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. 360j(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. 03–6892 Filed 3–21–03; 8:45 am]

BILLING CODE 4160–01–S

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. Wadhwani, 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 Schaer, (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 CPG 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 CPG discusses many of the areas that the ambulance industry, the OIG, or CMS have identified as common risks for many ambulance suppliers. However, this CPG does 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 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 CPG, 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.

1. 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 OEI 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,* 871 F.2d 105 (9th Cir. 1989); *United States* v. *Greber,* 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), (t), (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 heath 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.*, SNFs 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 of federal program business billable 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 suppliers (*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 stocking 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 G 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 payor 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 payor 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 median 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: *Htips@oig.hhs.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
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/incardir.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/afs/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/cbts.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://.uscode.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 overpayment 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 58851), which is located at *http://oig.hhs.gov/frdalrt*, for more information regarding excluded individuals and entities and the effect of employing or contracting with such individuals or entities.

6. OEI–09–95–00412, available on the OIG's Web site at *http://oig.hhs.gov/oei.*

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. Id. Section 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 Transmittal 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 1128(b)(6) of the Act (42 U.S.C. 1320a–7(b)(6)).)

Dated: February 14, 2003.

Janet Rehnquist,

Inspector General.

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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