EL PASO TEXAS FIRE DEPARTMENT COMPLIANCE PLAN

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OVERVIEW OF EL PASO TEXAS FIRE DEPARTMENT COMPLIANCE PLAN

El Paso Fire Department ("Department") is committed to conducting all of its business with ethical standards and in compliance with all applicable laws, rules, and regulations. Employees, vendors, and contractors of the Department are expected to recognize it as their duty to conduct their affairs consistent with this commitment.

The purpose of this Compliance Plan ("Plan") is to ensure that the employees of El Paso Fire Department adhere to all appropriate Medicare, Medicaid, and all other federally funded healthcare laws, rules, regulations, and policies for submission of claims for ambulance services and the general ambulance operations.

This Compliance Plan has been developed to assist the El Paso Fire Department in the prevention and avoidance of fraudulent billing practices. This plan promotes the prevention, early detection, and reporting of problems associated with the billing process before such can escalate to the point of governmental investigation and or litigation.

Key components of the Plan include, but are not limited to, the assurance of accurate and proper documentation of ambulance services, assignment of charges, accurate documentation of mileage, coding, submittal of claims, combined with policies and procedures to detect, prevent, and report fraudulent billing practices.

This Compliance Plan exhibits El Paso Fire Department's commitment to legally permissible and accurate documentation and billing for ambulance services to Medicare and other third party payers. It promotes prevention, detection and reporting acts of nonconformance in a proactive manner in order to mitigate risk and minimize exposure for El Paso Fire Department from the billing of inaccurate and invalid claims that would result in losses to the government and could bring about civil and/or criminal penalties for the Department.

The laws governing the provision of ambulance services are constantly evolving and continue to become increasingly more complex. To ensure compliance with those laws, the Department has developed this Compliance Plan. The Compliance Plan is designed to ensure that the Department's business and billing practices comply with applicable law. This Compliance Plan is intended to apply to all relationships between El Paso Fire Department and institutional health providers, and between El Paso Fire Department and its Vendors.

Observance and Adherence:

El Paso Fire Department is committed to making all efforts to comply with all rules, regulations, and applicable laws governing the provision of ambulance services and the billing for said services. This commitment includes the formalization of procedures through the development and adherence to this voluntary compliance plan developed in accordance with the U.S. Department of Health and Human Services, Office of Inspector General ("OIG") as outlined in the Federal Register Vol. 68, No. 56, *OIG Compliance Program Guidance for Ambulance Suppliers* attached as **Appendix A**.

This Plan illustrates the Department's dedication to proactive management of the billing process to ensure this compliance. The policies and procedures outlined in this Plan are applicable to all El Paso Fire Department employees and vendors who have a contractual relationship with the Department to provide billing and claims submission for or on behalf of the Department. It is El Paso Fire Department's goal to enforce the policies and procedures of this Plan in order to prevent and detect areas of noncompliance and take all reasonable and necessary steps to maintain compliance with established laws.

This Compliance Plan serves as the formal policy for El Paso Fire Department's methodology for billing Medicare, Medicaid, and third party payors. Employees or contractors who violate the policies and standards outlined in this Plan, whether intentionally or negligently, will be subject to appropriate disciplinary measures. Failure to comply with this Plan may result in disciplinary action up to and including reprimand, suspension without pay, termination, cessation of contract, and/or civil and criminal charges as applicable.

If an employee has questions about the application of this Compliance Plan, he or she should contact the Compliance Officer, or his or her direct supervisor. Employees should be generally familiar with the applicable laws, which govern the matters set forth in this Compliance Plan.

Contacting the Compliance Officer:

The City of El Paso has a toll free hotline, available 24 hours per day, seven days per week, for anonymous reporting of suspected fraudulent activity or compliance violations. The "Ethicsline" (866) 614-9688 handles calls through a third party, detailing the complaint and forwarding it to the Compliance Officer. Concerned parties are encouraged to utilize the service to report violations or concerns related to compliance. Questions or concerns regarding the Plan or other areas of compliance can be presented through the hotline or directly to the Compliance Officer. All communications with the Compliance Officer will be treated as confidential to the fullest extent allowed. The Department encourages voluntary reporting of any compliance concerns through the hotline or to the Compliance

Officer. Additionally, concerns may also be reported to the El Paso Fire Department's Office of Professional Standards. In the spirit of openness of communication and support of the Plan, the Department will take no adverse action or retaliation against employees making reports of compliance concerns in good faith.

Compliance Plan Summary:

The federal government has outlined and provided guidance for ambulance service compliance in the Federal Register, Vol. 68, No. 56, original publication date March 24, 2003, titled "OIG Compliance Program Guidance for Ambulance Suppliers". The publication provides seven "basic elements" for an "effective" compliance program. These elements include:

1. Development of Compliance Policies and Procedures
2. Designation of a Compliance Officer
3. Education and Training Programs
4. Internal Monitoring and Reviews
5. Responding Appropriately to Detected Misconduct
6. Developing Open Lines of Communication
7. Enforcing Disciplinary Standards Through Well-Publicized Guidelines

This Compliance Plan does not address every aspect of El Paso Fire Department's activities and the applicable legal issues they may entail. As such, employees should consult the Department's established policies and procedures and seek the guidance of the Compliance Officers or supervisors with respect to any other issues which may arise.

COMPLIANCE PLAN ELEMENTS

Development of Compliance Policies and Procedures

El Paso Fire Department has written standards of conduct and compliance policies and procedures that are to be followed by all employees, vendors, contractors, and others associated with the Department in order to reduce the risk of fraudulent billing and criminal activity. The standards of conduct and compliance policies and procedures serve as a testament to El Paso Fire Department's commitment to detection and prevention of fraud and abuse. These documents will be reviewed no less than annually and revised as necessary to ensure they are up-to-date and relevant to the operations of El Paso Fire Department.

Documentation of Compliance

It is the responsibility of El Paso Fire Department to comply with all applicable statutes and regulations and to document these efforts of compliance. The following activities will be included and recorded in the documentation of compliance:

- Exclusion List –assurance that all personnel, internal and external, with responsibilities directly or indirectly related to any activity associated with the provision of care or other services supplied to Medicare eligible patients shall be in good standing with the OIG and not excluded from participation in federal healthcare programs.
- Standards of Conduct – will be distributed to and reviewed with all existing and incoming employees.
- Compliance Training – will be provided to employees.
- Incidents – tracking mechanisms such as log sheets or other documents will be kept to track compliance incidents and/or inquiries and the disposition of these events and/or inquiries.
- Confidential Reporting – employees will be provided a method of confidential reporting of known or perceived compliance issues.
- Periodic Internal Audit of Billing Activities – evidence will be maintained that periodic audits, process reviews and other such relevant activities are performed in relation to billing activities to include baseline practice reviews, pre-billing activity assessments, post-claim submission analysis, and other examinations of the billing processes.
- Inquiries – any Medicare Administrative Contractor (MAC), Medicaid, or other third party payor inquiries and the outcome of said inquiries.

Principles

El Paso Fire Department provides a detailed Standards of Conduct and these Principles guide employees in the performance of their duties to ensure the highest level of conformance with legal and ethical standards for EMS transport operations.

- El Paso Fire Department requires all employees to operate in compliance with all laws, rules, and regulations governing transport operations. In any event of uncertainty of a law, rule, or regulation, employees will seek the guidance of the El Paso Fire Department Standards Office.
- El Paso Fire Department is committed to the highest levels of service and quality in the areas of patient care, documentation of patient care, claims submission, and billing and collection practices and measure quality through accuracy, reliability, timeliness, and validity.
- El Paso Fire Department, in the course of normal business, will maintain proper contacts with government officials and other government personnel, directly and indirectly, and will ensure proper business relationships in doing so. In the course of these relationships no undue influence will be placed on these contacts that would disparage, incriminate or otherwise cast doubt as to the integrity of El Paso Fire Department.
- El Paso Fire Department is committed to ensuring accuracy in filing claims for reimbursement to governmental payors, as well as all others, including the submittal of claims and supporting documents.
- El Paso Fire Department is committed to the maintenance of proper and accurate records that provide an accurate portrayal of services provided in the course of patient care and transport services to include the patient care report and all other supporting documentation related to the patient's care and transport.
- El Paso Fire Department will readily and properly disclose all disbursements, payments, or other distributions to which the Department is a party and will take immediate action to remedy any inaccuracies or overpayments.
- El Paso Fire Department expects and requires that all employees and contracted agents perform their duties with loyalty and ethics of the highest standard. Conflicts of interest such as the acceptance of gifts, personal investments, or other activities that could be interpreted as or provide the appearance of such are to be avoided. Any questions related to a potential conflict of interest is to be directed to the Compliance Officer.

Standards and Procedures

El Paso Fire Department is confident in the ability, integrity and commitment to ethical conduct of its employees. The Standards of Conduct has been developed to assist and guide employees in the course

of business and to prevent noncompliant performance or the manifestation of noncompliance or inappropriate activities. This Standards of Conduct is designed to serve as a guideline to assist employees with comprehension of and performance within the applicable laws, rules, and regulations governing medical transport service claims submission, protected health information, and general ambulance services operations.

This Standard of Conduct will be provided to all employees. Each staff member will be required to provide personal certification to their having been provided a copy of, having read, and fully understanding the Standards of Conduct. These certifications will be maintained by or at the direction of the Compliance Officer in a secure location.

Observation and compliance with this Plan and the Standards of Conduct and the legal and ethical requirements outlined in these documents will be a common element of all El Paso Fire Department employee performance evaluations.

El Paso Fire Department is committed to the highest levels of lawful and ethical performance and in doing so requires all employees and contractors to conduct business in compliance with the applicable laws, rules, and regulations governing El Paso Fire Department's operations. Specific areas associated with compliance as related to billing and operation of ambulance transport services include, but may not be limited to, the following:

- Proper call intake and dispatch procedures are to be followed at all times.
- Provision of services to the extent necessary for patient treatment.
- Only billing for services and supplies provided in the treatment and transportation of patients and only when they are accurately documented in the patient care report and supporting documents.
- Accurate documentation of calls resulting in "No Transport" and for calls where the patient has had a determination of death at the scene.
- Accurate documentation in the patient care report and on the claim submission when more than one patient is transported in the same ambulance at the same time.
- Accurate documentation of the utilization or involvement of all ambulances engaged in the treatment and transport of a patient.
- Accurate documentation, as applicable, of procedures for restocking of the ambulance with supplies and drugs used during or in connection with a patient transport when the patient is transported to a hospital or other facility receiving emergency transports.
- Ensure that patients are informed of their rights as governed under the Notice of Privacy Practices for Protected Health Information as outlined in 45 CFR 164.520 attached as **Appendix B**.

- Ensure that patient care reports and other supporting documentation that require correction or amendment are done so in a manner that is appropriate, consistent, and transparent so as to not distort, falsify, exaggerate or otherwise misstate the information.
- Oversight and monitoring of internal or external employees, personnel, entities, or agencies that perform coding and billing functions for the El Paso Fire Department to ensure accuracy in coding service levels, patient signs and symptoms, assignment of modifiers, and billing for service only when all required elements of documentation are provided in a complete and accurate manner. This will include ensuring that all documentation required and necessary for billing, including call intake and dispatch records, patient care reports, signature forms, prior authorizations, and any other relevant documents are provided at the time of claim preparation and are maintained and accessible in the records kept in the normal course of business as required by local, state, and/or federal laws, rules, and regulations.
- Ensure appropriate and consistent application of the rates for services and mileage as defined by the El Paso Fire Department Council located in **Schedule C of the Annual Budget Book** (www.elpasotexas.gov/omb). Ensure oversight and monitoring of internal and external employees in the assignment of charges for the purpose of billing.
- Oversight and monitoring of internal or external employees, personnel, entities, or agencies that perform coding and billing functions for the El Paso Fire Department to ensure that no instances of inappropriate balance billing occurs that would be in violation of mandatory assignment rules, as applicable, and to ensure processes are in place to prevent duplicate billing, charging for supplies or services not provided or performed, avoidance of instances of upcoding, and prevention of billing for services not medically necessary.
- Oversight and monitoring of internal or external employees, personnel, entities, or agencies that perform billing functions for the El Paso Fire Department to ensure correctness and accurate billing and collection of coinsurances and deductibles owed by the patient in the normal course of business unless excuse of such amounts is otherwise allowed through membership/subscription programs, contracts, or the patient meets the qualifications for a standardized charity or financial hardship program.
- Ensures that a process is in place to identify overpayments and process appropriate refunds for such in an expedient and timely manner.
- Maintain patient Protected Health Information (PHI) in accordance with HIPAA Privacy Regulations and in a manner that ensures security and confidentiality including assurance of the integrity of hardware, software, internet connections, firewalls and the system security measures internal to El Paso Fire Department, and those utilized any

external sources including contractors and vendors that have access to El Paso Fire Department patient data.

- Provision of HIPAA training to all new staff and annual training of employees to ensure the compliance with HIPAA Privacy Regulations.
- Perform documented OIG Exclusion List pre-employment screening and ongoing checks at intervals of no less than annually for all employees of El Paso Fire Department, City of El Paso personnel having duties related to or associated with the El Paso Fire Department, and vendors contracted with El Paso Fire Department, to assure they are not on the OIG exclusion lists and will employee or contract with only those who are not excluded from participation in federal health care programs (see **Appendix C**).
- Maintain a process for the prevention of incentive payments or provision of anything of value in return for the influence of referral of ambulance services that would be in violation of the anti-kickback statute or other related local, state, or federal regulations.
- Ensure all arrangements with facilities, to include hospital, nursing homes, skilled nursing facilities, clinics, etc., as well as assisting agencies are appropriately set at fair market value for transportation services provided.
- Ensure that any arrangements with patients or healthcare providers do not inappropriately influence, incentivize or cause the patient or provider to select El Paso Fire Department to provide ambulance service.
- Ensure only fair market value payments made, where appropriate, to assisting agencies providing services that have opportunity to influence the selection of ambulance service.

Any questions or suspected violation related to these key components should be directed appropriately through the chain of command as outlined by the El Paso Fire Department's Organizational Chart(s) found in **Attachment D,** to El Paso Fire Department's Compliance Officer, and or to the El Paso Fire Department Compliance Committee.

Documentation Practices

El Paso Fire Department will maintain a Best Practice approach in documentation of all ambulance services provided. In doing so they will pay particular attention to the following:

- El Paso Fire Department field crews will document ambulance transports with the highest levels of professionalism, ethical standards, and integrity without falsification, embellishment, over or understatement of facts.
- El Paso Fire Department field crews will document all ambulance services with consistency and accuracy without regard for whether the services will be reimbursable.

