

will be made on the basis of satisfactory progress and the availability of funds.

HRSA is limiting competition to the three regional areas because during the previously announced competitive cycle, applications submitted for the three regional areas did not successfully compete for funds. It is HRSA's intent to fund AETC Programs in all regions of the United States. This limited competition will focus on supporting a regional AETC Program in each of the three regions to provide state-of-the-art treatment education, training, consultation, and support to health care professionals treating HIV seropositive patients for the Health Resources and Services Administration's AETC Programs during the period of support.

DATES: Applications for these announced grants must be received in the Grants HRSA Application Center by the close of business September 1, 1999 to be considered for competition. Applications will meet the deadline if they are either (1) received on or before the deadline date or (2) postmarked on or before the deadline date, and received in time for submission to the objective review panel. A legibly dated receipt from a commercial carrier of U.S. Postal Service will be accepted as proof of timely mailing. Applications received after the deadline will be returned to the applicant.

ADDRESSES: All applications should be mailed or delivered to: Grants Management Officer, HRSA Grants Application Center, Parklawn Building, 5600 Fishers Lane, Room 4-91, Rockville, Maryland 20857. Grant applications sent to any address other than that above are subject to being returned. **Federal Register** notices and application guidance for the HIV/AIDS Bureau program are available on the World Wide Web via the Internet. The web site for the HIV/AIDS Bureau is: <http://www.hrsa.gov/hab/>. Federal grant application kits are available at the following Internet address: <http://forms.psc.gov/phsforms.htm>. For those applicants who are unable to access application materials electronically, a hard copy of the official grant application kit (PHS Form 6025-1) must be obtained from the HRSA Grants Application Center. The Center may be contacted by (telephone, 1-888-300-4772) FAX: 301-309-0579, or 3 e-mail, HRSA.GAC@ix.netcom.com.

FOR FURTHER INFORMATION CONTACT: Additional information may be obtained from Mrs. Juanita Koziol, Deputy Branch Director, HIV Education Branch, Division of Training and Technical Assistance, HIV/AIDS Bureau, Health Resources and Services Administration,

5600 Fishers Lane, Room 9A-39, Rockville, Maryland 20857. Telephone number (301) 443-6364 and the FAX: (301) 443-9887.

Dated: July 14, 1999.

Claude Earl Fox,
Administrator.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Draft OIG Compliance Program Guidance for Hospices

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

ACTION: Notice and comment period.

SUMMARY: This **Federal Register** notice seeks the comments of interested parties on draft compliance guidance developed by the Office of Inspector General (OIG) for the hospice industry. Through this notice, the OIG is setting forth its general views on the value and fundamental principles of hospice compliance programs, and the specific elements that the hospice industry should consider when developing and implementing an effective compliance program.

DATES: To assure consideration, comments must be delivered to the address provided below by no later than 5 p.m. on August 20, 1999.

ADDRESSES: Please mail or deliver written comments to the following address: Office of Inspector General, Department of Health and Human Services, Attention: OIG-6P-CPG, Room 5246, Cohen Building, 330 Independence Avenue, SW, Washington, DC 20201.

We do not accept comments by facsimile (FAX) transmission. In commenting, please refer to file code OIG-6P-CPG. Comments received timely will be available for public inspection as they are received, generally beginning approximately 2 weeks after publication of a document, in Room 5541 of the Office of Inspector General at 330 Independence Avenue, SW, Washington, DC 20201 on Monday through Friday of each week from 8:00 a.m. to 4:30 p.m.

FOR FURTHER INFORMATION CONTACT: Michael Shaw, Office of Counsel to the Inspector General, (202) 619-2078.

SUPPLEMENTARY INFORMATION:

Background

The creation of compliance program guidance is a major initiative of the OIG

in its effort to engage the private health care community in addressing and fighting fraud and abuse. In the last several years, the OIG has developed and issued compliance program guidance directed at the following segments of the health care industry:

- Clinical Laboratories (62 FR 9435; March 3, 1997, as amended in 63 FR 45076; August 24, 1998),
- Hospitals (63 FR 8987; February 23, 1998),
- Home Health Agencies (63 FR 42410; August 7, 1998),
- Third-Party Medical Billing Companies (63 FR 70138; December 18, 1998), and
- Durable Medical Equipment, Prosthetics, Orthotics and Supply Industry (64 FR 36368; July 6, 1999).

