

expenses other than local mileage for local participants; (11) organization dues; (12) honoraria or other payments for the purpose of conferring distinction or communicating respect, esteem, or admiration; (13) patient care; (14) alterations or renovations; and (15) indirect costs.

Grant funds may not be used to provide general support for international scientific conferences held outside the United States or Canada. Grant funds may be awarded to a U.S. component of an international organization to provide limited support for specified segments of an international conference held outside the United States or Canada if the conference is compatible with FDA's mission. An example of such support would be a selected symposium, panel, or workshop within the conference, including the cost of planning and the cost of travel for U.S. participants for the specified segment of the scientific conference. Any Public Health Service (PHS) foreign travel restrictions that are in effect at the time of the award must be followed, including but not limited to:

1. Limitations or restrictions on countries to which travel will be supported; or
2. Budgetary or other limitations on availability of funds for foreign travel.

The collection of information requested in PHS Form 398 and its instructions have been submitted by PHS to the Office of Management and Budget (OMB) and were approved and assigned OMB control number 0925-0001. Information collection requirements requested on PHS Form 5161-1 were approved and issued under OMB Circular A-102.

C. Legend

Unless disclosure is required by the Freedom of Information Act as amended (5 U.S.C. 552) as determined by the freedom of information officials of DHHS or by a court, data contained in the portions of this application that have been specifically identified by page number, paragraph, etc., by the applicant as containing restricted information shall not be used or disclosed except for evaluation purposes.

Dated: May 31, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02-14101 Filed 6-4-02; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Availability of Funds; Correction

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Correction and extension of time for application deadline.

SUMMARY: This notice corrects an Internet address for accessing application materials and extends the time that applications will be accepted for fiscal year 2002 competitive Cooperative Agreements for Health Workforce research that was published in the **Federal Register** on Thursday, May 23, 2002 (67 FR 36198) [FR Doc. 02-12928]. That notice announced that applications must be received by mail or delivered to the HRSA Grants Application Center by no later than June 19, 2002. The deadline for applications has been extended and applications must be received by mail or delivered to the HRSA Grants Application Center, 901 Russell Avenue, Suite 450, Gaithersburg Maryland, 20879, by no later than July 8, 2002. Additionally, the Internet address given in the above referenced **Federal Register** notice for accessing application materials was incorrect. The correct Internet address for accessing application materials is hrsagac@hrsa.gov.

FOR FURTHER INFORMATION CONTACT: Sarah Richards (phone 301-443-5452 or via e-mail at srichards@hrsa.gov) or Louis Kuta (phone 301-443-6634 or via e-mail at lkuta@hrsa.gov).

Dated: May 31, 2002.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 02-14170 Filed 6-5-02; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Committee; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92-463), announcement is made of the following National Advisory body scheduled to meet during the month of July 2002.

Name: Advisory Committee on Infant Mortality (ACIM).

Date and Time: July 10, 2002; 9 a.m.-5 p.m., July 11, 2002; 8:30 a.m.-3 p.m.

Place: Crowne Plaza Hotel, 14th and K Streets, NW., Washington, DC 20005, (202) 682-0111.

The meeting is open to the public.

Purpose: The Committee provides advice and recommendations to the Secretary of Health and Human Services on the following: Department programs which are directed at reducing infant mortality and improving the health status of pregnant women and infants; factors affecting the continuum of care with respect to maternal and child health care, including outcomes following childbirth; factors determining the length of hospital stay following childbirth; strategies to coordinate the variety of Federal, State, and local and private programs and efforts that are designed to deal with the health and social problems impacting on infant mortality; and the implementation of the Healthy Start initiative and infant mortality objectives from *Healthy People 2010*.

Agenda: Topics that will be discussed include the following: Early Postpartum Discharge; Low-Birth Weight; Disparities in Infant Mortality; and the Healthy Start Program.

Anyone requiring information regarding the Committee should contact Peter C. van Dyck, M.D., M.P.H., Executive Secretary, ACIM, Health Resources and Services Administration (HRSA), Room 18-05, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857, telephone: (301) 443-2170.

Individuals who are interested in attending any portion of the meeting or who have questions regarding the meeting should contact Ms. Kerry P. Nesseler, HRSA, Maternal and Child Health Bureau, telephone: (301) 443-2170.

Agenda items are subject to change as priorities are further determined.

Dated: May 31, 2002.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 02-14171 Filed 6-5-02; 8:45 am]

BILLING CODE 4165-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Draft OIG Compliance Program Guidance for Ambulance Suppliers

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

ACTION: Notice and comment period.

SUMMARY: This **Federal Register** notice seeks the comments of interested parties on draft compliance program guidance (CPG) developed by the Office of Inspector General (OIG) for the ambulance industry. Through this notice, the OIG is setting forth its general views on the value and fundamental principles of ambulance industry CPG, and the specific elements

that ambulance providers/suppliers should consider when developing a CPG initiative.

DATES: To ensure consideration, comments must be delivered to the address provided below by no later than 5 p.m. on July 22, 2002.