- Patient Care Reports (PCR) are to be complete, thorough and as concise and to the point as possible but containing all information required to convey the necessary information for the purpose of recording the patient's condition and need for ambulance transport.
- PCRs are to be written objectively and supported by facts, without inclusion of opinion or personal belief of the author. All documentation in the PCR should be accurate to the best of the author's knowledge with no false or deliberately inaccurate information.
- Accuracy in documentation will include the appropriate use of terminology, industry accepted acronyms and limited abbreviation of terms or words. Accuracy includes ensuring the correct spelling of words, to include the patient name.
- PCRs will contain documentation of the medically necessary reason for ambulance transport or the lack thereof in the event that no such reason can be documented.
- PCRs will be legible and organized with events in chronological order to include assessments, treatments, administering of medications, etc. with documented outcomes and/or effects of each. All signatures will be legible or will have supporting information, such as a signature log, or have the signature written in legible print next to the signature.
- El Paso Fire Department will obtain signatures of the beneficiary, or that of his or her representative for the purpose of accepting assignment and submitting claims to Medicare. If the beneficiary is unable to sign because of mental or physical condition, such must be legibly documented by the field crew on the signature form and an alternate signature will be obtained. The El Paso Fire Department Signature Form is attached as Appendix E. The following individuals may sign on behalf of the beneficiary:
  - The beneficiary's legal guardian.
  - A relative or person who receives social security or other governmental benefits on behalf of the beneficiary.
  - A relative or other person who arranges the beneficiary's treatment or exercises other responsibility for his or her affairs.
  - A representative of an agency or institution that did not furnish the service for which payment is claimed, but furnished other care, services, or assistance to the beneficiary.
  - A representative of the provider or of the non-participating hospital claiming payment for services it has furnished, if the provider or non-participating hospital is unable to have the claim signed in accordance with the Medicare rules and regulations (42 CFR 424.36(b) (1-4).
  - A representative of the ambulance provider or supplier who is present during the emergency or non-emergency transport, provided that the ambulance provider or supplier maintains this documentation in its records for at least 4 years from the date of service.

- El Paso Fire Department will not request payment from Medicare for services furnished when no signature is obtained unless circumstances are fully documented to show that the beneficiary is unable to sign and that no other person could sign.

- Mileage will be recorded accurately by utilizing the odometer or another accepted form of determining the patient loaded mileage for ambulance transport. Mileage will be recorded to the 1/10 (tenth) of a mile for the purpose of billing Medicare, as outlined in the Center for Medicare and Medicaid (CMS) transmittal 2103 of November 19, 2010, and will be rounded to the next whole mile for all other payors.
- In the event that a PCR requires correction or amendment such must be done so in a manner that clearly identifies when and by whom the changes or additions were made to the documents and should be done so in as timely a manner as possible after the initial completion of the PCR. Changes made will be initialed by the author and should never be made to look like they were done at the time of initial documentation.
- Only accurate and completely truthful information will be used for billing of ambulance services provided by El Paso Fire Department.
- El Paso Fire Department will maintain records of ambulance transport service, to include both patient care reports and financial/billing records in accordance with Texas Administrative Code 22 TAC 165, and Texas Medical Board Rule 165.1(b) which states that medical records for adults will be maintained for 7 years from the date of service and for minors for a period of 7 years from the date of service or until the patient reaches the age of 21, whichever date is later.

Designation of a Compliance Officer

The City of El Paso City Manager has designated a high-level individual as Compliance Officer and assigned this person the duties and responsibilities of oversight of the Plan and the associated standards, policies, and procedures. The Compliance Officer is assigned the duty and authorities associated with review of compliance related documents, information, educational and training material, and records maintenance, as related but not limited to, patient records, billing records, contracts, marketing materials for the service, client arrangements, vendor agreements, etc. The Compliance Officer is not responsible for the organization's compliance with the applicable laws, rules, and regulations governing billing for and general operation of ambulance transport services, rather he/she serves as the agent responsible for ensuring that El Paso Fire Department has a robust Compliance Plan with a Compliance Program in place that effectively communicates the policies, procedures and practices of the Plan and monitors the adherence to such in order to ensure and enforce the Department's dedication to compliance.

The Compliance Officer will be responsible for the following:

- Oversight of the development of compliance policies and standards.
- Oversight and monitoring of the execution of the Plan and all related compliance activities.
- Provision of compliance related activities reporting to senior management, boards, council, or other directing entities with the provision of a formal report no less than annually.
- Ensuring methods are in place to mitigate risk associated with fraud, abuse, and waste.
- Update of the Plan as necessary to reflect changes to laws, rules, and regulations governing the billing for and operation of ambulance transport services.
- Ensure that all new and existing employees have received a copy of the Standards of Conduct and maintain certification statements signed by employees acknowledging that they have read and understand the document.
- Oversee, coordinate, assist, or develop and provide training activities and communications for the elements of the Plan.
- Ensure employee references and credentialing are verified.
- Ensure that employees of El Paso Fire Department, The City of El Paso, vendors, contractors, and any other person(s) having direct or indirect responsibility for the provision of care, products or services utilized in the provision of care, billing of services, or any other services provided by El Paso Fire Department for Medicare Beneficiaries, has not been excluded from participation in federal programs as reported by the OIG's Exclusion List.
- Conduct, assist with, or coordinate internal compliance reviews.
- Ensure policies are developed, in place, and maintained that promote the responsible reporting of suspected fraudulent on noncompliant practices (without fear of retaliation).
- Serve as investigator for all compliance related issues with the responsibility of providing report to senior management, boards, or councils as appropriate.

A Compliance Committee shall be appointed by The City of El Paso City Manager. The Compliance Committee's ultimate responsibility shall be for the purpose of supervising the work of the Compliance Office and maintaining the Standards of Conduct and conformance with the Compliance Plan – subject to the ultimate authority of the mayor and council and the city manager. The Compliance Committee shall maintain written notes, records, correspondence, or minutes (as appropriate) of Compliance Committee meetings reflecting the reports made to the Compliance Committee and the Compliance Committee's decisions on any issues.

The Compliance Committee shall be responsible for:

- Oversight all of El Paso Fire Department's compliance efforts;
- Consulting with advisors as necessary;
- Coordinating with the Compliance Officer to ensure the adequacy of the Compliance Plan;
- Receiving periodic reports from the Compliance Officer concerning El Paso Fire Department's Compliance Program;
- Reporting to the mayor and council and the city manager regarding any compliance issues that were addressed by the reports of the Compliance Officer;
- Maintaining and improving the Compliance Program and this Compliance Plan
- Reviewing El Paso Fire Department and all Employees and Contractors in light of the Compliance Program and this Compliance Plan;
- Ensuring El Paso Fire Department meets the standards of business, legal and personal compliance;
- Ensuring that matters related to education, training, and communications in connection with the Compliance Program and this Compliance Plan are properly disseminated, understood, and followed; and
- Taking whatever actions are appropriate and necessary to ensure that El Paso Fire Department conducts its activities in compliance with the applicable law and regulations and sound business ethics.

Education and Training Programs

El Paso Fire Department commits to effectively communicating its standards, policies and procedures to all employees and applicable persons, vendors, contractors, and others associated with the Department. The Department will do so by providing regular trainings or distribution of updated publications that clarify expectations and requirements of the Plan. Such will be designed to assist in the avoidance of fraudulent practices and mitigation of risk to ensure compliance with the standards, policies and procedures. The information will be presented in a clear and consistent manner appropriate for all levels of persons receiving it in order to increase the probability comprehension.

El Paso Fire Department's information and education program shall be utilized to assist each staff member in understanding the Compliance Program and this Compliance Plan. Furthermore, all employees shall be informed of and made acquainted with applicable federal laws, regulations, and standards of ethical conduct, and the consequences of violation of those rules or the Compliance Program.

Educational training shall be conducted upon adoption of the Compliance Program and at a minimum on an annual basis thereafter to discuss this Compliance Plan, the Compliance Program, and applicable federal laws and regulations and any associated and relevant changes or updates.
Educational training shall be coordinated and led by the Compliance Officer and members of the Compliance Committee or by such consultants, staff or employees, as selected by these representatives or by the Compliance Officer or El Paso Fire Department.

- A copy of this Compliance Plan will be given to or made readily available to all existing El Paso Fire Department employees upon adoption of the Compliance Program.
- A copy of this Compliance Plan shall be provided or made readily available to all new employees upon commencement of their employment and shall be scheduled for training as soon as practical thereafter, but in no event later than thirty (30) days.
- All Employee training shall include instruction as to (1) compliance policies and the procedures for implementing the policies, focusing in particular on the policies and procedures applicable to each staff member's job responsibilities; and (2) the disciplinary system.
- Schedules, topic outlines, and sign-in sheets shall be included in all staff member program materials.
- All Compliance Program training documents shall be retained in accordance with the El Paso Fire Department Document Retention Policy.
- El Paso Fire Department shall post all relevant fraud alerts and advisory bulletins issued by the Department of Health and Human Services - Office of the Inspector General -on at least one prominent bulletin board at El Paso Fire Department headquarters and at any other appropriate areas.
- El Paso Fire Department shall post a notice at El Paso Fire Department headquarters and any other appropriate areas detailing El Paso Fire Department's commitment to ethical standards and compliance with all applicable laws and regulations in the conduct of its business.
- El Paso Fire Department shall use departmental memos and electronic communications (as appropriate) to inform employees of changes in applicable federal laws and regulations.

Employees shall be informed that they can obtain additional compliance information from their Chain of Command. Any questions, which cannot be answered by the Compliance Officer, shall be referred to the Compliance Committee and/or the City Attorney.

Internal Monitoring and Reviews

El Paso Fire Department will take all reasonable steps to maintain compliance through the monitoring and review of systems designed to prevent and detect fraudulent and noncompliant activity by employees, vendors, contracted agents, and others affiliated with the operations and billing of ambulances services performed by or on behalf of the Department. This will include, but may not be limited to, the development of processes to monitor and detect issues and prevent future issues. Claims for ambulance services and billing system reviews will be performed periodically to ensure compliance with the guidance outlined in the Plan and as required by federal rules, regulations, and laws governing the practices of billing for ambulance services. Department employees and others can report issues of noncompliance or suspected illegal activity by others within the organization or the organization's contracted providers of service without fear of retribution.

Coding

Accuracy in the assignment of Healthcare Common Procedure Coding System (HCPCS) codes for level of service and International Statistical Classification of Diseases and Related Health Problems (ICD-9 for dates of service prior to October 1, 2015 and ICD-10 for all services provided after that date codes for signs and symptoms, and physician assigned diagnosis as appropriate, is an essential element of El Paso Fire Department's coding and billing operations.

Effective January 1, 2001, HCFA implemented seven categories of ground ambulance service. All claims submitted for reimbursement must contain one of the following HCPCS codes designating the level of service provided to the patient:

- **Basic Life Support (BLS) A0428** - When medically necessary, the provision of BLS services as defined in the National EMS Education and Practice Blueprint for the EMT-Basic, including the establishment of a peripheral intravenous (IV) line.
- **Basic Life Support (BLS) - Emergency A0429** - When medically necessary, the provision of BLS services, as specified above, in the context of an emergency response. An emergency response is one that, at the time the ambulance supplier is called, is provided after the sudden onset of a medical condition manifesting itself by acute symptoms of sufficient severity such that the absence of immediate medical attention could reasonably be expected to result in placing the beneficiary's health in serious jeopardy; in impairment to bodily functions; or serious dysfunction to any bodily organ or part.
- **Advanced Life Support, Level 1 (ALS1) A0426** - When medically necessary, the provision of an assessment by an advanced life support (ALS) provider or supplier or the provision of one or more ALS interventions. An ALS provider/supplier is defined as a provider trained to the level of the EMT-Intermediate or Paramedic as defined in the National

EMS Education and Practice Blueprint. An ALS intervention is defined as a procedure beyond the scope of an EMT-Basic as defined in the National EMS Education and Practice Blueprint.

- **Advanced Life Support, Level 1 (ALS1) A0427** - Emergency - When medically necessary, the provision of ALS 1 services, as specified above, in the context of an emergency response. An emergency response is one that, at the time the ambulance supplier is called, is provided after the sudden onset of a medical condition manifesting itself by acute symptoms of sufficient severity such that the absence of immediate medical attention could reasonably be expected to result in placing the beneficiary's health in serious jeopardy; in impairment to bodily functions; or serious dysfunction to any bodily organ or part.
- **Advanced Life Support, Level 2 (ALS2) A0433** - When` medically necessary, the administration of three or more different medications and the provision of at least one of the following ALS procedures:
    - Manual defibrillation/cardioversion
    - Endotracheal intubation
    - Central venous line
    - Cardiac pacing
    - Chest decompression
    - Surgical airway
    - Intraosseous line

- **Specialty Care Transport (SCT) A0434** - When medically necessary, for a critically injured or ill beneficiary, a level of inter-facility service provided beyond the scope of the Paramedic as defined in the National EMS Education and Practice Blueprint. This is necessary when a beneficiary's condition requires ongoing care that must be provided by one or more health care professionals in an appropriate specialty area, e.g. nursing, medicine respiratory care, cardiovascular care, or a Paramedic with additional training.
- **Mileage A0425** – Effective January 1, 2011 all mileage billed to Medicare must be reported in actual fractional units to the nearest 1/10th of a mile for trips up to 100 covered miles. Mileage for trips under 1 mile will be reported at the closest 1/10th fraction (IE 0.1, 0.5, etc.) For trips in excess of 100 miles the mileage should be rounded up to the next whole number mile.

All claims coded for submission for reimbursement by or on behalf of El Paso Fire Department shall be accurate and have supporting documentation created and/or obtained by El Paso Fire Department staff and other appropriate and applicable sources, such as Dispatch, patient physicians, referral sources, etc.

The El Paso Fire Department has policies and established procedures to ensure appropriate practices for coding and billing of claims to all federal healthcare payors, and all other payor sources.

The El Paso Fire Department Compliance Officer will ensure these policies and procedures are communicated to the appropriate staff and will establish processes for regular review of these policies and procedures to provide appropriate updates to such as needed and assure that the changes are properly communicated to all appropriate employees and contracted billing service providers in a timely manner.

Remuneration and Prohibited Referrals

Federal and state anti-kickback laws prohibit the provision of anything of value in exchange for patient referrals. According to the United States Department of Health & Human Services (HHS) Office of Inspector General's (OIG) the Anti-Kickback Status (AKS) makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration directly or indirectly to induce or reward referrals of items or services reimbursable by a Federal health care program.