Copies of these compliance program guidances can also be found on the OIG web site at <http://www.os.dhhs.gov/oig>.

Developing Draft Compliance Program Guidance for the Hospice Industry

On January 13, 1999, the OIG published a solicitation notice seeking information and recommendations for developing formal guidance for the hospice industry (64 FR 2228). In response to that solicitation notice, the OIG received 11 comments from various outside sources. In developing this notice for formal public comment, we have considered those comments, as well as previous OIG publications, such as other compliance program guidances and Special Fraud Alerts. We have also taken into account past and recent fraud investigations conducted by the OIG's Office of Investigations and the Department of Justice, and have consulted with the Health Care Financing Administration.

This draft guidance for the hospice industry contains seven elements that the OIG has determined are fundamental to an effective compliance program:

- Implementing written policies;
- Designating a compliance officer and compliance committee;
- Conducting effective training and education;
- Developing effective lines of communication;
- Conducting internal monitoring and auditing;
- Enforcing standards through well-publicized disciplinary guidelines; and
- Responding promptly to detected offenses and developing corrective action.

These elements are contained in the other guidance issued by the OIG, indicated above. As with the previously-issued guidances, this draft compliance program guidance represents the OIG's

suggestions on how the hospice industry can best establish internal controls and prevent fraudulent activities. The contents of this guidance should not be viewed as mandatory or as an exclusive discussion of the advisable elements of a compliance program; the guidance is intended to present voluntary guidance to the industry and not represent binding standards for hospices.

Public Input and Comment in Developing Final Guidance

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

Draft Compliance Program Guidance for the Hospice Industry (July 1999)

I. Introduction

The Office of Inspector General (OIG) of the Department of Health and Human Services (HHS) continues to promote voluntarily developed and implemented compliance programs for the health care industry. The following compliance program guidance is intended to assist hospices¹ and their agents and subproviders (referred to collectively in this document as "hospices") develop effective internal controls that promote adherence to applicable Federal and State law, and the program requirements of Federal, State, and private health plans. The adoption and implementation of voluntary compliance programs significantly advance the prevention of fraud, abuse, and waste in these health care plans while at the same time further the fundamental mission of all hospices, which is to provide palliative care² to patients.

¹ The term "hospice" is applied in this document as the term "hospice program" is defined in 42 U.S.C. 1395x(dd).

² Palliative care is an intensive program of care that focuses on the relief of pain and suffering associated with a terminal illness. Through this emphasis on palliative rather than curative services, individuals have a choice whenever conventional approaches for medical treatment may no longer be appropriate. Hospice addresses the needs of terminally ill individuals by including the patient and family, specially trained volunteers, caregivers from the community, and representatives from medicine, nursing, social work, and spiritual counseling in the caregiving team.

Within this document, the OIG first provides its general views on the value and fundamental principles of hospice compliance programs, and then provides the specific elements that each hospice should consider when developing and implementing an effective compliance program. While this document presents basic procedural and structural guidance for designing a compliance program, it is not in itself a compliance program. Rather, it is a set of guidelines to be considered by a hospice interested in implementing a compliance program.

The OIG recognizes the size-differential that exists between operations of the different hospices and organizations that compose the hospice industry. Appropriately, this guidance is pertinent for all hospices, whether for-profit or non-profit, hospital-based or free-standing, community-based or volunteer-based, large or small, urban or rural. The applicability of the recommendations and guidelines provided in this document depends on the circumstances of each particular hospice. However, regardless of a hospice's size and structure, the OIG believes that every hospice can and should strive to accomplish the objectives and principles underlying all of the compliance policies and procedures recommended within this guidance.