ADDRESSES: Please mail or deliver written comments to the following address: Office of Inspector General, Department of Health and Human Services, Attention: OIG-415-CPG, Room 5246, Cohen Building, 330 Independence Avenue, SW., Washington, DC 20201.

We do not accept comments by facsimile (FAX) transmission. In commenting, please refer to file code OIG-415-CPG. Comments received timely will be available for public inspection as they are received, generally beginning approximately 2 weeks after publication of a document, in Room 5541 of the Office of Inspector General at 330 Independence Avenue, SW., Washington, DC 20201 on Monday through Friday of each week from 8 a.m. to 4:30 p.m.

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 ambulance industry has experienced a number of instances of ambulance provider and supplier fraud and abuse and has expressed interest in increasing the awareness of the industry to assist in protecting against such conduct. In response to the industry's concerns, the OIG has, to date, written several Advisory Opinions on a variety of ambulance-related issues¹ and has published final rulemaking concerning a safe harbor for ambulance restocking arrangements.²

In an effort to provide further guidance, the OIG published a **Federal Register** notice on August 17, 2000 (65 FR 50204) that solicited 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. The OIG expects that final guidance will outline the most common and prevalent fraud and abuse risk areas for the ambulance industry, and provide 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.

Public Input and Comment in Developing Final CPG

In response to our earlier solicitation notice, the OIG received 37 comments from various organizations and associations. In developing this notice for formal public comment, we have considered those specific comments as well as previous OIG issuances, such as OIG-issued Advisory Opinions, and have consulted with the Centers for Medicare and Medicaid Services and the Department of Justice.

To ensure that all parties have an opportunity to provide input, we are publishing this CPG in draft form, and welcome specific comments from all interested parties. The OIG will consider all comments that are received within the above-cited time frame, incorporate any specific recommendations, as appropriate, and prepare a final version of the CPG thereafter for publication in the **Federal Register**.

Draft Compliance Program Guidance for Ambulance Suppliers (May 2002)

I. Introduction

In keeping with the previous efforts of the Office of Inspector General (OIG) to provide guidance to various health care industry sectors on sound compliance program measures, the OIG is publishing this draft compliance program guidance (CPG)¹ for the ambulance industry and other parties that are affected by the services provided by ambulance suppliers.² This CPG is divided into five separate sections with an appendix:

- Section I is a brief introduction about this CPG;
- Section II provides information about the basic elements of a compliance program for ambulance suppliers;

¹ In its solicitation of information and recommendations for developing guidance for the ambulance industry (published in the **Federal Register** on August 17, 2000 (65 FR 50204), the OIG indicated that it expected to refer to the ambulance compliance guidance as a "compliance risk guidance." After additional input and to remain consistent with the name and format of prior OIG compliance guidances, the OIG has decided to call this document a compliance program guidance.

² Ambulance providers are all Medicare-participating institutional providers that submit claims for Medicare ambulance services (hospitals, including critical access hospitals; skilled nursing facilities; and home health agencies). 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.

- Section III of this document 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; and
- Section V discusses various risks the ambulance industry faces 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.

The OIG is especially interested in the comments and suggestions the ambulance industry and affiliated providers may have regarding this draft CPG. The OIG recognizes that the ambulance industry is made up 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 on ambulance supplier compliance programs. Rather, like the previous OIG CPGs, this guidance is intended as a helpful tool for those entities that are considering establishing a voluntary compliance program, or for those that have already done so and are seeking to analyze, improve or expand existing programs.³ As with the OIG's previous guidance, the guidelines discussed in this CPG are not mandatory. Nor do they represent 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 also be used in developing a compliance guidance.

A. Scope of the Compliance Program Guidance

This guidance focuses on compliance measures related to services furnished primarily to the Medicare program, and to a limited extent, other Federal health care programs. (See, e.g., section IV for a brief discussion of Medicaid)

³ 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 website at www.oig.hhs.gov in the Fraud Prevention and Detection section.

¹ See footnote 23 in section V.F. of the draft compliance program guidance.

² See 66 FR 62979; December 4, 2001.

ambulance coverage.) Issues related to private payor claims and services covered by private payors may also be covered by an ambulance supplier compliance program if the supplier so desires.

B. Basic Elements of a Compliance Program

While information and guidance furnished in this CPG may form the basic framework for developing a compliance program, this guidance is not by itself a compliance program. The basic components that have become accepted as the building blocks of an effective compliance program are: (1) Developing compliance policies and procedures; (2) designating a compliance officer or contact person(s); (3) conducting appropriate training and education; (4) conducting internal monitoring and reviews; (5) responding appropriately to detected offenses and developing corrective actions; (6) developing open lines of communication; and (7) enforcing disciplinary standards through well-publicized guidelines. The components of a compliance program are briefly discussed below with a more in-depth discussion in section II of this CPG.

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, which promote 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. (See section II.A.1 of this CPG for a more in-depth discussion of the development of policies and procedures.)