Limited exceptions to items of material value may be meals of moderate value provided in conjunction with face-to-face marketing, and promotional materials of nominal value such as pens, notepads, key chains, penlights, etc.

The penalties for violation of the AKS can be both Civil and Criminal in nature. Civil penalties may include fines of up to three times the amount of the kickback. Criminal penalties may include fines, imprisonment, or both.

The (U.S.) Department of Health & Human Services (HHS) Office of Inspector General's (OIG) website https://oig.hhs.gov/compliance/safe-harbor-regulations states that certain types of arrangements *may* satisfy regulatory safe harbors and the AKS will not treat these arrangements as offenses. The Compliance Officer, the OIG website, and other resources including legal counsel will be consulted prior to entering into any arrangement that could be questionable or in potential violation of the AKS. Safe harbor regulations may be found at 42 CFR 1001.952.

Claims Billing and Submission

El Paso Fire Department is committed to prompt, complete and accurate billing of all services. Billing shall be made only for services provided pursuant to all laws, terms and conditions, rules and regulations specified by the government or other payor and in a manner consistent with known industry standards. No falsification of documentation or misleading entries shall be made or submitted on any

bills or claim forms, and no staff member shall engage in any arrangement, or participate in such an arrangement at the direction of another staff member (including any officer, supervisor, or other person in a position of command for or in the contracted employment of El Paso Fire Department) that results in such prohibited acts. Any false statement on any bill shall subject the employee to disciplinary action by El Paso Fire Department, including possible termination of employment, termination of contract, and referral to appropriate the government agencies.

El Paso Fire Department and all El Paso Fire Department Employees and contractors of billing services shall become familiar with the Medicare and Medicaid policies and procedures regarding billing and reimbursement as set forth by the United States Department of Health and Human Services (Medicare Reimbursement) and The Texas Health and Human Services Commission (Medicaid Reimbursement) regarding the general policies and procedures necessary to obtain reimbursement under Medicare and Medicaid. El Paso Fire Department and El Paso Fire Department Employees and contractors of billing services should consult specific Medicare and Medicaid laws, rules, regulations, and program materials (including, but not limited to, the TMHP Ambulance Services Handbook, the Medicare Claims Processing Manual - Chapter 15, and the specific Medicare Administrative Contractor's Manual) in regard to any specific questions regarding reimbursement.

The Compliance Officer and/or the contracted provider of billing services shall ensure that every employee responsible for billing is provided with: 1) copies of the applicable sections of the rules, regulations, and program materials relating to the billing of government programs; 2) comprehensive instructional materials explaining such matters; 3) regular updates whenever changes are made or new interpretations are provided by the applicable government agency or the carriers; 4) annual training on such policies to ensure complete knowledge by all employees in the billing department.
El Paso Fire Department requires that the Department's contracted vendor of billing services comply with all billing and claims submission requirements set forth by all federal, state, and other payors.

El Paso Fire Department and the contracted vendor of billing services will observe and obey the following doctrines:

- Timely and accurate documentation of all services provided to patients shall maintained in order to safeguard against the billing of services that are inaccurate and/or undocumented.
- Claims will never, under any circumstance, be submitted for services not provided or for a level of service that exceeds the level of service actually provided.
- All forms of documentation, paper or electronic, related to or in support of a patient transport, including but not limited to, patient care reports, dispatch records, physician certification statements, medical and nursing notes, and other documentation used as a

basis for a claim submission will be appropriately organized, and maintained and in a legible and easily accessible format so they may be audited and reviewed.

- Levels of service, patient condition and procedures reported on claims for reimbursement will be based on the patient care report as documented by the caregiver at the time of service and other legitimate supporting documentation.

Additionally, in order for El Paso Fire Department to seek reimbursement from Medicare for ambulance services the patient must have been transported to the Closest Appropriate Facility and there must be a documented Medically Necessary reason for ambulance transport.

The term "Closest Appropriate Facility" means that the institution is generally equipped to provide the necessary hospital services for the illness or injury involved, and that a physician or specialist is available to provide the necessary care required to treat the patient's condition. A particular physician's lack of staff privileges at a hospital is not considered in determining whether a hospital is the Closest Appropriate Facility. Further, the fact that a more distant hospital is better equipped does not necessarily mean that a closer hospital is not appropriate by definition.

Medical necessity is an area of very significant concern to Medicare, and all El Paso Fire Department employees and contractors must attempt at all times to ensure that ambulance services are provided and billed only when medical necessity is present for the trip.
Medical Necessity for ambulance transportation is established when the patient's condition, at the time of transport, is such that use of any other method of transportation is contraindicated, whether or not other transportation is actually available.

Medical Necessity is presumed to have been met if the patient, at the time of the transport:

- Was transported in an emergency situation, i.e., as a result of an accident, injury, or acute illness
- Needed to be restrained; was unconscious or in shock
- Required oxygen or other emergency treatment on the way to the destination
- Had to remain immobile because of a fracture that had not been set or the possibility of a fracture
- Sustained an acute stroke or myocardial infarction
- Was experiencing severe hemorrhage
- Was bed confined before and after the ambulance trip and going for the purpose of a stated medically necessary treatment (bed confinement alone does not necessitate ambulance transport) or
- The patient could be moved only by stretcher (for the purpose of receipt of a medically necessary treatment)

If any billed claim is later found to be lacking in medical necessity, the appropriate El Paso Fire Department representative/designee will determine if there are additional sources of information and documentation which can either confirm or deny medical necessity, and obtain such. Upon review of such information and documentation, if the claim is determined to be without medical necessity, the claim monies are to be returned to Medicare expediently. Failure to remit Medicare monies, known to be retained without medical necessity having been present, is a federal offense.

False claims and billing fraud may take a variety forms, including, but not limited to, false statements supporting claims for payments, misrepresentation of facts, concealment of facts, or theft of benefits or payments from the party who is entitled to receive it. Although not an exhaustive list, El Paso Fire Department, its employees, and any contracted vendor shall specifically refrain from engaging in the following billing practices:

- Billing for services not rendered or for unnecessary services.
- Fraudulent changing procedure codes.
- Double billing.

Regular Claims Audits

To ensure observance of the rules and regulations directing billing of ambulance services and to detect potential errors in coding, documentation, and medical appropriateness the Compliance Officer will regularly request an audit of fifty randomly selected claims that have been billed to Medicare to determine if medical necessity and other coverage requirements are being met. The Compliance Officer will coordinate the audit efforts to be performed by internal or external sources who have experience in coding and billing, are familiar with reimbursement requirements and that have expert knowledge in the areas of federal and state health care statutes, rules, regulation, policies, and laws governing the billing of ambulance services. This will be done so at intervals of no less than one year apart.

The Compliance Officer will ensure that findings of the claims audits are reported to the Compliance Committee and the Financial and Audit Oversight Committee (FAOC). Those reviews that provide no evidence of violations but do indicate areas for improvement or need for additional or remedial training will be addressed internally. There is no need to report these finding to external sources such as the MAC or other governmental agencies. This includes isolated overpayments that have been resolved by refund to the appropriate party.

In the event of the discovery of repetitious compliance errors, significant overpayments, or violations of the law during these claims audits the Compliance Officer will inform and seek the advice of the City Attorney's Office. Legal counsel will advise as matters of attorney/client privilege, disclosure, and as to

whether El Paso Fire Department is required to report the violations and/or make restitution for errors and overpayments. El Paso Fire Department's legal counsel may advise or recommend procedures for notification of the MAC or as to the utilization of the OIG's Provider Self-Disclosure Protocol.

Overpayments

A Medicare or Medicaid overpayment is defined as funds paid in excess of the amount that would be properly payable for a service provided under Medicare or Medicaid statutes and regulations. Medicare overpayments may be the result of:

- Duplicate billing for the same claim
- Billing for service levels above what was necessary or provided
- Billing for services that were not medically necessary
- Payments made to the incorrect payee
-

Section 6402 of the Patient Protection and Affordable Care Act requires that providers report and refund Medicare overpayments within 60 days of the date that the overpayment is "identified". Identified for this purpose is classified as the time when a person has actual knowledge of the overpayment or acts in "reckless disregard or deliberate ignorance" of the existence of an overpayment. Failure to process refunds in this manner could be a violation of the False Claims Act and could result in civil monetary or other penalties. While this rule does not address Medicaid payments, El Paso Fire Department will process refunds in the same manner as those identified for Medicare trips.

Employee Responsibility

In the event an employee has any reason to believe that anyone is engaging in false billing practices, that person shall immediately report the practices to the Compliance Officer (or any other designated officer) and/or the Compliance Committee by a verbal or a written report. Failure to act, when an employee has knowledge that someone is engaged in false billing practices, shall also be considered a breach of that staff member's responsibilities and shall subject the them to disciplinary action by El Paso Fire Department, including possible termination of employment and/or contract.

Appropriate Response to Detected Misconduct

The intention of the Plan is to detect and prevent noncompliant activity that results in violation of governing laws, established reimbursement regulations, and policies outlined and expressed by the federal government and/or payors of ambulance services.

El Paso Fire Department commits to taking all reasonable steps to promptly respond appropriately to all detected and reported compliance offenses, taking corrective action against the offense/offender(s), and providing for prevention of similar offenses in the future. Modifications to the Plan will be made as necessary upon the detection and reporting of any offense in order to strengthen the Plan. The Compliance Officer, and legal counsel in circumstances serious enough in nature to require such, will be involved in the response to identified compliance misconduct.

Government Investigations

El Paso Fire Department's policy is to cooperate with reasonable demands of governmental agencies and investigations while also ensuring the protection of the Department's legal rights.
In the event of an onsite governmental agent visit, management should be contacted immediately. In turn the supervisor/manager will immediately contact the Compliance Officer. The Compliance Officer will notify El Paso Fire Department legal counsel for advisement as to how to proceed based upon the situation and nature of the visit.

Requests for Data

Requests for data in the form of a subpoena that are delivered to the El Paso Fire Department or contracted billing agent will most often have a specific future date for response to the request.

i. Upon being served with a subpoena these steps will be followed;
    1. Request the agent or servers identification and obtain a business card from them.
    2. Politely inform the agent that you will need to contact your supervisor or manager and ask them to wait in the waiting area while you make the call.
    3. Management should immediately call the Compliance Official or a designated Compliance Committee member. Follow their instructions.
    4. In a professional manner accept the subpoena. Discussion should be as limited as possible with the agent serving the subpoena.
    5. Immediately forward the subpoena to the Compliance Officer or designated Compliance Committee member who will confer with legal counsel.

Government agents also can arrive with search warrants granting them the right to take documents, electronic media and specified documents.

ii. Upon being served with a search warrant by a government agent these steps will be followed:
    1. Request the agent's identification and obtain a business card from the agent in charge.
    2. Ask to review and receive or copy the search warrant and thoroughly read the document to determine the scope of the warrant.

3. Contact the Compliance Officer or designated Compliance Committee member who will contact El Paso Fire Department legal counsel.
4. Assign a person or persons to accompany all agents and to record what is taken and what is said.
5. Keep discussion to a minimum. Answer only questions related to location of documents or information they are requesting.
6. Be truthful and objective. Do not make any false or misleading statements.
7. It is to be understood that El Paso Fire Department and contracted billing agency employees should not volunteer information to agents during the execution of the search and that they are not obligated to answer questions during the execution of the search that may be prohibited by regulations and laws regarding protected health information and patient privacy rights.
8. Do not interfere, or obstruct the agents in the performance of their duties. In the event that their actions are extending beyond the scope of the document you may make a polite objection.
9. Obtain and copy or compile list of all documents requested.
10. Make a request of the agent(s) for permission to copy all documents prior their removal from the premises.
11. Document all responses and conversations by agents.
12. Do not destroy, alter, remove, or otherwise conceal any documents, computer files or items subject to the warrant.

Developing and Maintaining Open Lines of Communication

El Paso Fire Department has developed and will maintain a process for receipt and process of compliance related concerns and complaints. This process will ensure that open and effective lines of communication are established and preserved between the Compliance Officer and all employees. Procedures have been adopted to protect the anonymity of complainants, where the complainants desire anonymity, and to protect whistleblowers, making good faith reporting of potential breaches of compliance, from retaliation.

Mechanisms for Violations Reporting

Employees are required to report violations of this Compliance Plan, the Standards of Conduct, unethical behavior, or incidents of fraud and abuse. The City of El Paso has a compliance hotline available 24 hours per days 7 days per week for anonymous reporting of suspected compliance violations. Employees can also report this information in person to the Compliance Officer who will maintain their confidentiality

to the extent reasonably possible without fear of retaliation when for those who provide good faith report of compliance related concerns.
Furthermore employees shall not face punishment provided that their report was what was reasonably believed to be a violation of the Compliance Plan, Standards of Conduct, or of a legal nature. El Paso Fire Department commits to following the rules of and providing all the protections set for in the applicable laws regarding anti-retaliation for the reporting of potential law violations.

Additionally, employees are protected from retaliation under the Federal False Claims Act (31 U.S.C. §§ 3729-3733) section 3730 subsection (h) which states verbatim:

1. In general**.—** Any employee, contractor, or agent shall be entitled to all relief necessary to make that employee, contractor, or agent whole, if that employee, contractor, or agent is discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in the terms and conditions of employment because of lawful acts done by the employee, contractor, agent or associated others in furtherance of an action under this section or other efforts to stop 1 or more violations of this subchapter.

2. Relief**.—** Relief under paragraph (1) shall include reinstatement with the same seniority status that employee, contractor, or agent would have had but for the discrimination, 2 times the amount of back pay, interest on the back pay, and compensation for any special damages sustained as a result of the discrimination, including litigation costs and reasonable attorneys' fees. An action under this subsection may be brought in the appropriate district court of the United States for the relief provided in this subsection.

Conversely if an employee knowingly provides a false report, fabrication, exaggeration, willful distortion or minimization of events, in order to injure or cover for someone else or to cover for themselves, El Paso Fire Department will take disciplinary actions as appropriate.

El Paso Fire Department will take the accurate and truthful self-reporting of wrongdoing into account when reviewing the course of disciplinary action provided it was not willfully negligent, was not previously known to the Department, or was not imminently discoverable. Self-admission, however, does not provide a guaranteed protection from disciplinary actions as such must be measured against the infractions and all the facts of the case.