Fundamentally, compliance efforts are designed to establish a culture within a hospice that promotes prevention, detection, and resolution of instances of conduct that do not conform to Federal and State law, and Federal, State, and private payor health care program requirements, as well as the hospice's business policies. In practice, the compliance program should effectively articulate and demonstrate the organization's commitment to ethical conduct. Compliance programs guide a hospice's governing body (e.g., board of directors or trustees), chief executive officer (CEO), managers, physicians, clinicians, billing personnel, and other employees in the efficient management and operation of a hospice. Eventually, a compliance program should become part of the fabric of routine hospice operations.

It is incumbent upon a hospice's corporate officers and managers to provide ethical leadership to the organization and to assure that adequate systems are in place to facilitate ethical and legal conduct. Employees, managers, and the Government will focus on the words and actions of a hospice's leadership as a measure of the organization's commitment to

compliance. Indeed, many hospices have adopted mission statements articulating their commitment to high ethical standards. A formal compliance program, as an additional element in this process, offers a hospice a further concrete method that may improve the appropriateness and quality of care and reduce waste. Compliance programs also provide a central coordinating mechanism for furnishing and disseminating information and guidance on applicable Federal and State statutes, regulations, and other requirements.

Implementing an effective compliance program requires a substantial commitment of time, energy, and resources by senior management and the hospice's governing body.³ Superficial programs that simply purport to comply with the elements discussed and described in this guidance or programs that are hastily constructed and implemented without appropriate ongoing monitoring will likely be ineffective and could expose the hospice to greater liability than no program at all. While it may require significant additional resources or reallocation of existing resources to implement an effective compliance program, the OIG believes that the long term benefits of implementing the program outweigh the costs.⁴

A. Benefits of a Compliance Program

The OIG believes an effective compliance program provides a mechanism that brings the public and private sectors together to reach mutual goals of reducing fraud and abuse, strengthening operational quality, improving the quality of health care services, and reducing the cost of health care. Attaining these goals provides positive results to hospices, the Government, and individual citizens alike. In addition to fulfilling its legal duty to ensure that it is not submitting false or inaccurate claims to Government and private payors, a hospice may gain numerous additional benefits by voluntarily implementing an effective compliance program. These benefits may include the ability to:

³ Recent case law suggests that the failure of a corporate director to attempt in good faith to institute a compliance program in certain situations may be a breach of a director's fiduciary obligation. See, e.g., *In re Caremark International Inc. Derivative Litigation*, 698 A.2d 959 (Ct. Chanc. Del. 1996).

⁴ The conclusion of a recent report by the United States General Accounting Office (GAO) to Congress stated that "despite the investment of time and resources that compliance programs entail, many hospitals believe the benefits of these programs * * * outweigh their costs * * * and providers themselves believe that compliance programs can reduce improper Medicare payments." See GAO report GAO/HEHS-99-59 (April 1999).

- Formulate effective controls to assure compliance with Federal and State statutes, rules, and regulations, and Federal, State and private payor health care program requirements, and internal guidelines;
 - Concretely demonstrate to employees and the community at large the hospice's strong commitment to honest and responsible provider and corporate conduct;
 - Identify and prevent illegal and unethical conduct;
 - Improve internal communication;
 - More quickly and accurately react to employees' operational compliance concerns and target resources to address those concerns;
 - Improve the quality, efficiency, and consistency of patient care;
 - Create a centralized source for distributing information on health care statutes, regulations, and other program directives regarding fraud, waste, and abuse, and related issues;
 - Formulate a methodology that encourages employees to report potential problems;
 - Develop procedures that allow the prompt, thorough investigation of alleged misconduct by corporate officers, managers, employees, independent contractors, consultants, volunteers, physicians, nurses, and other health care professionals;
 - Initiate immediate, appropriate, and decisive corrective action; and
 - Minimize, through early detection and reporting, the loss to the Government from false claims, and thereby reduce the hospice's exposure to civil damages and penalties, criminal sanctions, and administrative remedies, such as program exclusion.⁵

Overall, the OIG believes that an effective compliance program is a sound investment on the part of a hospice.