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 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 a 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

Compliance programs must include as a key element the 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. This CPG discusses training in more detail in section II.A.2.

4. Internal Monitoring and Reviews

Ambulance suppliers should develop and use appropriate monitoring methods to detect and identify problems, and to help reduce the future likelihood of problems. Claims and system reviews are a common internal monitoring method and are discussed in greater detail in section II.A.3 of this CPG.

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 complainant desires 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.⁴

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.

Accordingly, the OIG has attempted to take into consideration the Centers for Medicare and Medicaid Services' (CMS) recent adoption of the fee schedule for payment of ambulance services. The CMS's ambulance fee schedule is the product of a negotiated rulemaking process and will replace the current retrospective, reasonable cost reimbursement system for providers and the reasonable charge system for suppliers of ambulance services.⁵ As appropriate, the OIG may update or supplement this CPG to address new identified risk areas following the implementation of the ambulance fee schedule.

II. Elements of a Compliance Program for Ambulance Suppliers

Like other sectors of the health care industry, most ambulance suppliers are honest suppliers trying to deliver quality ambulance transportation 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 practices in the ambulance transport field involving, among others:

- Situations when individuals had other acceptable means of transportation;
- Medically unnecessary trips;

⁴ The term "Federal health care programs" is applied in this CPG as defined in 42 U.S.C. 1320a-7b(f), which includes any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States Government (*i.e.*, through programs such as Medicare, Federal Employees' Compensation Act, Black Lung, or the Longshore and Harbor Workers' Compensation Act) and any State health plan (*e.g.*, Medicaid, or a program receiving funds from block grants for social services or child health services). Also, for purposes of this CPG, the term "Federal health care program requirements" refers to statutes, regulations, rules, requirements, directives, and instructions governing the Medicare and other Federal health care programs.

⁵ The CMS's final ambulance fee schedule was published in the **Federal Register** on February 27, 2002 (67 FR 9100) and went into effect on April 1, 2002.

- Submission of excessive claims;
- Trips were 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; and
- Upcoding from basic life support to advanced life support services.

To help reduce the incidence and prevalence of fraudulent or abusive conduct, an ambulance supplier should consider the following guidance and adapt the OIG's suggestions to conform with any unique ambulance supplier elements.

A. Evaluation and Risk Analysis

It is prudent for ambulance suppliers conducting a risk analysis to begin by performing an evaluation of internal operations as well as factors that affect such operations (e.g., Federal health care program requirements). In many cases, such evaluation will result either in the creation and adoption of written policies and procedures or the revision thereof. 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 when there are no pre-existing written policies and procedures and the subsequent analysis of whether the particular supplier's practices comply with applicable statutes, regulations, and other program requirements.

The evaluation process should furnish ambulance suppliers with a snapshot of their strengths and weaknesses and thus 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 an 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 (ACR) 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. If certain policies and practices become genuinely impractical, we recommend that such policies and procedures be updated to reflect alternative, acceptable practices that conform to legal and regulatory requirements.

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 pertinent personnel.

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. Such appropriate cross-training improves 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 as 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 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 they should be 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. Additionally, the appearance of a lack of independence may also 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 (*i.e.*, coding accuracy) or it may include all aspects of the claims submission and payment process. The universe⁶ 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 will vary as will the variability of items in the universe, 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 sufficiently 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 promptly correct them. In this example, at a minimum, additional employee training would be required along with the repayment of any identified overpayment. Such a detailed and logical process of analysis will make claims reviews useful tools for identifying risks, correcting weaknesses, and preventing future occurrences of errors.

Ambulance suppliers should also consider using a baseline audit to develop a benchmark from which to measure performance. This audit will establish a consistent methodology for selecting and examining records in future audits. It is helpful to chart and track the results of each of the audits to document progress. The results of each subsequent audit will indicate whether further actions are appropriate. 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. For example, results of audits of a supplier's compliance with the physician certification statement requirements for non-emergency transports and a supplier's compliance with ambulance and vehicle licensure cannot be readily compared. The trending information may need to be broken out and separately analyzed to track compliance.

As part of its compliance efforts, an ambulance supplier should document (i) how often audits or reviews are conducted and (ii) the information reviewed for each audit. In addition, the results of such reviews should be compared to previous findings to determine if a problem persists or if the supplier's corrective actions are working. 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 carriers). Additionally, risk areas may be identified from the results of the audits.

If, as a result of the audit, 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.⁷ 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.

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 for payment until it is determined by a responsible person within the organization that the appropriate, adequate documentation exists to support the claim. Pre-billing reviews also allow suppliers to review the medical necessity of their claims before they are submitted for reimbursement. 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 (see section II.C), which would include a 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 periodically should review their claims denials from payors to determine if denial patterns exist. If a pattern of claims denials is detected, the patterns should be evaluated to determine the cause and appropriate course of action. Employee education regarding proper

⁷ 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 overpayment problems. The OIG's Self-Disclosure Protocol can be found on the OIG web site at www.oig.hhs.gov.