Enforcement & Discipline

El Paso Fire Department has developed standards, policies and procedures to respond to infractions and violations of compliance, and provide disciplinary mechanism in a fair and consistent manner where needed. The stated standards, policies and procedures address situations in which employees, vendors,

or contractors violate, whether intentionally or negligently, internal compliance policies, applicable statutes, regulations, or other federal health care program requirements.
El Paso Fire Department maintains a "zero tolerance" policy towards any illegal conduct. Any staff member engaging in a violation of any laws or regulations (depending on the magnitude of the violation) may be terminated from employment. El Paso Fire Department shall accord no weight to an employee's claim that any improper conduct was undertaken for the benefit of El Paso Fire Department. Any such conduct is not for El Paso Fire Department's benefit and is expressly prohibited. Where appropriate, discipline shall be enforced against employees for failing to detect or report wrongdoing.

Performance Evaluations

Adherence to the Standards of Conduct, the rules, regulations, and guidelines of this Compliance Plan, and the laws governing ambulance operations will be a key element of El Paso Fire Department Employee Performance Evaluation. Employees who fail to steadfastly observe these standards will subject to disciplinary action.

Disciplinary Actions

The standards established in this Compliance Program and Compliance Plan, and those in the Standards of Conduct, and the Personnel Manual, shall be consistently enforced through disciplinary proceedings, actions, and sanctions.
El Paso Fire Department will not tolerate deviance from the guidelines outlined in this plan or the rules, regulations, or laws governing ambulance transport services by employees, business associates, and/or contracted vendors providing service to the Department. Likewise the Department will not abide illegal or unethical conduct of any sort from these parties and will take disciplinary action against those persons engaging in illegal or unethical behavior.
El Paso Fire Department has developed standards and protocol for disciplinary action which is outlined in the Administrative Policies and Procedures for Non-Uniformed Employees which can be found at: https://www.elpasotexas.gov/~/media/files/coep/human%20resources/disciplinary%20policy%20and%20matrix.ashx?la=en;

And for Uniformed Employees in *Section 16 of the Administrative Procedures* for El Paso Fire Department.

In determining the appropriate discipline for any violation of the Compliance Program and this Compliance Plan, El Paso Fire Department shall not take into consideration a particular staff member's economic benefit to the corporation.

Appendix A

Federal Register OIG Guidance for Ambulance Compliance

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.

[FR Doc. 03–6866 Filed 3–21–03; 8:45 am]

BILLING CODE 4152–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

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

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

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

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

Appendix B

El Paso Fire Department
Notice of Privacy Practices

- **Right to Amend Your PHI**
  You have the right to ask us to amend written PHI that we may have about you. We will generally amend your information within 60 days of your request and will notify you when we have amended the information. We are permitted by law to deny your request for amendment of your PHI if:

  1. The amendment is not permitted by law
  2. It is not part of the medical record
  3. We feel that the medical record is accurate and complete

  You can appeal our denial of your request to amend your PHI. If you wish to amend the PHI that we have about you, contact the privacy officer listed at the end of this notice.

- **Right to a Report of Releases**
  You have the right to request a report of the use and releases of your PHI that we have made in the last six (6) years before the date of your request. We are not required to give you a report of information we have used or released for purposes of treatment, payment or health care operations. We also are not required to give you a report of the uses or releases made before April 14, 2003. We may charge you a reasonable fee for postage, copies and staff time. If you wish to request a report of your PHI, contact the Privacy Officer listed at the bottom of this notice.

- **Right to Request Restrictions**
  You have the right to limit how your PHI is used or released. However, the **FIRE DEPARTMENT IS NOT REQUIRED TO AGREE TO YOUR REQUEST.**

LEGAL RIGHTS AND COMPLAINTS

We will update the Notice when we make any significant changes in our privacy practices. The Fire Department reserves the right to change the terms of this Notice at any time. The changes will be effective immediately. We also reserve the right to make any changes apply to PHI that we already created or received before the effective date of the Notice clause that was changed.

You have the right to make a complaint about our privacy policies. If you are concerned that we have violated your privacy rights, you may file a complaint with our Privacy Officer. The contact information is listed at the bottom of this page. You may also file a written complaint with the Texas Attorney General. Or, you may file a complaint with the Department of Health and Human Services. We will provide you with their address upon request. We will not retaliate against you for making a complaint to our office, the Texas Attorney General or the Department of Health and Human Services.

If you have any questions or if you wish to file a complaint or use any rights listed in this Notice, please contact:

Irene Y. Morales
El Paso Fire Department
416 N. Stanton, Suite 200
El Paso, Texas 79901-1242
(915) 485-5600

Effective Date of the Notice: February 16, 2012

We will revise this Notice if we have to make major changes to it. You can get a copy of the latest version of this notice. Contact the Privacy Officer or any staff member at (915) 485-5600

El Paso Fire Department
416 N. Stanton, Suite 200
El Paso, Texas 79901-1242
(915) 485-5600

El Paso Fire Department

NOTICE OF PRIVACY PRACTICE

CITY OF EL PASO FIRE DEPARTMENT
NOTICE OF PRIVACY PRACTICES

Effective Date: February 16, 2012

THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND RELEASED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.

If you have any questions about this Notice, please contact the Fire Department Privacy Officer at (915) 485-5600

WHO WILL FOLLOW THIS NOTICE?

City of El Paso Fire Department

Protected Health Information (PHI) is health information that can be identified for each individual. It includes any information that is oral or recorded. It identifies a person and his or her physical or mental health. Law protects this information. The Fire Department knows the importance of patient privacy and the need to protect PHI. This notice explains your legal rights. It advises you of our privacy practices. It tells you how the Fire Department is allowed to use and release PHI about you. The Fire Department must follow the conditions of the version of this notice that is currently in effect.

OUR RESPONSIBILITIES:

The Fire Department shall:

- Preserve privacy of PHI
- Give notice of legal duties
- Follow the terms of this notice

WE MAY USE AND RELEASE MEDICAL INFORMATION ABOUT YOU IN THESE SITUATIONS:

- **For Treatment:** We may release your PHI for treatment reasons. For example: This is oral and written information that we get about you. It contains information about your medical condition and the treatment we gave you. It contains information from other medical personnel including doctors who give orders that let us treat you. It contains information we give to other health care givers when we turn over your treatment. It includes reporting PHI to the hospital by using the radio or telephone. We also give the hospital a copy of the written record that we create if we treat and transport you.
- **For Payment:** We will give your PHI to our billing company (a third party billing company) so we can get payment. This includes any activities we must do in order to get paid for the services that we supplied to you. For example, our billing company will send bills to insurance companies. They will handle the billed claims. They will take care of medical necessity determinations and reviews. They will run utilization reviews. The billing company will also collect unpaid bills.
- **For Health Care Operations:** We may release your PHI for quality assurance, for licensing, and for training. For example, this lets us know that our personnel meet our standard of care. It tells us that they follow our policies and procedures. It also lets us get legal and financial services. It lets us do business planning, deal with complaints, and make reports from collected data that do not identify you.
- **As Required by Law:** We will release your PHI for legal and administrative proceedings as required by law. In some cases, we may release your PHI as a result of a subpoena or other legal process. For example, we will release your PHI as directed by Chapter 773 of the Texas Health and Safety Code.
- **For Law Enforcement Activities in Limited Situations:** We may release your PHI for law enforcement activities in limited situations. For example, we will release your PHI when there is a warrant for the information. We will also release the PHI when it is needed to stop a crime.
- **In Special Situations:** We may release your PHI in special situations. These include organ and tissue donation. We may release it for public health risks. We may release it for workman's compensation as required by law. We may release your PHI for military and veterans as required by law. We also may release your PHI for Department of Health and Human Service (HHS) investigations. We may release it for national defense and security. We may release it for other special government functions.

We will not use or release any other PHI, other than those listed above, without your written consent or an authorization. An authorization specifically identifies the information we want to use or release. It also spells out when and how we want to use or release it. **You may withdraw your consent or authorization at any time. The withdrawal must be in writing. The withdrawal does not cover information that we have already used or released because of your authorization.**

YOUR RIGHTS REGARDING MEDICAL INFORMATION ABOUT YOU.

- **Right to Inspect and Copy**

  With certain exceptions, you have the right to inspect and copy your protected health information. You may do this by coming to our office at 8600 Montana and filling out a written request. You may also mail a written request to the Privacy Officer listed at the end of this notice. If you come to our office, you need to bring a government issued photo ID. If you request your information by mail or facsimile you must have your signature notarized on the request. Your request should also give us the following information:

  1. What information is to be released?
  2. Who should we release it to?
  3. Why (for what purpose) is it being released?

  We will normally give you this information within 30 days of your request. We will charge you a reasonable fee for postage, staff time, and copies of any medical information that you have the right to access. In limited circumstances, we may deny you access to your PHI. Certain types of denials may be appealed. We have forms available to request PHI. We will give you a written response if we deny you access to the information. We will let you know your appeal rights. If you wish to inspect and copy your PHI, you should get in touch with the privacy officer listed at the end of this notice.

I _____ acknowledge that I have received the ***El Paso Fire Department Notice of Privacy Practice*** and that I can call the **Privacy Officer at (915) 485-5600** if I have a question or complaint.

(Print Your Name)

Signature _____ Date _____ EPFD Case NBumber _____

- **Derecho a Enmendar Su PHI**
  Usted tiene el derecho de pedirnos que enmendemos la "PHI" escrita que pudiéramos tener acerca de a usted. Generalmente enmendaremos su información dentro de 60 días de su solicitud y le notificaremos cuándo hayamos enmendado la información. Nos permite la ley negar su solicitud para la enmienda de su "PHI" si:

  1. La enmienda no es permitida por ley
  2. No es parte del registro médico
  3. Consideramos que el registro médico es preciso y completo

  Usted puede apelar nuestra negación de su petición para enmendar su "PHI". Si usted desea enmendar la "PHI" que tenemos acerca de a usted, contacte al "Privacy Officer" listado al final de este aviso.

- **Derecho A Un Informe De Liberaciones**
  Usted tiene el derecho a solicitar un informe de utilización y liberaciones de su "PHI" que hayamos hecho en los últimos seis (6) años antes de la fecha su solicitud. No estamos obligados a darle un informe de información que hayamos usado o publicado para los propósitos de operaciones de tratamiento, de pago o de cuidado de la salud. También no estamos obligados a darle un informe de los usos o las liberaciones hechos antes del 14 de abril, 2003. Le podemos cobrar una tarifa razonable por franqueo, copias y tiempo del personal. Si usted desea solicitar un informe de su "PHI", entonces contacte al "Privacy Officer" listado al pie de este aviso.

- **Derecho A Solicitar Restricciones**
  Usted tiene el derecho de limitar cómo se usa o divulga su "PHI". Sin embargo, el **CUERPO DE BOMBEROS NO ESTÁ OBLIGADO A ACEPTAR SU SOLICITUD.**

DERECHOS LEGALES Y QUEJAS

Pondremos al día el Aviso cuando hagamos cualesquier cambios significativos en nuestras prácticas de privacidad. El Cuerpo De Bomberos se reserva el derecho a cambiar las condiciones de este Aviso en cualquier momento. Los cambios serán efectivos inmediatamente. También nos reservamos el derecho a hacer que cualesquier cambios se apliquen a la "PHI" que ya creamos o recibimos antes de la fecha de efectividad de la cláusula de Aviso que se haya cambiado.

Usted tiene el derecho de presentar una queja acerca de nuestras políticas de privacidad. Si está preocupado que hayamos violado sus derechos de privacidad, podrá presentar una queja con nuestro "Privacy Officer". La información de contacto está listada al pie de esta página. Usted también podrá archivar una queja por escrito con el "Texas Attorney General". O, podrá presentar una queja con el "Department of Health and Human Services". Le proveeremos su dirección cuando se la solicite. No tomaremos represalias en contra de usted por presentar una queja a nuestra oficina, al "Texas Attorney General" o al "Department of Health and Human Services". Si usted tiene cualesquier preguntas o si desea archivar una queja o usar cualesquier derecho listado en este Aviso, por favor contacte:

Irene Y. Morales
El Paso Fire Department
416 N. Stanton, Suite 200
El Paso, Texas 79901-1242
(915) 485-5600

Fecha De Efectividad Del Aviso: *16 de Febrero, 2012*

Revisaremos este Aviso si tenemos que efectuar cambios de consideración. Usted podrá obtener una copia de la última versión de este aviso. Contacte al "Privacy Officer" o cualquier miembro del personal al (915) 485-5600

El Paso Fire Department
416 N. Stanton, Suite 200
El Paso, Texas 79901-1242
(915) 485-5600

El Paso Fire Department

AVISO DE PRÁCTICAS DE PRIVACIDAD

CITY OF EL PASO FIRE DEPARTMENT
AVISO DE PRÁCTICAS DE PRIVACIDAD

Fecha de vigencia 16 de Febrero, 2012

ESTE AVISO DESCRIBE CÓMO PUEDE USARSE Y DIVULGARSE LA INFORMACIÓN MÉDICA ACERCA DE USTED Y CÓMO USTED PUEDE GANAR ACCESO A ESTA INFORMACIÓN. POR FAVOR REVÍSELO CUIDADOSAMENTE

Si usted tiene, cualesquier preguntas acerca de este Aviso, por favor contacte al "Fire Department Privacy Officer" al (915) 485-5600

¿QUIÉN SE GUIARÁ POR ESTE AVISO?

El "City Of El Paso Fire Department"

La Información Protegida de Salud (""PHI"") es información de salud que podría ser identificada para cada individuo. Incluye cualquier información que sea oral o grabada. Identifica a una persona y su salud física o mental La ley protege esta información El Cuerpo de Bomberos sabe la importancia de la privacidad del paciente y la necesidad de proteger la "PHI". Este aviso explica sus derechos legales Le informa acerca de nuestras prácticas de privacidad. Le dice cómo el Cuerpo de Bomberos tiene permiso de usar y divulgar la "PHI" acerca de usted. El Cuerpo de Bomberos debe seguir las condiciones de la versión de este aviso que está actualmente vigente

NUESTRAS RESPONSABILIDADES:

"The Fire Department" hará lo siguiente:

- Resguardar la privacidad de la "PHI"
- Proporcionar notificación de las obligaciones legales
- Seguir las condiciones de este aviso

PODEMOS USAR Y DIVULGAR INFORMACIÓN MÉDICA ACERCA DE USTED EN ESTAS SITUACIONES:

- **Para Tratamiento:** Podemos divulgar su "PHI" por razones de tratamiento. Por ejemplo: Ésta es información escrita y oral que obtenemos acerca de usted. Contiene información acerca de su condición médica y el tratamiento que le suministramos. Contiene información de otros empleados médicos incluyendo a doctores que hayan dado órdenes que nos permitan tratarle. Contiene información que damos a otros suministradores de cuidado de la salud cuando les entregamos su tratamiento. Incluye reportar la "PHI" al hospital usando el radio o el teléfono. También le damos al hospital una copia de la constancia escrita que creamos si le tratamos y transportamos

- **Para Pago:** Entregaremos su "PHI" a nuestra compañía de facturación (una compañía de facturación de tercera parte) para que podamos obtener pago. Esto incluye cualesquier actividades que debamos realizar para recibir el pago por los servicios que le suministramos a usted. Por ejemplo, nuestra compañía de facturación enviará las cuentas a las compañías de seguros. Manejarán las reclamaciones facturadas. Se encargarán de las determinaciones médicas de necesidad y las revisiones. Ejecutarán revisiones de utilización. La compañía facturadora también cobrará cuentas no pagadas.