The OIG recognizes that the implementation of a compliance program may not entirely eliminate fraud, abuse, and waste from the hospice system. However, a sincere effort by hospices to comply with applicable Federal and State standards, as well as the requirements of private health care programs, through the establishment of an effective

⁵The OIG, for example, will consider the existence of an *effective* compliance program that pre-dated any governmental investigation when addressing the appropriateness of administrative sanctions. See 62 FR 67392 (December 24, 1997). The burden is on the provider to demonstrate the operational effectiveness of a compliance program. Further, the False Claims Act, 31 U.S.C. 3729-3733, provides that a person who has violated the Act, but who voluntarily discloses the violation to the Government, in certain circumstances will be subject to not less than double, as opposed to treble, damages. See 31 U.S.C. 3729(a).

compliance program, significantly reduces the risk of unlawful or improper conduct.

B. Application of Compliance Program Guidance

Given the diversity within the industry, there is no single "best" hospice compliance program. The OIG understands the variances and complexities within the hospice industry and is sensitive to the differences among large national and regional multi-hospice organizations, small independent hospices, and other types of hospice organizations and systems. However, elements of this guidance can be used by all hospices, regardless of size, location, or corporate structure, to establish an effective compliance program. Similarly, a hospital or corporation that owns a hospice or provides hospice services may incorporate these elements into its system-wide compliance or managerial structure. We recognize that some hospices may not be able to adopt certain elements to the same comprehensive degree that others with more extensive resources may achieve. This guidance represents the OIG's suggestions on how a hospice can best establish internal controls and monitoring to correct and prevent fraudulent activities. By no means should the contents of this guidance be viewed as an exclusive discussion of the advisable elements of a compliance program. On the contrary, the OIG strongly encourages a hospice to develop and implement compliance elements that uniquely address its own particular risk areas.

The OIG believes that input and support by the individuals and organizations that will use the tools set forth in this document are critical to the development and success of this compliance program guidance. In a continuing effort to collaborate closely with the private sector, the OIG placed a notice in the **Federal Register** soliciting recommendations and suggestions on what should be included in this Compliance Program Guidance.⁶ Further, we took into consideration previous OIG publications, such as Special Fraud Alerts, the recent findings and recommendations in reports issued by OIG's Office of Audit Services and Office of Evaluation and Inspections, as well as the experience of past and recent fraud investigations related to hospices conducted by OIG's Office of

⁶ See 64 FR 2228 (January 13, 1999), Notice for Solicitation of Information Recommendations for Developing OIG Compliance Program Guidance for the Hospice Industry.

Investigations and the Department of Justice. As appropriate, this guidance may be modified and expanded as more information and knowledge is obtained by the OIG, and as changes in the law, rules, policies, and procedures of the Federal, State, and private health plans occur.

The OIG recognizes that the development and implementation of compliance programs in hospices often raise sensitive and complex legal and managerial issues.⁷ However, the OIG wishes to offer what it believes is critical guidance for providers who are sincerely attempting to comply with the relevant health care statutes and regulations.

II. Compliance Program Elements

The elements proposed by these guidelines are similar to those of other compliance program guidances⁸ and the OIG's corporate integrity agreements.⁹ The elements represent a guide that can be tailored to fit the needs and financial realities of a particular hospice. The OIG is cognizant that, with regard to compliance programs, one model is not suitable to every hospice.

The OIG believes that every effective compliance program must begin with a formal commitment¹⁰ by the hospice's governing body to include all of the applicable elements listed below. These elements are based on the seven steps of the Federal Sentencing Guidelines.¹¹ Further, we believe that every hospice can implement most of our recommended elements that expand upon these seven steps. We recognize that full implementation of all elements

⁷Nothing stated within this document should be substituted for, or used in lieu of, competent legal advice from counsel.