⁶ The term "universe" is referred to in this CPG to mean the generally accepted definition used when performing a statistical analysis. Specifically, the term "universe" means the total number of sampling units from which the sample was selected.

documentation, coding, or medical necessity may be appropriate. If an ambulance supplier believes its carrier or 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, documentation of ambulance transports must now indicate the point of pick-up of the beneficiary. Under CMS's new fee schedule for ambulance services, 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 improper claims, such as emergency codes used when the destination is something other than an emergency room. 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 carrier when they are implementing significant changes to their system to alert the carrier to any unexpected delays, or increases or decreases in claims submissions.

Ambulance suppliers have the responsibility of ensuring that their electronic or computer billing systems are not automatically inserting information that is not supported by the documentation of the medical or trip sheets (e.g., whether physician signature was obtained). Billing systems targeting optimum efficiency may be set with defaults to indicate, for example, that a physician's signature was obtained following an emergency room transport.

Conversely, 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 such a 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, with respect to its existing employees and contractors, ambulance suppliers should periodically (at least yearly) check the OIG's and General Services Administration's (GSA) web sites to ensure that they do not employ or contract with individuals or entities that have been recently convicted of a criminal offense related to health care or who are listed as debarred, excluded or otherwise ineligible for participation in Federal health care programs. Additionally, ambulance suppliers should query the OIG and GSA exclusion and debarments lists before they employ or contract with new employees and new contractors. The OIG and GSA websites are listed at www.oig.hhs.gov and www.arnet.gov/epl respectively, and contain specific instructions for searching the exclusion and debarment databases.⁸

B. Identification of Risks

This ambulance CPG discusses many of the areas that the ambulance industry, the OIG, and CMS have identified as common risks for many ambulance suppliers. Apart from the risks identified in this CPG, ambulance suppliers of all types (e.g., small, large, rural, emergency, non-emergency) should identify if they have any unique risks attendant to their business relationships or processes. An ambulance supplier may have certain unique characteristics that will affect its risk areas. For example, small, rural not-for-profit ambulance suppliers may identify risk areas different from those of a large, for-profit ambulance chain that competes with multiple other ambulance suppliers. This CPG may not identify or discuss all risks that an ambulance supplier may itself identify. Moreover, the CPG may ascribe more or less risk to a particular practice area

⁸ 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 58851) and is located at www.oig.hhs.gov/frdalrt, for more information regarding excluded individuals and entities and the effect of employing such individuals or entities.

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.

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, Office of Evaluations and Inspections (OEI) reports, and Office of Audit Services (OAS) reports, all located on the OIG's web site at www.oig.hhs.gov. A review of industry specific trade publications will also help ambulance suppliers stay current on the industry changes. Ambulance suppliers, like others in the health care industry, should devote the necessary resources to ensure compliance with relevant requirements. Effective internal controls will help to prevent or reduce instances of mistakes, errors, fraud and/or abuse.

C. Response to Identified Risks

Following an ambulance supplier's process of evaluation and identification of its risks, a reasonable response should be developed to address appropriately identified risk areas. Determining how identified problems respond to corrective actions may require continual oversight. However, developing timely and appropriate responsive actions demonstrates to an ambulance supplier's employees and other interested parties (e.g., payors, the OIG, etc.) its level of commitment to address problems and concerns.

Ambulance suppliers should develop protocols and reasonable timeframes for responding to identified problems. Ambulance suppliers can identify in advance and through a written protocol how certain situations will be addressed, including the internal reporting obligations and involvement, if appropriate, of legal counsel. Such response protocols should include a monitoring process by which the issue will be revisited on an as needed basis.

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

Ambulance suppliers should, at a minimum, 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

standards set forth. The new Medicare ambulance 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.⁹ 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 (e.g., a transport from a skilled nursing facility to a hospital).

A. Medical Necessity

There have been a number of transportation fraud cases against the Medicare and Medicaid programs involving medically unnecessary transport. 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; or
- Round trip from a hospital, CAH, or SNF to an outside supplier to receive medically necessary therapeutic or diagnostic services.

1. Upcoding

Notwithstanding local or state ordinance requirements regarding ambulance staffing and all-ALS mandated services,¹⁰ ambulance suppliers should use caution 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 5-year Corporate Integrity Agreement (CIA).

2. Non-Emergency Transports

There have also been a number of Medicare fraud cases involving (i) non-emergency transports to non-covered destinations and (ii) transports that were not medically necessary. An OIG OEI report¹¹ 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.¹² The report indicated, for example, that certain surveyed patients had been sitting unaided in a chair the day of and the day after the ambulance transport. Another patient was found sitting in a wheelchair when the ambulance arrived and refused assistance to get back to bed. These patients did not meet the Medicare coverage criteria for non-emergency transports and could have been transported by means other than by ambulance.

In addition, an August 2001 report¹³ conducted by the OIG's OAS at the request of a Medicare Part B carrier, determined that an ambulance supplier received significant overpayments. For example, of the 100 trip sheets reviewed by the OIG, 99 of the trip sheets did not indicate whether the beneficiary was bed-confined.