- **Para Operaciones De Cuidado De La Salud:** Podemos divulgar su "PHI" para la comprobación de calidad, para el otorgamiento de licencias, y para entrenamiento. Por ejemplo, esto nos deja saber que nuestros empleados se responsabilizan por nuestras pautas de cuidado. Nos informa que siguen nuestras políticas y procedimientos. También nos permite obtener servicios financieros y legales. Nos permite hacer planificación comercial, ocuparnos de quejas, y hacer informes de datos coleccionados que no le identifiquen.

- **Conforme Exige La Ley:** Divulgaremos su "PHI" para procesos legales y administrativos conforme exige la ley En algunos casos, podemos divulgar su "PHI" como resultado de una citación u otro proceso judicial. Por ejemplo, divulgaremos su "PHI" según lo dictado por "Chapter 773" de la "Texas Health and Safety Code"

- **Para Las Actividades De Aplicación De La Ley En Situaciones Limitadas:** Podemos divulgar su "PHI" para las actividades de aplicación de la ley en situaciones limitadas. Por ejemplo, divulgaremos su "PHI" cuando haya una orden judicial para la información. También divulgaremos la "PHI" cuando sea necesario para prevenir un crimen

- **En Situaciones Especiales:** Podemos divulgar su "PHI" en situaciones especiales. Estos incluyen donación de órganos y tejido celular La podemos divulgar por riesgos de salud pública Lo podemos divulgar para la compensación de trabajador conforme exige la ley Podemos divulgar su "PHI" a las Fuerzas Armadas y los veteranos conforme exige la ley. También podemos divulgar su "PHI" para investigaciones del "Department of Health and Human Services (HHS)" La podemos divulgar por la seguridad y defensa nacional. Lo podemos divulgar para otras funciones especiales de gobierno

No usaremos ni divulgaremos ninguna otra "PHI", aparte de la listada arriba, sin su consentimiento escrito o una autorización Una autorización específicamente identifica la información que queremos usar o divulgar. También indica cuándo y cómo queremos usarla o divulgarla. **Usted puede retirar su consentimiento o autorización en cualquier momento. El retiro debe ser por escrito. El retiro no cubre información que ya hayamos usado o divulgamos a raíz de su autorización.**

- **Derecho A Inspeccionar Y Copiar**

Con ciertas excepciones, usted tiene el derecho de inspeccionar y copiar su información protegida de salud. Podrá hacer esto llegando a nuestra oficina en la 8600 Montana y llenando una requisición escrita. También puede enviar por correo una requisición escrita al "Privacy Officer" listado al final de este aviso. Si usted llega a nuestra oficina, entonces necesita llevar un documento de identidad con foto expedido por el gobierno Si solicita su información por correo o facsímil, entonces debe tener su firma notariada en la solicitud. Su solicitud también nos debería proporcionar la siguiente información:

1. ¿Qué información será divulgada?
2. ¿A quién se la deberíamos divulgar?
3. ¿Por qué (para qué propósito) está siendo divulgada?

Normalmente le daremos esta información dentro de 30 días de su solicitud. Le cobraremos una tarifa razonable por gastos de correo, el tiempo del personal, y las copias de cualquier información médica que usted tenga el derecho de accesar. En circunstancias limitadas, le podemos negar acceso a su "PHI." Ciertos tipos de negaciones podrán ser apeladas. Tenemos formularios disponibles para solicitar la "PHI." Le daremos una contestación escrita si le negamos acceso a la información. Le dejaremos saber sus derechos de apelación Si usted tiene el deseo de inspeccionar y copiar su "PHI", entonces debería ponerse en comunicación con el "privacy officer" listado al final de este aviso.

I _____ reconozco que he recibido el ***El Paso Fire Department***

(Print Your Name)

Notice of Privacy Practice y que puedo llamar al **Privacy Officer al (915) 485-5600** si tengo una pregunta o queja.

Firma _____ Fecha _____ EPFD Case NBumber _____

Appendix C

OIG

Exclusion Guidelines

UPDATED

Special Advisory Bulletin on the Effect of Exclusion from Participation in Federal Health Care Programs

Issued May 8, 2013

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

Updated Special Advisory Bulletin on the Effect of Exclusion from Participation in Federal Health Care Programs

Issued May 8, 2013

This updated Special Advisory Bulletin describes the scope and effect of the legal prohibition on payment by Federal health care programs for items or services furnished (1) by an excluded person or (2) at the medical direction or on the prescription of an excluded person. For purposes of Office of Inspector General (OIG) exclusion, payment by a Federal health care program includes amounts based on a cost report, fee schedule, prospective payment system, capitated rate, or other payment methodology. It describes how exclusions can be violated and the administrative sanctions OIG can pursue against those who have violated an exclusion. The updated Bulletin provides guidance to the health care industry on the scope and frequency of screening employees and contractors to determine whether they are excluded persons.

INTRODUCTION

OIG was established in the U.S. Department of Health and Human Services (Department) to identify and eliminate fraud, waste, and abuse in the Department's programs and to promote efficiency and economy in Departmental operations. OIG carries out this mission through a nationwide program of audits, inspections, and investigations. In addition, the Secretary has delegated authority to OIG to exclude from participation in

Medicare, Medicaid, and other Federal health care programs[1] persons[2] that have engaged in fraud or abuse and to impose civil money penalties (CMPs) for certain misconduct related to Federal health care programs.[3]

OIG originally published a Special Advisory Bulletin in September 1999 (1999 Bulletin) on the effect of exclusion from participation in Federal health care programs.[4] The publication of the 1999 Bulletin coincided with the beginning of a significant and ongoing OIG initiative to ensure compliance with and enforcement of exclusions. The 1999 Bulletin provided guidance to excluded persons as to the scope and effect of their exclusions and the activities that might result in a violation of their exclusions. The 1999 Bulletin also provided guidance to providers[5] that might arrange with, contract with, or employ an excluded person regarding (1) what the scope of the prohibition on employment or contracting is, (2) when the provider might be subject to CMPs for violating this prohibition, and (3) how to determine whether a potential employee or contractor is excluded.

The health care industry and OIG have now had more than a decade of experience with the questions that arise in determining the effect of an

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[1] A Federal health care program is defined as any plan or program that provides health benefits, whether directly, through insurance, or otherwise, and that is funded directly, in whole or in part, by the U.S. Government or a State health care program (except for the Federal Employees Health Benefits Program) (section 1128B(f) of the Social Security Act (the Act)). Among the most significant Federal health care programs are Medicare, Medicaid, TRICARE, and the veterans' programs.

[2] The exclusions statute applies to "individuals and entities." We use the term "person" throughout this document to encompass all individuals and entities.

[3] See the Act §§ 1128, 1128A, and 1156.

[4] See 64 Fed. Reg. 52791, September 30, 1999.

[5] The term "provider" is used broadly throughout this guidance to include providers, suppliers, manufacturers, and any other individual or entity, including a drug plan sponsor or managed care entity, that directly or indirectly furnishes, arranges, or pays for items or services.

exclusion across the broad spectrum of items and services that are furnished, directly or indirectly, within the health care industry and payable by Federal health care programs. The 1999 Bulletin has been the primary source of published guidance from OIG in this area and has proven to be important both to excluded persons and to efforts by providers to ensure compliance with the restrictions on employing or contracting with excluded individuals or entities.

Since the 1999 Bulletin, we have received many questions about exclusions, including the following:

- May an excluded person provide an item or a service that a health care provider needs but that is not for direct patient care or billing? Is a provider that employs or contracts with an excluded person to provide such item or service subject to CMP liability?
- What is the scope of the obligation to screen current and potential employees and contractors against OIG's List of Excluded Individuals and Entities (LEIE) to determine whether they are excluded? How frequently should providers screen against the LEIE? How far downstream do they need to screen (e.g., do they have an obligation to screen the employees of contractors and subcontractors in addition to screening contractors)?
- How should a provider disclose to OIG that it has employed or contracted with an excluded person?
- What is the distinction between the information that appears on the LEIE and the information that appears on the General Services Administration's (GSA) System for Award Management (SAM) and other systems that report sanctions or adverse actions taken with

respect to health care practitioners (e.g., the National Practitioner Data Bank (NPDB))?[6]

We address these and other issues in this updated Bulletin. In developing this Bulletin, we considered, among other things, the public comments received in response to a solicitation notice published in the Federal Register, our experience resolving numerous self-disclosure cases, and questions we have received.[7] This updated Bulletin replaces and supersedes the 1999 Bulletin.

STATUTORY BACKGROUND

In 1977, in the Medicare-Medicaid Anti-Fraud and Abuse Amendments, Public Law 95-142 (now codified at section 1128 of the Act), Congress first mandated the exclusion of physicians and other practitioners convicted of program-related crimes from participation in Medicare and Medicaid. This was followed in 1981 with enactment of the Civil Monetary Penalties Law (CMPL), Public Law 97-35 (codified at section 1128A of the Act), to further address health care fraud and abuse. The CMPL authorizes the Department and OIG to impose CMPs, assessments, and program exclusions against any person that submits false or fraudulent or certain other types of improper claims for Medicare or Medicaid payment. Claims submitted by an excluded person for items or services furnished during the person's exclusion violate the CMPL.

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[6] In July 2012, GSA migrated its Excluded Parties List System (EPLS) and other systems to the new SAM. SAM is a comprehensive database that Federal agencies can use to determine the eligibility of individuals or entities to participate in their programs.

[7] 75 Fed. Reg. 69452, November 12, 2010.

To enhance OIG's ability to protect the Medicare and Medicaid programs and beneficiaries, the Medicare and Medicaid Patient and Program Protection Act of 1987, Public Law 100-93, expanded and revised OIG's administrative sanction authorities by, among other things, establishing certain additional mandatory and discretionary exclusions for various types of misconduct.

The enactment of the Health Insurance Portability and Accountability Act (HIPAA), Public Law 104-191, in 1996 and the Balanced Budget Act (BBA) of 1997, Public Law 105-33, further expanded OIG's sanction authorities. These statutes extended the application and scope of the current CMP and exclusion authorities beyond programs funded by the Department to all "Federal health care programs." BBA also authorized a new CMP authority to be imposed against health care providers or entities that employ or enter into contracts with an excluded person to provide items or services for which payment may be made under a Federal health care program.

Since the publication of the 1999 Bulletin, various statutory amendments have strengthened and expanded OIG's authority to exclude individuals and entities from the Federal health care programs. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care Education Reconciliation Act of 2010 (ACA), expanded OIG's exclusion waiver authority. The ACA also modified and expanded OIG's permissive exclusion authorities and amended the CMPL by adding a new provision that subjects an excluded person to liability if the person orders or prescribes an item or a service while excluded and knows or should know that a claim for the item or service may be made to a Federal health care program.

EXCLUSION FROM FEDERAL HEALTH CARE PROGRAMS

The effect of an OIG exclusion is that no Federal health care program payment may be made for any items or services furnished (1) by an excluded person or (2) at the medical direction or on the prescription of an excluded person.[8] The exclusion and the payment prohibition continue to apply to an individual even if he or she changes from one health care profession to another while excluded.[9] This payment prohibition applies to all methods of Federal health care program payment, whether from itemized claims, cost reports, fee schedules, capitated payments, a prospective payment system or other bundled payment, or other payment system and applies even if the payment is made to a State agency or a person that is not excluded. For example, no payment may be made to a hospital for the items or services furnished by an excluded nurse to Federal health care program beneficiaries, even if the nurse's services are not separately billed and are paid for as part of a Medicare diagnosis-related group payment received by the hospital. Also, the excluded nurse would be in violation of her exclusion for causing a claim to be submitted by the hospital for items or services the nurse furnished while excluded.

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[8] An excluded provider may refer a patient to a non-excluded provider if the excluded provider does not furnish, order, or prescribe any services for the referred patient, and the non-excluded provider treats the patient and independently bills Federal health care programs for the items or services that he or she provides. Covered items or services furnished by a non-excluded provider to a Federal health care program beneficiary are payable, even when an excluded provider referred the patient.

[9] For example, the prohibition against Federal health care program payment for items and services would continue to apply to a person who was excluded while a pharmacist even after the person earns his or her medical degree and becomes a licensed physician.

The prohibition on Federal health care program payment for items or services furnished by an excluded individual includes items and services beyond direct patient care. For instance, the prohibition applies to services performed by excluded individuals who work for or under an arrangement with a hospital, nursing home, home health agency, or managed care entity when such services are related to, for example, preparation of surgical trays or review of treatment plans, regardless of whether such services are separately billable or are included in a bundled payment. Another example is services performed by excluded pharmacists or other excluded individuals who input prescription information for pharmacy billing or who are involved in any way in filling prescriptions for drugs that are billed to a Federal health care program. Also, excluded individuals are prohibited from providing transportation services that are paid for by a Federal health care program, such as those provided by ambulance drivers or ambulance company dispatchers.

Excluded persons are prohibited from furnishing administrative and management services that are payable by the Federal health care programs. This prohibition applies even if the administrative and management services are not separately billable. For example, an excluded individual may not serve in an executive or leadership role (e.g., chief executive officer, chief financial officer, general counsel, director of health information management, director of human resources, physician practice office manager, etc.) at a provider that furnishes items or services payable by Federal health care programs. Also, an excluded individual may not provide other types of administrative and management services, such as health information technology services and support, strategic planning, billing and accounting, staff training, and human resources, unless wholly unrelated to Federal health care programs.