⁸ See 63 FR 70138 (December 18, 1998) for the Compliance Program Guidance for Third Party Medical Billing Companies; 63 FR 42410 (August 7, 1998) for the Compliance Program Guidance for Home Health Agencies; 63 FR 45076 (August 24, 1998) for the Compliance Program Guidance for Clinical Laboratories, as revised; 63 FR 8987 (1998) for the Compliance Program Guidance for Hospitals. These documents are also located on the Internet at <http://www.dhhs.gov/progorg/oig>.

⁹ Corporate integrity agreements are executed as part of a civil settlement between the health care provider and the Government to resolve a case based on allegations of health care fraud or abuse. These OIG-imposed programs are in effect for a period of three to five years and require many of the elements included in this compliance program guidance.

¹⁰ *E.g.*, a resolution by the board of directors, owner(s) or president, where applicable, and the allocation of adequate resources to ensure that each of the elements is addressed.

¹¹ See United States Sentencing Commission Guidelines, *Guidelines Manual*, 8A1.2, Application Note 3(k). The Federal Sentencing Guidelines are detailed policies and practices for the Federal criminal justice system that prescribe the appropriate sanctions for offenders convicted of Federal crimes.

may not be immediately feasible for all hospices. However, as a first step, a good faith and meaningful commitment on the part of the hospice administration, especially the governing body and the CEO, will substantially contribute to a program's successful implementation. As the compliance program is implemented, that commitment should cascade down through the management of the hospice to every employee at all levels in the organization.

At a minimum, comprehensive compliance programs should include the following seven elements:

(1) The development and distribution of written standards of conduct, as well as written policies and procedures, which promote the hospice's commitment to compliance and address specific areas of potential fraud, such as assessment of Medicare eligibility, quality assurance, and financial relationships with nursing facilities and other health care professionals and entities.

(2) The designation of a compliance officer and other appropriate bodies, e.g., a corporate compliance committee, charged with the responsibility for operating and monitoring the compliance program, and who report directly to the CEO and the governing body.¹²

(3) The development and implementation of regular, effective education and training programs for all affected employees.

(4) The creation and maintenance of a process, such as a hotline or other reporting system, to receive complaints and ensure effective lines of communication between the compliance officer and all employees, and the adoption of procedures to protect the anonymity of complainants and to protect whistleblowers from retaliation.

(5) The use of audits and/or other evaluation techniques to monitor compliance, identify problem areas, and assist in the reduction of identified problem areas.

(6) The development of appropriate disciplinary mechanisms to enforce standards and the development of policies to address (i) employees who have violated internal compliance

¹² The integral functions of a compliance officer and a corporate compliance committee in implementing an effective compliance program are discussed throughout this compliance program guidance. However, the OIG recognizes that a hospice may tailor the structure of those positions in consideration of the size and design of the hospice, while endeavoring to address and accomplish all of the underlying objectives of a compliance officer and a corporate compliance committee. See section II.B. and accompanying notes.

policies, applicable statutes, regulations, or Federal health care program requirements¹³ and (ii) the employment of sanctioned and other specified individuals.

(7) The development of policies that direct prompt and proper responses to detected offenses, including the initiation of appropriate corrective action and preventative measures.

A. Written Policies and Procedures

Every compliance program should require the development and distribution of written compliance policies, standards, and practices that identify specific areas of risk and vulnerability to the hospice. These policies, standards, and practices should be developed under the direction and supervision of, or subject to review by, the compliance officer and compliance committee and, at a minimum, should be provided to all individuals who are affected by the particular policy at issue, including the hospice's agents and independent contractors.¹⁴

1. Standards of Conduct

Hospices should develop standards of conduct for all affected employees that include a clearly delineated commitment to compliance by the hospice's senior management¹⁵ and its divisions, including affiliated providers

¹³ The term "Federal health care programs" is applied in this document as defined in 42 U.S.C. 1320a-7b(f), which includes any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States Government i.e., via programs such as Medicare, Federal Employees' Compensation Act, Black Lung, or the Longshore and Harbor Worker's Compensation Act) or any State health plan (e.g., Medicaid, or a program receiving funds from block grants for social services or child health services). Also, for the purpose of this document, the term "Federal health care program requirements" refers to the statutes, regulations, rules, requirements, directives, and instructions governing Medicare, Medicaid, and all other Federal health care programs.