There are instances when an ambulance supplier receives a call for assistance or transport of a patient who does not meet the medical necessity requirements. Due to various patient

care and liability reasons, ambulance suppliers often transport patients who do not appear to meet Medicare's non-emergency medical necessity requirements. If an ambulance supplier determines that a transport is not covered by Medicare, the ambulance supplier should attempt to obtain a signed Advanced Beneficiary Notice (ABN) from the Medicare beneficiary. As part of the ABN process, the ambulance supplier should explain to the beneficiary that the service may not be covered by Medicare, in which case the patient will be responsible for payment of the transport and other non-covered services.

Under no circumstances should ambulance suppliers intentionally mischaracterize the condition of the patient at the time of transport in an effort to claim inappropriately that the transport was medically necessary under Medicare coverage requirements. In instances where it is not clear whether the service will be covered by Medicare, the ambulance provider should nonetheless appropriately document the condition of the patient and maintain records of the transport.

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.¹⁴ 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.¹⁵ 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. For example, Medicare does not normally pay for non-emergency scheduled or unscheduled ambulance transportation to a physician's office from a personal residence or nursing facility when a

¹¹ OIG Report, OEI-09-95-00412 is available on the OIG's web site at www.oig.hhs.gov/oei.

¹² Medicare's ambulance fee schedule identifies non-emergency transport as appropriate if the beneficiary is bed confined and it is documented that the beneficiary's medical condition is such that other methods of transportation are contraindicated, or if his or her medical condition, regardless of bed-confinement, is such that transportation by ambulance is medically required. In determining whether a beneficiary is bed-confined, the following criteria must be met: (1) The beneficiary is unable to get up from bed without assistance; (2) the beneficiary is unable to ambulate; and (3) the beneficiary is unable to sit in a chair or wheelchair. 42 CFR 410.40(d).

¹³ August 20, 2001, OIG Report, A-03-01-00001 is available on the OIG's web site at www.oig.hhs.gov/oas.

¹⁴ CMS (formerly the Health Care Financing Administration (HCFA)) Program Memorandum B-00-09 describes different options for ambulance suppliers having difficulty obtaining PCSs. See 42 CFR 410.40(d)(3)(iii), (iv). For beneficiaries not under the direct care of a physician, whether they reside at home or in a facility, a PCS is not required. Id. § 410.40(d)(3)(ii).

¹⁵ 42 CFR 410.40(d).

⁹ The Negotiated Rulemaking Committee on the Medicare Ambulance Services Fee Schedule used the National EMS Education and Practice Blueprint as the basis for defining the levels of ambulance service.

¹⁰ Payment for ALS transports provided at the BLS level will be phased in over CMS's ambulance fee schedule transition period.

patient is able to ambulate. 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 provider was required to pay over \$1 million dollars 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.¹⁶

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 bed-confined status of the individual;
- Who ordered the trip;
- Time spent on the trip;
- Dispatch, arrival at scene, and destination times;

¹⁶ 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.

- Mileage traveled;
- Pick up and destination codes;
- Appropriate zip codes; and
- Services provided, including drugs or supplies.

1. HCPCS and Diagnosis Code Selection

The appropriate diagnosis and procedure codes (e.g., ICD-9, HCPCS/CPT) should be used when submitting claims for reimbursement. The codes reported on the ambulance trip sheets or claim forms should be selected to describe most accurately the illness, injury, signs or symptoms associated with the patient and transport. Although ICD-9 codes are universally known as diagnosis codes, coders use them to describe signs and symptoms.¹⁷ Coders are taught that the patient's condition should be coded to the highest level of certainty and specificity. Diagnostic code information should not be based on past medical history or prior conditions, unless such information also specifically relates to the patient's condition at the time of transport.

False or uncertain diagnoses should never be added to the trip sheets or claims to justify reimbursement. If there is a question on the proper code to use when coding from the trip sheet or preparing a bill that cannot be appropriately resolved within the organization's proper chain of command, the ambulance supplier should seek guidance, in writing, from its local carrier. In addition to obtaining written guidance, ambulance suppliers should maintain documentation of communication with its carrier. If the ambulance supplier experiences difficulty in obtaining clarification, it should submit with the claim a narrative explaining the issue and the basis for the selected choice. Copies of any carrier correspondence should be appropriately maintained by the ambulance supplier.

2. Origin/Destination Requirements—Loaded Miles¹⁸

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 pick-up" zip code on each ambulance claim form.¹⁹ Under the new Medicare ambulance fee schedule, the point of pick-up will determine the mileage payment rate as well as whether

¹⁷ Only licensed physicians and certain other licensed practitioners can make determinations on a patient's diagnosis.

¹⁸ Loaded miles refers to the number of miles that the patient is physically on board the emergency vehicle.