In addition, any items and services furnished at the medical direction or on the prescription of an excluded person are not payable when the person furnishing the items or services either knows or should know of the exclusion. This prohibition applies even when the Federal payment itself is made to a State agency or a provider that is not excluded. Many providers that furnish items and services on the basis of orders or prescriptions, such as laboratories, imaging centers, durable medical equipment suppliers, and pharmacies, have asked whether they could be subject to liability if they furnish items or services to a Federal program beneficiary on the basis of an order or a prescription that was written by an excluded physician. Payment for such items or services is prohibited.[10] To avoid liability, providers should ensure, at the point of service, that the ordering or prescribing physician is not excluded.[11]

VIOLATION OF OIG EXCLUSION BY AN EXCLUDED PERSON

An excluded person violates the exclusion if the person furnishes to Federal health care program beneficiaries items or services for which Federal health care program payment is sought. An excluded person that submits a claim

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[10] See Act § 1862(e)(1)(B). Some excluded practitioners will have valid licenses or Drug Enforcement Agency (DEA) numbers. Therefore, it is important not to assume that because a prescription contains a valid license number or DEA number, the practitioner is not excluded.

[11] In some cases, pharmacies and laboratories rely on Medicare Part D plans and/or State agencies to ensure that prescribers are not excluded through, for example, computer system edits. These alternative screening mechanisms may effectively identify excluded individuals and prevent the pharmacies or laboratories from submitting claims for services ordered or prescribed by excluded individuals. However, pharmacies and laboratories that rely on a third party to determine whether prescribers are excluded should be aware that they may be responsible for overpayments and CMPs relating to items or services that have been ordered or prescribed by excluded individuals.

for payment to a Federal health care program, or causes such a claim to be submitted, may be subject to a CMP of $10,000 for each claimed item or service furnished during the period that the person was excluded.[12] The person may also be subject to an assessment of up to three times the amount claimed for each item or service. In addition, violation of an exclusion is grounds for OIG to deny reinstatement to Federal health care programs.[13]

Such exclusion violations may lead to criminal prosecutions or civil actions in addition to the CMPs for violation of OIG exclusion. An excluded person that knowingly conceals or fails to disclose any action affecting the ability to receive any benefit or payment with the intent to fraudulently receive such benefit or payment may be subject to criminal liability.[14] Other criminal statutes may also apply to such violations. An excluded person may be civilly liable under the False Claims Act for knowingly presenting or causing to be presented a false or fraudulent claim for payment.[15]

Moreover, persons that order or prescribe items or services while excluded are subject to CMP liability when the excluded person knows or should know that a claim for the item or service may be made to a Federal health care program.[16]

Although an exclusion does not directly prohibit the excluded person from owning a provider that participates in Federal health care programs, there are several risks to such ownership. OIG may exclude the provider if certain

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[12] See section 1128A(a)(1)(D) of the Act.
[13] See 42 CFR § 1001.3002.
[14] See section 1128B(a)(3) of the Act.
[15] See 31 U.S.C. §§ 3729-3733.
[16] See section 1128A(a)(8) of the Act.

circumstances regarding the ownership are present.[17] Although this authority to exclude is not mandatory and OIG exercises it at its discretion, any provider owned in part (5 percent or more) by an excluded person is potentially subject to exclusion. In addition, an excluded individual may be subject to CMPL liability if he or she has an ownership or control interest in a provider participating in Medicare or State health care programs or if he or she is an officer or a managing employee of such an entity.[18] Further, the provider may not seek Federal health care program payment for any services, including the administrative and management services described above, furnished by the excluded owner. As a practical matter, this means that an excluded person may own a provider, but may not provide any items or services, including administrative and management services, that are payable by Federal health care programs. If an excluded owner does, for example, participate in billing activities or management of the business, both the owner and the provider will risk CMPL liability.

CMP LIABILITY FOR EMPLOYING OR CONTRACTING WITH AN EXCLUDED PERSON

BBA authorized the imposition of CMPs against providers that employ or enter into contracts with excluded persons to provide items or services payable by Federal health care programs.[19] This authority parallels the CMP for health maintenance organizations that employ or contract with excluded individuals.[20]

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[17] See section 1128(b)(8) of the Act.
[18] See section 1128A(a)(4) of the Act; 42 CFR § 1003.102(a)(12).
[19] See section 1128A(a)(6) of the Act; 42 CFR § 1003.102(a)(2).
[20] See section 1857(g)(1)(G) of the Act.

If a health care provider arranges or contracts (by employment or otherwise) with a person that the provider knows or should know is excluded by OIG, the provider may be subject to CMP liability if the excluded person provides services payable, directly or indirectly, by a Federal health care program. OIG may impose CMPs of up to $10,000 for each item or service furnished by the excluded person for which Federal program payment is sought, as well as an assessment of up to three times the amount claimed, and program exclusion.

At least since 1999, providers have been able to use the LEIE, which is available on OIG's Web site (and discussed in more detail below), to determine whether a person is excluded. In the 1999 Bulletin, we alerted providers about the availability of the LEIE to determine whether individuals and entities were excluded.

A provider could be subject to CMP liability if an excluded person participates in any way in the furnishing of items or services that are payable by a Federal health care program. CMP liability would apply to the furnishing of all of the categories of items or services that are violations of an OIG exclusion, including direct patient care, indirect patient care, administrative and management services, and items or services furnished at the medical direction or on the prescription of an excluded person when the person furnishing the services either knows or should know of the exclusion. CMP liability could result if the provider's claim to the Federal health care program includes any items or services furnished by an excluded person, even if the excluded person does not receive payments from the provider for his or her services (e.g., a non-employed excluded physician who is a member of a hospital's medical staff or an excluded health care professional who works at a hospital or nursing home as a volunteer). An excluded

person may not provide services that are payable by Federal health care programs, regardless of whether the person is an employee, a contractor, or a volunteer or has any other relationship with the provider. For example, if a hospital contracts with a staffing agency for temporary or per diem nurses, the hospital will be subject to overpayment liability and may be subject to CMP liability if an excluded nurse from that staffing agency furnishes items or services to Federal health care program beneficiaries.[21]

We offer the following guidance regarding the circumstances under which an excluded person may be employed by, or contract with, a provider that receives payments from Federal health care programs.[22] First, if Federal health care programs do not pay, directly or indirectly, for the items or services being provided by the excluded individual, then a provider that participates in Federal health care programs may employ or contract with an excluded person to provide such items or services. Second, a provider that employs or contracts with an excluded person to furnish items or services solely to non-Federal health care program beneficiaries would not be subject to CMP liability. A provider need not maintain a separate account from which to pay the excluded person, as long as no claims are submitted to or payment is received from Federal health care programs for items or services that the excluded person provides and such items or services relate solely to non-Federal health care program patients.

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[21] The hospital may reduce or eliminate its CMP liability if the hospital is able to demonstrate that it reasonably relied on the staffing agency to perform a check of the LEIE for the nurses furnished by the staffing agency (e.g., the staffing agency agreed by contract to perform the screening of the LEIE and the hospital exercised due diligence in ensuring that the staffing agency was meeting its contractual obligation.)

[22] This guidance applies only with respect to assisting providers in determining whether they are in compliance with the Act.

Thus, a provider that receives Federal health care program payments may employ or contract with an excluded person only in limited situations. Providers that identify potential CMP liability on the basis of the employment of, contracting with, or arranging with an excluded person may use OIG's Provider Self-Disclosure Protocol (SDP) to disclose and resolve the potential CMP liability.[23]

HOW TO DETERMINE WHETHER A PERSON IS EXCLUDED

OIG maintains the LEIE on the OIG Web site (http://oig.hhs.gov/exclusions), which contains OIG program exclusion information.

- *List of Excluded Individuals and Entities*

The Exclusions Web site and the LEIE have undergone extensive updates and revisions in the past several years. The LEIE is accessible through a searchable online database and downloadable data files. In addition to housing the LEIE and LEIE Downloadable Data File, OIG's Exclusions Page contains Quick Tips on how to use the LEIE, Frequently Asked Questions regarding OIG's Exclusions Program, information regarding how to apply for reinstatement, video podcasts, and contact information for the OIG Exclusions Program.

The online database contains the following information: (1) the name of the excluded person at the time of the exclusion, (2) the person's provider type, (3) the authority under which the person was excluded, (4) the State where the excluded individual resided at the time of exclusion or the State where

[23] Information on the SDP can be found at http://oig.hhs.gov/compliance/self-disclosure-info/index.asp.

the entity was doing business, and (5) a mechanism to verify search results via Social Security Number (SSN) or Employer Identification Number (EIN). OIG plans to update the LEIE soon to include a National Provider Identifier, or NPI, for individuals and entities excluded after 2009 that have such an identifier and to include information regarding waivers of exclusion granted by OIG.[24] This will allow for an additional verification mechanism separate from SSN or EIN verification.

The LEIE Downloadable Data File enables users to download the entire LEIE. Supplemental exclusion and reinstatement files are posted monthly to OIG's Web site, and these updates can be merged with a previously downloaded data file. The Downloadable Data File does not contain SSNs or EINs. Therefore, verification of specific individuals or entities through the use of the SSN or EIN must be done via the Online Searchable Database. When checking the LEIE, providers should maintain documentation of the initial name search performed (such as a printed screen-shot showing the results of the name search) and any additional searches conducted, in order to verify results of potential name matches.[25] Some providers may choose to contract with another entity to perform their screening against the LEIE. These providers should be aware that because it is the provider's responsibility to determine whether employees are excluded, the providers will retain the potential CMP liability if they employ or contract with an excluded person.

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[24] A list of individuals and entities that have been granted an exclusion waiver by OIG is currently available on the OIG's website at oig.hhs.gov/exclusions/waivers.asp .

[25] Because the LEIE includes only the name known to OIG at the time of the individual's exclusion, all names used by the individual (e.g., maiden names) should be searched. OIG has provided a number of additional tips related to searching the LEIE at oig.hhs.gov/exclusions/tips.asp.

- *Frequency of Screening*

To avoid potential CMP liability, providers should check the LEIE prior to employing or contracting with persons and periodically check the LEIE to determine the exclusion status of current employees and contractors. Providers are not required by statute or regulation to check the LEIE. The LEIE is a tool that OIG has made available to providers to enable them to identify potential and current employees or contractors that are excluded by OIG. Because there is no statutory or regulatory requirement to check the LEIE, providers may decide how frequently to check the LEIE. OIG updates the LEIE monthly, so screening employees and contractors each month best minimizes potential overpayment and CMP liability. Additionally, in January 2009, CMS issued a State Medicaid Director Letter (SMDL) recommending that States require providers to screen all employees and contractors monthly.[26] In 2011, CMS issued final regulations mandating States to screen all enrolled providers monthly.[27]

- *Determining Which Individuals and Entities To Screen*

OIG recommends that to determine which persons should be screened against the LEIE, the provider review each job category or contractual relationship to determine whether the item or service being provided is directly or indirectly, in whole or in part, payable by a Federal health care

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[26] SMDL #09-001.

[27] See 42 CFR § 455.436. In response to comments, CMS clarified that this regulation does not mandate States to require their Medicaid providers to screen the providers' employees and contractors against the LEIE each month. However, CMS recommends that States consider making this a requirement for all providers and contractors, including managed care entities. See 76 Fed. Reg. 5862, 5897 (February 2, 2011).

program. If the answer is yes, then the best mechanism for limiting CMP liability is to screen all persons that perform under that contract or that are in that job category.

Providers should determine whether or not to screen contractors, subcontractors, and the employees of contractors using the same analysis that they would for their own employees. The risk of potential CMP liability is greatest for those persons that provide items or services integral to the provision of patient care because it is more likely that such items or services are payable by the Federal health care programs. For example, OIG recommends that providers screen nurses provided by staffing agencies, physician groups that contract with hospitals to provide emergency room coverage, and billing or coding contractors. Alternatively, the provider could choose to rely on screening conducted by the contractor (e.g., staffing agency, physician group, or third-party billing or coding company), but OIG recommends that the provider validate that the contractor is conducting such screening on behalf of the provider (e.g., by requesting and maintaining screening documentation from the contractor). Regardless of whether and by whom screening is performed and the status of the person (e.g., employee, subcontractor, employee of contractor, or volunteer), the provider is subject to overpayment liability for any items or services furnished by any excluded person for which the provider received Federal health care program reimbursement and may be subject to CMP liability if the provider does not ensure that an appropriate exclusion screening was performed.

- *Other Government Exclusion and Debarment Lists*

We have received questions regarding the differences between the LEIE and GSA's EPLS, which was recently merged into SAM. SAM includes OIG's exclusions but also includes debarment actions taken by Federal agencies. The LEIE lists only exclusion actions taken by OIG. We recommend that providers use the LEIE as the primary source of information about OIG exclusions because the LEIE is maintained by OIG; is updated monthly; and provides more details about persons excluded by OIG than GSA's SAM, such as the statutory basis for the exclusion action, the person's occupation at the time of exclusion, the person's date of birth, and address information. Also, because the LEIE is maintained directly by OIG, OIG's exclusions staff can respond to questions and verify information regarding persons identified on the LEIE. The effect of OIG exclusion is to preclude payment by Federal health care programs for items or services furnished, ordered, or prescribed by the excluded party. OIG exclusion does not affect a person's ability to participate in other Government procurement or non-procurement transactions. Moreover, OIG has no authority to impose CMPs on the basis of employment of (or contracting with) a debarred person. Additional information regarding SAM and debarment is available at https://www.sam.gov.

- *The National Practitioner Data Bank and the Healthcare Integrity and Protection Databank*

We have received questions regarding whether other sanction databases, specifically the NPDB and the Health Care Integrity and Protection Databank (HIPDB), can or should be used in addition to or instead of the LEIE as a means to identify sanctions imposed against providers. The NPDB was

established under the Health Care Quality Improvement Act of 1986. The NPDB is an information clearinghouse that originally collected medical malpractice payments paid on behalf of physicians, adverse actions taken by licensing agencies against health care practitioners and health care entities, adverse privileging actions, and any negative actions or findings taken against health care practitioners or entities by Quality Improvement Organizations and Private Accreditation Organizations. HIPDB was created by HIPAA to provide information on adverse licensing and certification actions, criminal convictions (health care related), civil judgments, exclusions from Federal or State health care programs, and other adjudicated actions or decisions.

Section 6403 of the ACA required the Secretary of Health and Human Services to eliminate duplicative data reporting and access requirements between the NPDB and HIPDB.[28] On April 5, 2013, the Secretary issued regulations to implement the changes required by section 6403 of the ACA to merge the two databanks. The NPDB will continue to collect and disclose both the traditional NPDB information (medical malpractice payments, adverse licensing actions, adverse privileging actions, and any negative actions or findings taken by peer review organizations) and the information previously collected and disclosed through the HIPDB.[29]

Although providers may choose to check the NPDB to obtain information about other types of sanctions reported in that database, the OIG recommends that providers use the LEIE as the primary database for purposes of exclusion screening for current and potential employees and contractors.

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[28] See section 6403 of the Patient Protection and Affordable Care Act, P.L. 111-148.
[29] See 78 Fed. Reg. 20473 (April 5, 2013); 42 C.F.R. 60.

