representatives Internet Library Web site (<http://usc.house.gov/usc.htm>) provides access to the United States Code, which contains laws pertaining to federal health care programs.

Endnotes

1. To date, the OIG has issued compliance program guidance for the following nine industry sectors: (1) Hospitals; (2) clinical laboratories; (3) home health agencies; (4) durable medical equipment suppliers; (5) third-party medical billing companies; (6) hospices; (7) Medicare+Choice organizations offering coordinated care plans; (8) nursing facilities; and (9) individual and small group physician practices. The guidances listed here and referenced in this document are available on the OIG Web site at <http://oig.hhs.gov> in the Fraud Prevention and Detection section.

2. The CMS's final ambulance fee schedule rule was published in the **Federal Register** on February 27, 2002 (67 FR 9100) and went into effect on April 1, 2002.

3. The term "universe" is used in this CPG to mean the generally accepted definition of the term for purposes of performing a statistical analysis. Specifically, the term "universe" means the total number of sampling units from which the sample was selected.

4. The OIG encourages that providers/suppliers police themselves, correct underlying problems, and work with the government to resolve any problematic practices. The OIG's Provider Self-Disclosure Protocol, published in the **Federal Register** on October 30, 1998 (63 FR 58399), sets forth the steps, including a detailed audit methodology, that may be undertaken if suppliers wish to work openly and cooperatively with the OIG. The Provider Self-Disclosure Protocol is open to all health care providers and other entities and is intended to facilitate the resolution of matters that, in the provider's reasonable assessment, may potentially violate federal criminal, civil, or administrative laws. The Provider Self-Disclosure Protocol is not intended to resolve simple mistakes or compliance problems. The OIG's Self-Disclosure Protocol can be found on the OIG Web site at <http://oig.hhs.gov>.

5. Ambulance suppliers should read the OIG's September 1999 Special Advisory Bulletin entitled "The Effect of Exclusion from Participation in the Federal Health Care Programs," published in the **Federal Register** on October 7, 1999 (64 FR 53831), which is located at <http://oig.hhs.gov/audit>. For more information regarding excluded individuals and entities and the effect of employing or contracting with such individuals or entities,

6. OIG-09-95-00412, available on the OIG's Web site at <http://oig.hhs.gov/oa>.

7. CMS Program Memorandum B-00-09 describes different options for ambulance suppliers having difficulty obtaining PCSs. (See 42 CFR 410.40(d)(3)(iii) and (iv)). A PCS is not required, for beneficiaries who are not under the direct care of a physician, whether the beneficiary resides at home or in a facility. (42 CFR 410.40(d)(3)(ii)).

8. 42 CFR 410.42(d).

9. On December 28, 2000, the Department of Health and Human Services (HHS) released its final rule implementing the privacy provisions of the Health Insurance Portability and Accountability Act of 1996. The rule became effective in April 2001, and regulates access, use, and disclosure of personally identifiable health information by covered entities (health providers, plans, and clearinghouses). Guidance on an ambulance supplier's compliance with the HHS Privacy Regulations is beyond the scope of this CPG; however, it will be the responsibility of ambulance suppliers to comply. Most health plans and providers must comply with the rule by April 14, 2003. In the meantime, many organizations are considering and analyzing the privacy issues.

10. Loaded miles refers to the number of miles that the patient is physically on board the ambulance.

11. HCFA Program Memorandum Transmitted AB-00-118, issued on November 30, 2000.

12. In addition to Medicare and Medicaid, the federal health care programs include, but are not limited to, TRICARE, Veterans Health Care, Public Health Service programs, and the Indian Health Services.