¹⁹ HCFA Program Memorandum Transmittal AB-00-118, issued on November 30, 2000.

a rural adjustment factor will be applied to the base rate. The ambulance supplier should document the address of the point of pick-up to verify that the zip code is accurate.

The ambulance crew should accurately report the mileage traveled from the point of pick-up 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 lack of equipment), the beneficiary should be taken to the next closest and 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 insurance. Claims for payment should not be submitted to more than one payor, except for purposes of coordinating benefits (e.g., Medicare as secondary payer). Section 1862(b)(6) of the Social Security 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 monetary penalty (CMP).

The OIG recognizes, particularly for ambulance suppliers that may have incomplete insurance information from a transported patient, that there are instances when the secondary payor is not known or cannot be determined before the ambulance transportation claim is submitted. In such situations, if it is determined that an inappropriate or duplicate payment is received, 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, including transports for patients of a SNF, hospital or CAH, Medicare Part A covers ambulance transports. Ambulance suppliers that provide such inpatient transports "under arrangements" should not bill Medicare for these transports. Medicare reimburses the facility under

the Part A payment for the patient's entire Part A stay, including any pre-discharge ambulance transports. Thus, ambulance suppliers should not submit a claim to Medicare Part A or B for a service that was provided under arrangement with a Part A provider. In addition, 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 of this CPG.

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. Medicaid regulations, to which ambulance suppliers must adhere, vary depending on the applicable State regulations. However, two Federal regulations form the basis for all Medicaid reimbursement for transportation services and ensure a minimum level of coverage for transportation services. All States that receive Federal Medicaid funds are required to assure transportation for Medicaid recipients to and from medical appointments (42 CFR 431.53). 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 ambulance transports that are not typically covered by Medicare, such as coverage of transports in wheelchair vans, cabs and ambulettes. 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 the generation of Federal health care program business, including Medicare and Medicaid business.²⁰ (*See* section 1128B(b) of the Social Security 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 and the party soliciting or receiving it. The key inquiry under the statute is whether the parties intend to pay, or be paid, for referrals. An ambulance supplier should neither make nor accept payments intended to generate Federal health care program business.

B. What Are the "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://www.dhhs.gov/progorg/oig/ak/index.htm#>. The safe harbor regulations are *voluntary* regulations. Thus, failure to comply with a safe harbor does not mean that an arrangement is illegal. Rather, arrangements that do not fit 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 of a violation, ambulance suppliers should structure arrangements to take advantage of the protection offered by the safe harbors. Among the safe harbors potentially relevant to ambulance suppliers are the safe harbors for space and equipment rentals, personal services and management contracts, discounts, employees, price reductions offered to health plans, shared risk arrangements, and ambulance restocking arrangements.²¹

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 in paid 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 rent, meals, travel, gifts, and investment interests. 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* section 1128B of the Social Security Act (42 U.S.C. 1320a-7b).)

D. Who Is a Referral Source for Ambulance Suppliers?

Any person or entity in a position to generate Federal health care program business for an ambulance supplier is a potential referral source. Typically, these 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 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, may also 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 inappropriately steer patients to certain 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 with 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 particular existing or proposed arrangements may obtain binding advisory opinions from the OIG.²²

Ambulance suppliers should exercise common sense when evaluating existing

²⁰ 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.

²¹ 42 CFR 1001.952 (b), (c), (d), (h), (i), (t), (u) and (v).

²² The procedures for applying for advisory opinions are set forth at 42 CFR part 1008 and on the OIG web page at www.oig.hhs.gov/advopn/index.htm. All OIG advisory opinions are published on the OIG web page. Several published opinions involve ambulance arrangements and may provide useful guidance for ambulance suppliers. These include OIG Advisory Opinions 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 and 02-3.

or prospective arrangements under the anti-kickback statute. One good rule of thumb is that all arrangements for items or services between potential referral sources should be *fair market value* in an arm's-length transaction *not* taking into account the volume or value of existing or potential referrals. For each arrangement, ambulance suppliers should carefully and accurately document how fair market value is determined (e.g., by market comparables, open competitive bidding, cost basis, etc.). Discounts should be accurately reflected and appropriately disclosed on all claims and cost reports filed with the Federal health care programs, and accurate and complete records should be kept of all discount arrangements. Ambulance suppliers should consult the safe harbor for discounts (42 CFR 1001.952(h)) when entering into discount arrangements.

Another good rule of thumb is that ambulance suppliers should exercise caution when selling services to purchasers who are also in a position to generate Federal health care program business for the ambulance supplier (e.g., skilled nursing facilities that purchase ambulance services for private pay and Part A patients, but refer Part B and Medicaid patients to the ambulance supplier). Any link or connection between the price offered to the seller and referrals of Federal program business will implicate the anti-kickback statute. In other words, ambulance suppliers should not offer purchasers with Federal health care program business a price that is lower than the price they would charge a purchaser with a comparable volume of business and no Federal health care program referrals.