For more information on the databanks, go to http://www.npdb-hipdb.hrsa.gov/.

CONCLUSION

Since the publication of the 1999 Bulletin, the health care industry has significantly increased its efforts to comply with the rules governing the scope and effect of exclusion. This updated Bulletin:

- iterates earlier guidance on the scope and effect of an OIG exclusion,
- provides additional guidance on the scope of the payment prohibition and potential CMP liability,
- provides guidance on best practices for screening against the LEIE to ensure that providers do not employ or contract with an excluded individual, and
- directs providers to use OIG's SDP to self-disclose the employment of or contracting with an excluded person.

If you are an excluded person or are considering hiring or contracting with an excluded person and question whether or not an arrangement may violate the law, the OIG Advisory Opinion process is available to offer formal binding guidance on whether an employment or contractual arrangement may constitute grounds for the imposition of sanctions under OIG's exclusion and CMP authorities at sections 1128 and 1128A of the Act. The process and procedure for submitting an advisory opinion request may be found at 42 CFR 1008, or on the OIG Web site at http://oig.hhs.gov/compliance/advisory-opinions.

Appendix D

Organizational Charts

For more information on the databanks, go to http://www.npdb-hipdb.hrsa.gov/.

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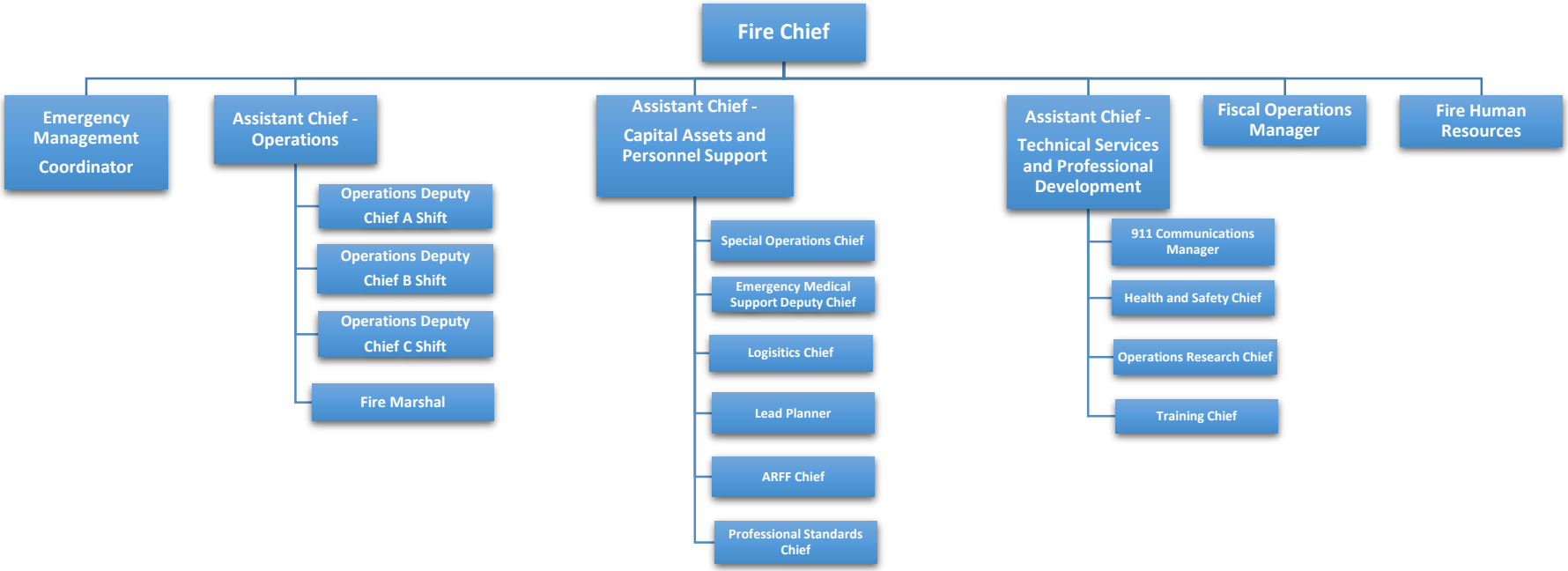
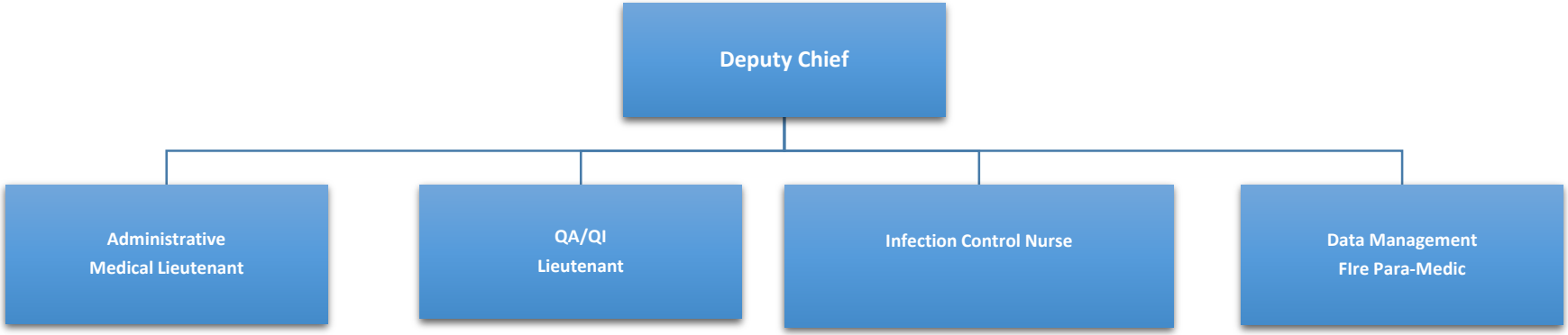
If you are an excluded person or are considering hiring or contracting with an excluded person and question whether or not an arrangement may violate the law, the OIG Advisory Opinion process is available to offer formal binding guidance on whether an employment or contractual arrangement may constitute grounds for the imposition of sanctions under OIG's exclusion and CMP authorities at sections 1128 and 1128A of the Act. The process and procedure for submitting an advisory opinion request may be found at 42 CFR 1008, or on the OIG Web site at http://oig.hhs.gov/compliance/advisory-opinions.

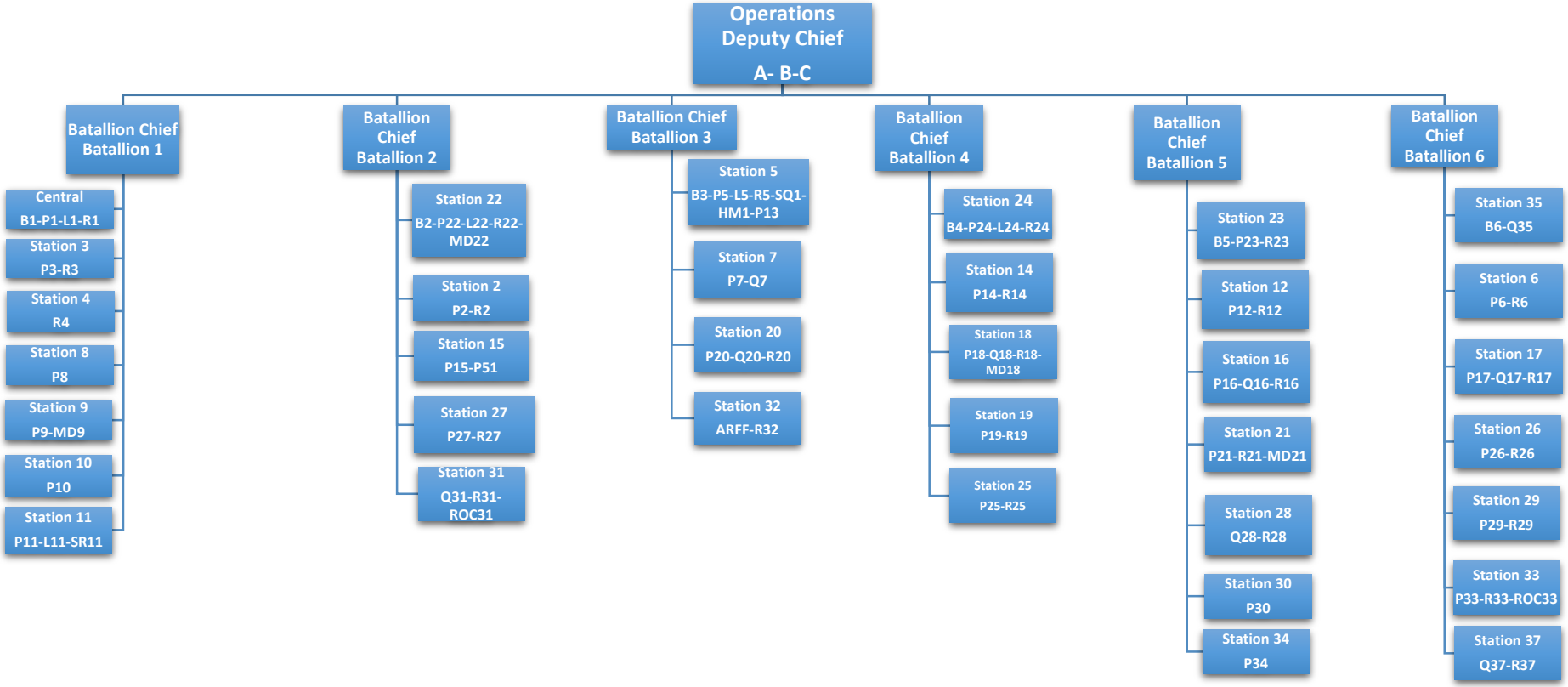
FIRE DEPARTMENT ORGANIZATIONAL CHART



FIRE MEDICAL RESARCH PROGRAM



EMERGENCY OPERATIONS DIVISION



For more information on the databanks, go to http://www.npdb-hipdb.hrsa.gov/.

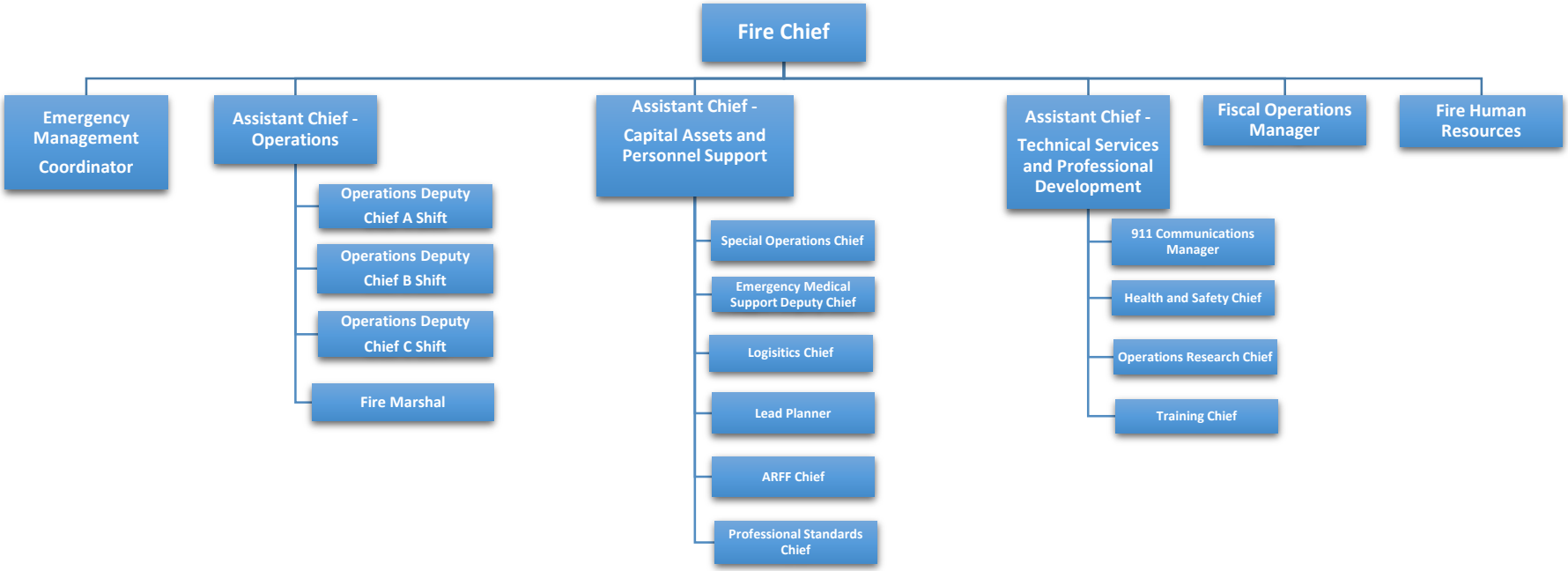
CONCLUSION

Since the publication of the 1999 Bulletin, the health care industry has significantly increased its efforts to comply with the rules governing the scope and effect of exclusion. This updated Bulletin:

- iterates earlier guidance on the scope and effect of an OIG exclusion,
- provides additional guidance on the scope of the payment prohibition and potential CMP liability,
- provides guidance on best practices for screening against the LEIE to ensure that providers do not employ or contract with an excluded individual, and
- directs providers to use OIG's SDP to self-disclose the employment of or contracting with an excluded person.

If you are an excluded person or are considering hiring or contracting with an excluded person and question whether or not an arrangement may violate the law, the OIG Advisory Opinion process is available to offer formal binding guidance on whether an employment or contractual arrangement may constitute grounds for the imposition of sanctions under OIG's exclusion and CMP authorities at sections 1128 and 1128A of the Act. The process and procedure for submitting an advisory opinion request may be found at 42 CFR 1008, or on the OIG Web site at http://oig.hhs.gov/compliance/advisory-opinions.