13. The procedures for applying for an advisory opinion are set forth at 42 CFR part 1008, and on the OIG Web page at <http://www.oig.hhs.gov/fraud/advisoryopinions.html#3>. All OIG advisory opinions are published on the OIG web page. A number of published opinions involving ambulance arrangements provide useful guidance for ambulance suppliers. These include OIG Advisory Opinions Nos. 97-6, 98-3, 98-7, 98-13, 99-1, 99-2, 99-5, 00-7, 00-9, 00-11, 01-10, 01-11, 01-12, 01-18, 02-2, 02-3, 02-8, and 02-15. Other advisory opinions not specifically involving ambulance arrangements may also provide useful guidance.

14. See 65 FR 24400; April 26, 2000.

15. See Special Advisory Bulletin: Offering Gifts and Other Inducement to Beneficiaries, located on the OIG Web page at <http://www.oig.hhs.gov/fraud/fraudalerts.html#2>.

16. See Special Fraud Alert: Routine Waiver of Copayments or Deductibles Under Medicare Part B (59 FR 65372, 65374 (1994)), located on the OIG Web page at <http://www.oig.hhs.gov/fraud/fraudalerts.html#1>.

17. The OIG may exclude from participation in the federal health care programs any provider that submits, or causes to be submitted bills or requests for payment (based on charges or costs) under Medicare or Medicaid that are substantially in excess of such providers' usual charges or costs, unless the Secretary finds good cause for such bills or requests. (See section 112(d)(6) of the Act (42 U.S.C. 1320a-7(b)(6)).

Dated: February 14, 2003.

Janet Rehnquist,

Inspector General.

[FR Doc. 03-0866 Filed 3-21-03; 8:45 am]

BILLING CODE 4152-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (301) 443-7978.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: National Cross-Site Assessment of the Addiction Technology Transfer

Centers Network—(OMB No. 0930-0216, Revision—The Substance Abuse and Mental Health Administration's (SAMHSA) Center for Substance Abuse Treatment (CSAT) intends to continue an assessment of its Addiction Technology Transfer Centers (ATTCs). The data collection instruments are being modified, and the methodology will be updated to comply with CSAT's new Government Performance and Results Act (GPRA) requirements. CSAT is requiring all of its programs to use standard GPRA Customer Satisfaction forms for training, technical assistance and meeting events, approved by OMB under OMB control number 0930-0197. In response to these new requirements, the ATTC Network will modify the

Exhibit 6

2006 Senate Bill 6231

SENATE BILL 6231

Passed Legislature - 2006 Regular Session

State of Washington 59th Legislature 2006 Regular Session

By Senator Spanel; by request of Insurance Commissioner

Read first time 01/09/2006. Referred to Committee on Financial Institutions, Housing & Consumer Protection.

1 AN ACT Relating to exempting certain private air ambulance services
2 from licensing under the insurance code; and adding a new section to
3 chapter 48.01 RCW.

4 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF WASHINGTON:

5 NEW SECTION. Sec. 1. A new section is added to chapter 48.01 RCW
6 to read as follows:

7 A private air ambulance service that solicits membership
8 subscriptions, accepts membership applications, charges membership
9 fees, and provides air ambulance services, to subscription members and
10 designated members of their household is not an insurer under RCW
11 48.01.050, a health carrier under chapter 48.43 RCW, a health care
12 services contractor under chapter 48.44 RCW, or a health maintenance
13 organization under chapter 48.46 RCW if the private air ambulance
14 service:

15 (1) Is licensed in accordance with RCW 18.73.130;

16 (2) Attains and maintains accreditation by the commission on
17 accreditation of medical transport services or another accrediting
18 organization approved by the department of health as having equivalent
19 requirements as the commission for aeromedical transport;

1 (3) Has been in operation in Washington for at least two years; and
2 (4) Has submitted evidence of its compliance with this section, the
3 licensing requirements of RCW 18.73.130, and accreditation from the
4 commission or another accrediting organization approved by the
5 department of health as having equivalent requirements as the
6 commission for aeromedical transport to the commissioner.

Passed by the Senate February 3, 2006.

Passed by the House February 28, 2006.

Approved by the Governor March 15, 2006.

Filed in Office of Secretary of State March 15, 2006.