A third good rule of thumb is that an ambulance supplier should not offer or provide gifts, free items or services, or other incentives of greater than nominal value to referral sources 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:²³

²³ This list of arrangements is intended to be illustrative, not exhaustive, of potential areas of risk under the anti-kickback statute.

1. Arrangements for Emergency Medical Services (EMS)

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, nor should they condition an EMS contract on obtaining non-EMS ambulance business.²⁴ 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.

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, in particular, the second rule of thumb described 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 prohibition against giving inducements to Medicare and Medicaid beneficiaries.²⁵ Potentially prohibited

²⁴ In general, ambulance suppliers may offer cities or other municipal entities free or reduced cost services for uninsured, indigent patients.

²⁵ The CMP law prohibits giving anything of value to a Medicare or Medicaid beneficiary that the giver knows, or should know, is 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 Social Security Act (42 U.S.C. 1320a-7a)(5)). The statute contains several narrow exceptions, including financial hardship copayment waivers,

areas include, but are not limited to, routine waivers of copayments,²⁶ "insurance programs" offering patients purported coverage for the ambulance supplier's services only, and free goods and services. Ambulance suppliers may waive copayments based on good faith individualized assessments of financial need, so long as the availability of financial hardship waivers is not advertised.²⁷

V. Conclusion

This ambulance compliance risk guidance is intended as a resource for ambulance suppliers to decrease the incidence of errors, fraud and abuse that occur due to, among other factors, lack of knowledge, inadequate training and inadvertent noncompliance. The Government has increased its scrutiny of the health care industry in part in an effort to decrease errors and/or fraudulent and abusive practices. Similarly, we encourage ambulance suppliers to scrutinize their internal practices via their compliance efforts.

Compliance programs should reflect each ambulance supplier's individual and unique circumstances. It has been the OIG's experience that those health care providers that have developed compliance programs not only better understand applicable Federal health care program requirements, but also better understand their 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 no transportation of a patient is subsequently required due to the

incentives to promote the delivery of preventive care services, and health plan differentials in copayments. 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.

²⁶ See Special Fraud Alert: Routine Waiver of Copayments or Deductibles Under Medicare Part B, 59 FR 65372, 65374 (1994) contained on the OIG web page at <http://oig.hhs.gov/frdalrt/index.htm>.

²⁷ Under a special rule, ambulance suppliers owned and operated by a State or a political subdivision of a State, such as a municipality or a fire district, may waive Medicare copayments for residents. See CMS *Carrier Manual* section 2309.4; CMS *Intermediary Manual* section 3153.3A. This rule does not apply to private ambulance suppliers providing services under contract. However, States and political subdivisions of States may pay uncollected, out-of-pocket copayments on behalf of residents. Such payments may be made through lump sum or periodic payments, if the aggregate payments reasonably approximate the otherwise uncollected copayment amounts.

patient's death or patient's refusal to be transported, there are three Medicare rules that 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 carrier in that region. Under CMS's new ambulance 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. The non-transporting ambulance company should receive payment directly from the transporting supplier based on a negotiated arrangement if that company's ambulance crew had provided services to the patient, but had not actually transported the patient to a treatment facility.²⁸ On occasion, when multiple ambulance crews respond to a call, a BLS ambulance may have provided the transport, but the level of services provided may have been at the ALS level. If a BLS supplier is billing at the ALS level because of the services furnished by an additional ALS crew member, appropriate documentation should accompany the claim to indicate to the carrier 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

²⁸ 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.

exclusion by the OIG.²⁹ This exclusion authority is not implicated unless the supplier's charge for Medicare or Medicaid patients is substantially more than its median non-Medicare/Medicaid charge. A supplier should identify as a risk area its billing practices if it is discounting close to half of its non-Medicare/Medicaid business. Thus, 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.

Appendix B—OIG—HHS Contact Information

The OIG's web site (www.oig.hhs.gov) contains various links describing the following: (1) The OIG's four different components (Audit Services, Investigations, Evaluations and Inspections, Counsel to the IG); (2) External Information such as how to subscribe to the OIG's mailing list and OIG's Hearing Testimony; (3) Compliance Tools that include a list of the OIG's Compliance Guidance, Corporate Integrity Agreements, and Self-Disclosure Information; (4) Fraud Detection and Prevention efforts including anti-kickback information, Advisory Opinions, and Fraud Alerts & Bulletins; and (5) Reports and Publications. 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 problems 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: Htips@os.dhhs.gov

By TTY: 1-800-377-4950

By Mail: Office of Inspector General,
Department of Health and Human Services,
Attn: HOTLINE, 330 Independence Ave.,
SW, Washington, DC 20201

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

²⁹ 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 1128(b)(6) of the Social Security Act (42 U.S.C. 1320a-7(b)(6)).

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 www.hcfa.gov/medicare/incardir.htm.

2. Medicaid

Contact information (address, phone number, e-mail address) for each State Medicaid director can be found on the CMS web site at www.hcfa.gov/medicaid/mcontact.htm. 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 www.hcfa.gov/medicare/ambmain.htm.