FIRE DEPARTMENT ORGANIZATIONAL CHART



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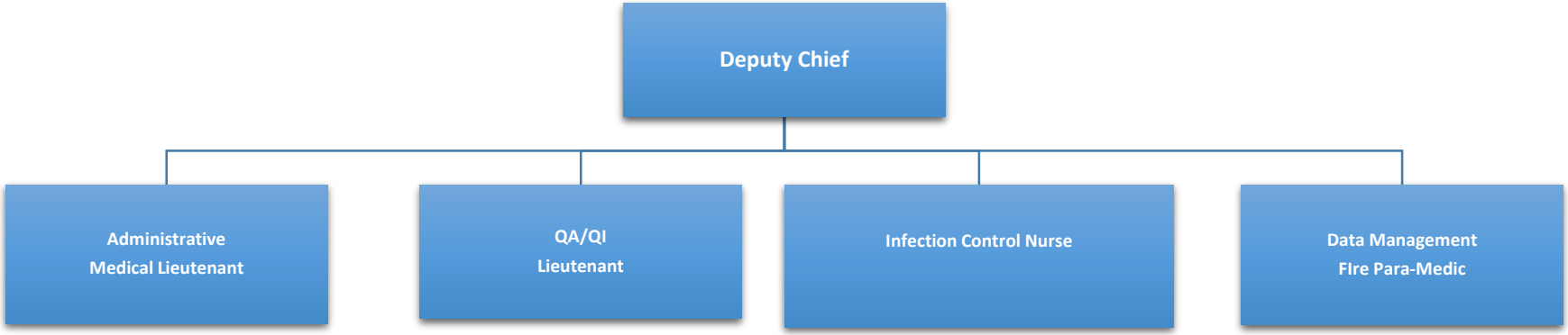

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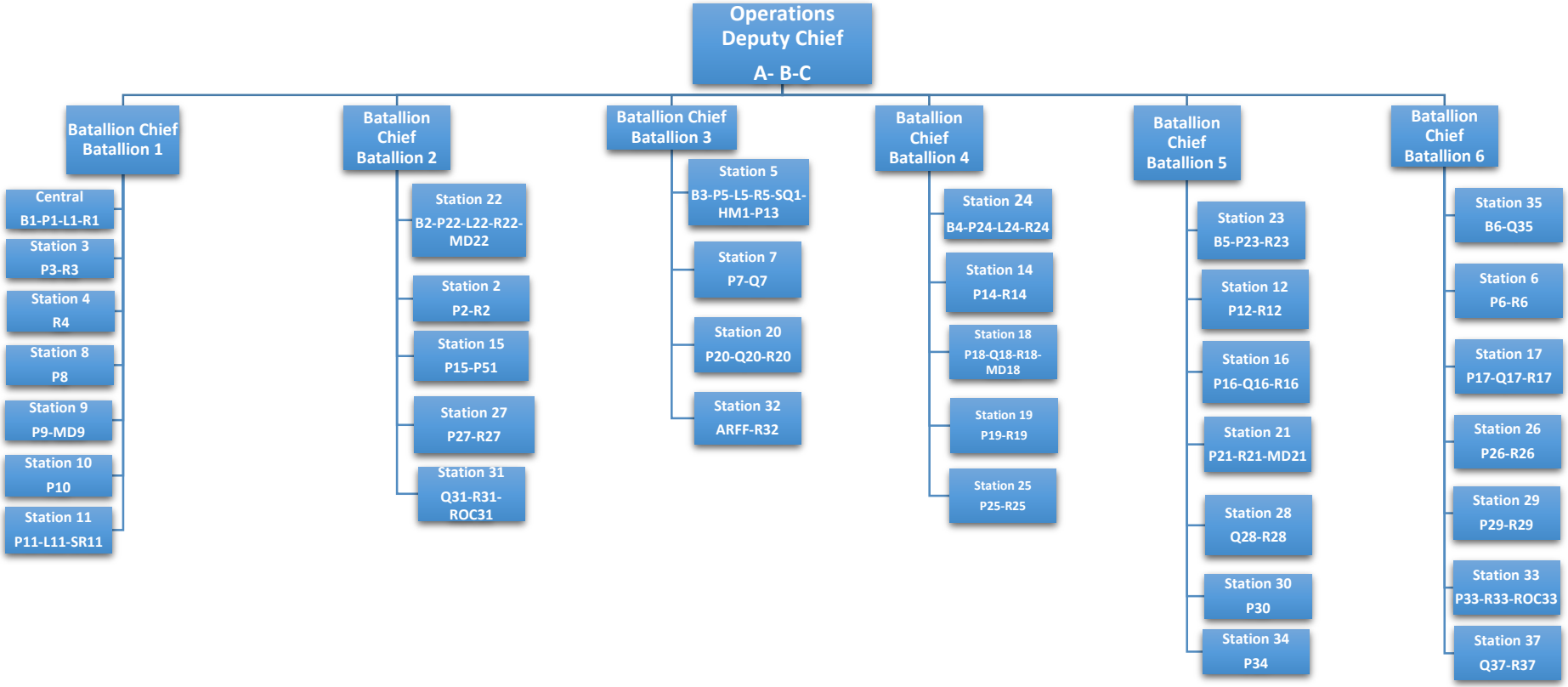
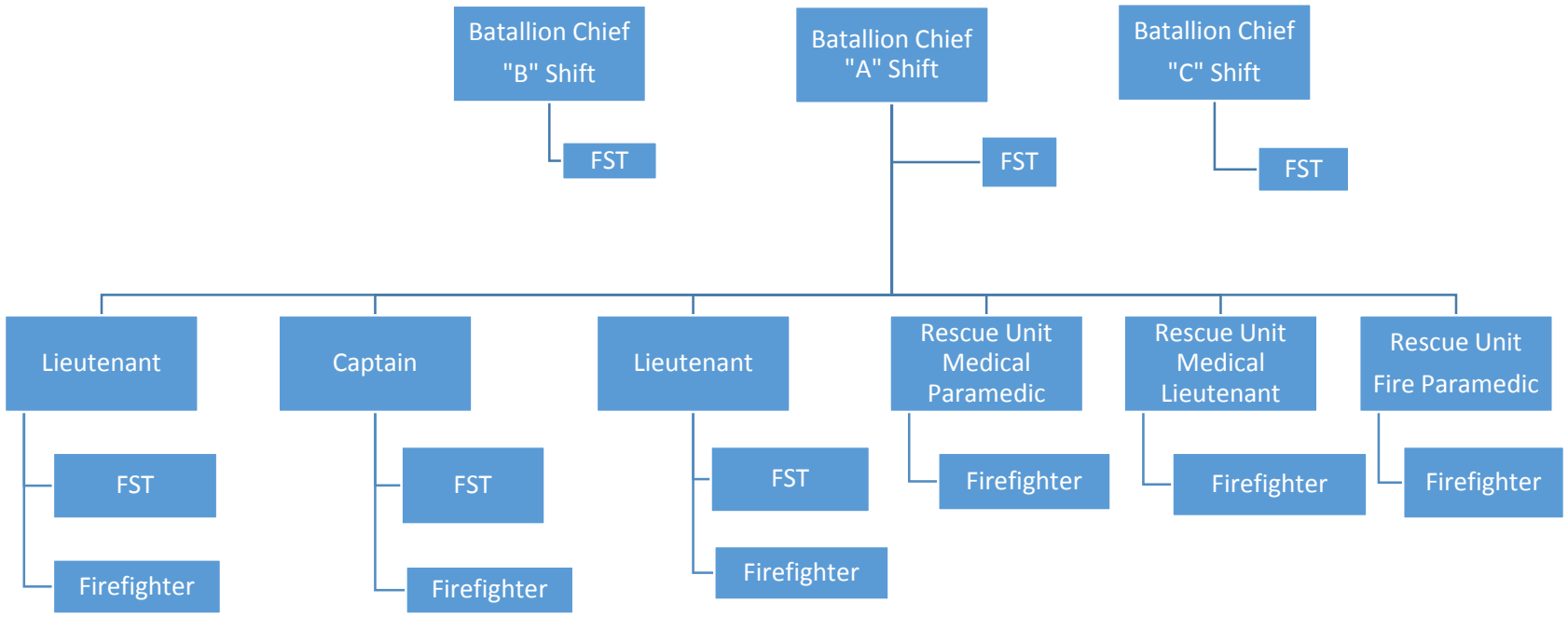
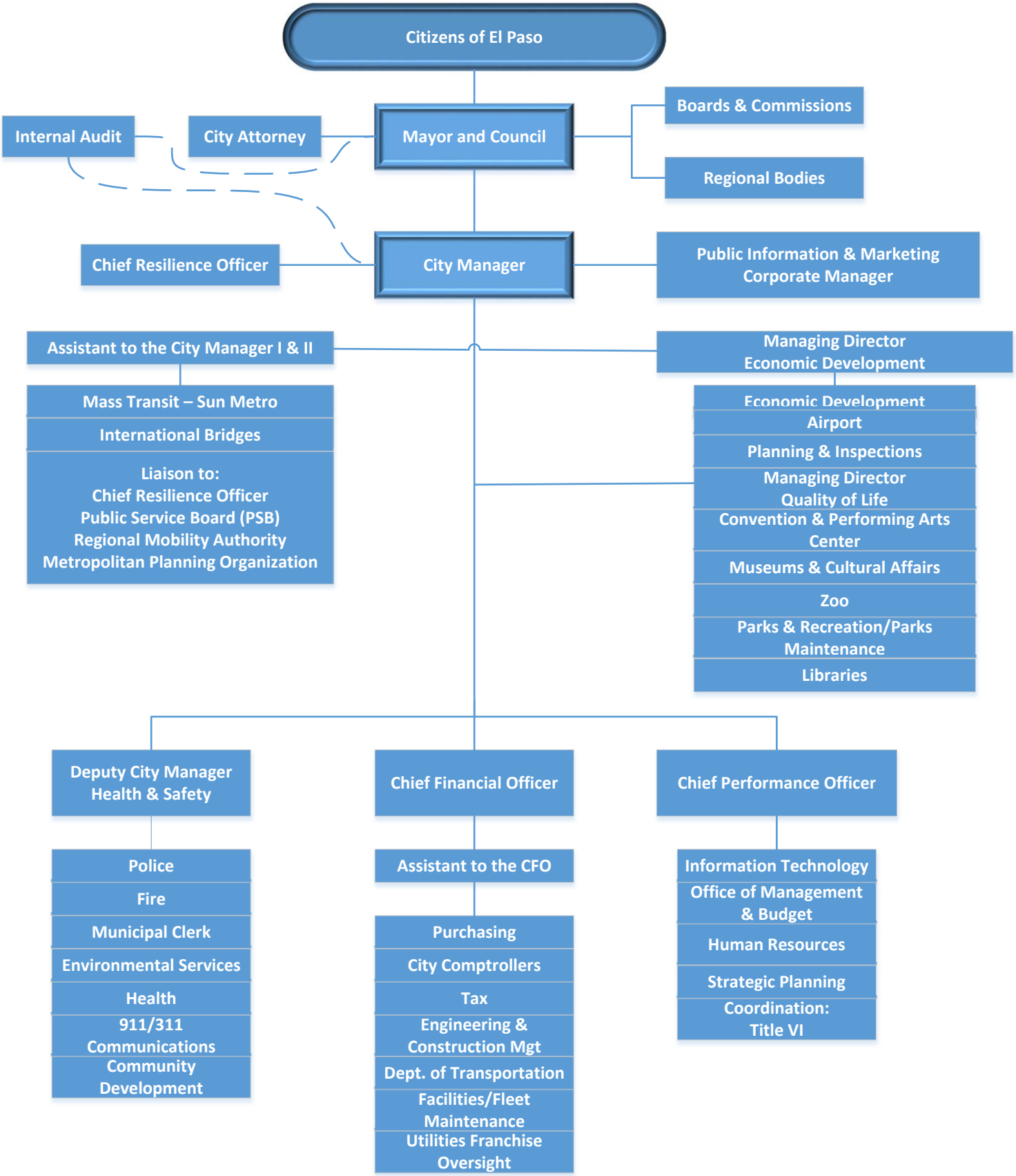


COMPANY ACCOUNTABILITY



City of El Paso Organizational Structure as of November 25, 2014



Appendix E

El Paso Fire Department
Signature Form

Assignment of Benefits/HIPAA Acknowledgement Form

Patient Name: [PatientName] Date: [CurrentDate]

I understand that I am financially responsible for the services provided to me by The City of El Paso, in including legally assessable finance and/or service charges, court costs, expenses and reasonable attorney's fees in the collection of any amounts due. I request that payment of authorized Medicare, Medicaid, or other insurance benefits be made on my behalf to The City of El Paso for any services provided to me by The City of El Paso now or in the future. I agree to immediately remit to The City of El Paso any payments that I receive directly from any source whatsoever for the services provided to me now or in the future. I assign all rights and/or benefits to such payments to The City of El Paso for compensation of services provided to me now or in the future.
I authorize and direct any holder of medical information or documentation about me to release such information to the Centers for Medicare and Medicaid Services and its carriers and agents, and/or The City of El Paso and its billing agents, and/or any other payers or insurers, as may be necessary to determine these benefits or other benefits payable for services provided to me by the City of El Paso.

Patient hereby consents to being contacted by The City of El Paso, or by any agents or other entities acting on behalf of The City of El Paso, by telephone, cell phone, email or other methods of communication, in connection with the billing or collection of amounts due, or otherwise in connection with the services rendered by The City of El Paso and/or payment therefore, including, without limitation, calls (including text messages) to any telephone number assigned to a cellular telephone service, and including any such calls made using an automatic telephone dialing system and/or an artificial or prerecorded voice.

Yes, I acknowledge that I have received a copy of The City of El Paso Notice of Privacy Practices.A copy of this form is as valid as the original.

Patient Signature	Printed Name	Date

AUTHORIZED REPRESENTATIVE SIGNATURE

Patient Name: [PatientName] Date: [CurrentDate]

Complete this section **only** if the patient is physically or mentally incapable of signing.

I am signing on behalf of the patient to authorize the submission of a claim for payment to Medicare, Medicaid, or any other payor for any services provided to the patient by **The City of El Paso Fire Department** now or in the past, (or in the future, where permitted). By signing below, I acknowledge that I am one of the authorized signers listed below. **My signature is not an acceptance of financial responsibility for the services rendered.**

_____	_____	_____
Patient Representative Signature	Printed Name	Date

Signed by: [PatientSignatureSignedBy]

Relationship to Patient: [RelationshipToPatient]

Reason the Pt. was unable to sign: [UnableToSign]

AMBULANCE CREW SIGNATURES

Complete this section **only** if:
(1) the patient was physically or mentally incapable of signing, **and**
(2) no authorized representative was available or willing to sign on behalf of the patient at the time of service.

Patient Name: [PatientName] Date: [CurrentDate]

Ambulance Crew Member Statement (*must* be completed by crew member at time of transport)

My signature below indicates that, at the time of service, the patient named above was physically or mentally incapable of signing, and that none of the authorized representatives listed in Section II of this form were available or willing to sign on the patient's behalf. **My signature is not an acceptance of financial responsibility for the services rendered.**

Crew Signature	Printed Name	Date

Signed by: [PatientSignatureSignedBy]

Reason Patient Unable to Sign: [UnableToSign]