Appendix D—Internet Resources

1. Office Of Inspector General (www.oig.hhs.gov)

This web site includes a variety of information relating to Federal health care programs, including the following:

Components

- Audit Services
- Investigations
- Evaluation and Inspections
- Counsel to the IG
- Management and Policy

Compliance Tools

- Compliance Guidance
- Corporate Integrity Agreements

- Self-Disclosure Information

Press Information

- Subscribe to Mailing List
- OIG News
- Hearing Testimony

Fraud Detection and Prevention

- Anti-Kickback Information
- Advisory Opinion
- Fraud Alerts and Bulletins

Reports and Publications

- Audit Reports
- Evaluation Reports
- Semi-Annual Reports
- Orange Book
- Red Book
- Work Plan
- Regulations and **Federal Register** Notices

2. Centers for Medicare and Medicaid Services (www.hcfa.gov)

This web site includes information on a wide array of topics, including the following:

a. Medicare

- National Correct Coding Initiative
- Intermediary-Carrier Directory
- Payment
- Program Manuals
- Program Transmittals and Memorandum
- Provider Billing/CMS Forms
- Statistics and Data

b. Medicaid CMS Regional Offices

- Letters to State Medicaid Directors
- Medicaid Hotline Numbers
- Policy and Program Information
- State Medicaid Contacts
- State Medicaid Manual
- State Survey Agencies
- Statistics and Data

3. CMS Medicare Training (www.hcfa.gov/learning)

This web site provides computer-based training on the following topics:

- CMS 1500 Form
- Fraud and Abuse
- ICD-9-CM Diagnosis Coding
- Medicare Secondary Payer
- Introduction to the World of Medicare
- CMS 1450 (UB92)

4. Government Printing Office (www.access.gpo.gov)

This web site provides access to Federal statutes and regulations pertaining to Federal health care programs.

5. The U.S. House of Representatives Internet Library (<http://uscode.house.gov/usc.htm>)

This web site provides access to the United States Code, which contains laws pertaining to Federal health care programs.

Dated: May 20, 2002.

Janet Rehnquist,
Inspector General.

[FR Doc. 02-14163 Filed 6-5-02; 8:45 am]

BILLING CODE 4152-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Partner and Customer Satisfaction Surveys

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the Center for Scientific Review (CSR), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection: Title: partner and Customer Satisfaction Surveys. *Type of Information Collection Request:* Revision OMB #0925-0474; expires September 30, 2002. *Need and Use of Information Collection:* The information collection in these surveys will be used by Center for Scientific Review personnel: (1) To assess the quality of operations and processes used by CSR to review grant applications; (2) to assess the quality of service provided to our partners and customers; (3) to assist with the design of modifications of these operations, processes and services, based on partner and customer input; (4) to develop new modes of operation based on partner and customer need; and (5) to obtain partner and customer feedback about the efficacy of implemented modifications. These surveys will almost certainly lead to quality improvement activities that will enhance and/or streamline CSR's operations. The major mechanism by which CSR will request input is through surveys. The survey for partners is generic and tailored for Scientific Review Group (SRG) past and present members and chairs. The survey for customers (*i.e.*, grant applicants) will have slight variations determined by which category of scientific review group the researcher/investigator's grant application is reviewed. Surveys will be collected as written documents or via the Internet. Information gathered from these surveys will be presented to, and used directly by, CSR management to enhance the operations, processes, and services of our organization. *Frequency of Response:* Yearly. *Affected Public:* Universities, not-for-profit institutions, business or other for-profit, small businesses and organizations, and individuals. *Type of Respondents:* Adult scientific professionals. The annual reporting burden is as follows: *Estimated Number of Respondents:*

6,081 respondents in FY 2003, 6081 respondents in FY 2004 and 6081 respondents in FY 2005. *Estimated Number of Responses per Respondent:* 1 in FY 2003, 1 in FY 2004, and 1 in FY 2005. *Average Burden Hours Per Response:* 0.33. *Estimated Total Annual Burden Hours Requested:* 2007 in FY 2003, 2007 in FY 2004 and 2007 in FY 2005. Costs for time were estimated using the rate of \$38.00 per hour for SRG members, SRG chairs, and principal investigators/grant applicants. The estimated annual cost each year for which the generic clearance is requested is \$76,266 for FY 2003, \$76,266 for FY 2004 and \$76,266 for FY 2005. Respondents or recordkeepers should incur no additional costs.

Request for Comments: Written comments and/or suggestions from the public and affected agencies should address one or more of the following points: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Karl Malik, Ph.D., Office of the Director, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Rockledge II, Rm. 3016, Bethesda, MD 20892-7814, or call non-toll free: 301-435-1114, or E-mail your request, including your address to: malikk@csr.nih.gov.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received on or before August 5, 2002.

Dated: May 30, 2002.

John Czajkowski,

Acting Executive Officer, Center for Scientific Review, NIH.

[FR Doc. 02-14118 Filed 6-5-02; 8:45 am]

BILLING CODE 4140-01-M