¹⁴ According to the Federal Sentencing Guidelines, an organization must have established compliance standards and procedures to be followed by its employees and other agents in order to receive sentencing credit for an "effective" compliance program. The Federal Sentencing Guidelines define "agent" as "any individual, including a director, an officer, an employee, or an independent contractor, authorized to act on behalf of the organization." See United States Sentencing Commission Guidelines, *Guidelines Manual*, 8A1.2, Application Note 3.

¹⁵ The OIG strongly encourages high-level involvement by the hospice's governing body, CEO, chief operating officer, general counsel, and chief financial officer, as well as other medical or clinical personnel, as appropriate, in the development of standards of conduct. Such involvement should help communicate a strong and explicit statement of compliance goals and standards.

operating under the hospice's control¹⁶ and other health care professionals (e.g., hospice physicians,¹⁷ nurses, physical therapists, occupational therapists, social workers, spiritual counselors, bereavement counselors, and volunteers). Standards should articulate the hospice's commitment to comply with all Federal, State, and private insurer standards, with an emphasis on preventing fraud and abuse. They should explicitly state the organization's mission, goals, and ethical requirements of compliance and reflect a carefully crafted, clear expression of expectations for all hospice governing body members, officers, managers, employees, physicians, clinicians, and, where appropriate, volunteers, contractors and other agents. These standards should promote integrity, support objectivity, and foster trust. Standards should not only address compliance with statutes and regulations, but should also set forth broad principles that guide employees in conducting business professionally and properly.

The standards should be distributed to, and comprehensible by, all affected employees (e.g., translated into other languages when necessary and written at appropriate reading levels). Standards should not only address compliance with statutes and regulations, but should also set forth broad principles that guide employees in conducting business professionally and properly. Further, to assist in ensuring that employees continuously meet the expected high standards set forth in the code of conduct, any employee handbook delineating or expanding upon these standards of conduct should be regularly updated as applicable statutes, regulations, and Federal health care program requirements are modified and/or clarified.¹⁸

¹⁶ E.g., attending physicians, pharmacies, durable medical equipment suppliers, hospitals, nursing homes, home health agencies, and supplemental staffing entities.

¹⁷ When the term "hospice physician" is applied in this document, it refers to the hospice's medical director or the physician member of a hospice's Interdisciplinary Group. The "Interdisciplinary Group," which is composed of at least a doctor of medicine or osteopathy, registered nurse, medical social worker, and pastoral or other counselor, is responsible for: (1) participation in the establishment of the plan of care; (2) provision of supervision of hospice care and services; (3) periodic review and updating of the plan of care for each individual receiving hospice care; (4) establishment of policies governing the day-to-day provision of hospice care and services. See 42 CFR 418.68.

¹⁸ The OIG recognizes that not all standards, policies, and procedures need to be communicated to all employees. However, the OIG believes that the bulk of the standards that relate to complying with fraud and abuse laws and other ethical areas

When they first begin working for the hospice, and each time new standards of conduct are issued, employees should be asked to sign a statement certifying that they have received, read, and understood the standards of conduct. An employee's certification should be retained by the hospice in the employee's personnel file, and available for review by the compliance officer.

2. Risk Areas

The OIG believes that a hospice's written policies and procedures should take into consideration the particular statutes, rules, and program instructions that apply to each function or department of the hospice.¹⁹ In contrast to the standards of conduct, which are designed to be a clear and concise collection of fundamental standards, the written policies should articulate specific procedures that hospice staff should follow.

Consequently, we recommend that these policies and procedures be coordinated with the appropriate training and educational programs, with an emphasis on areas of special concern that have been identified by the OIG through its investigative and audit functions.²⁰ Some of the special areas of OIG concern include:²¹

- Uninformed consent to elect the Medicare Hospice Benefit;²²
- Discriminatory admission;²³
- Admitting patients to hospice care who are not terminally ill;²⁴
- Arrangement with another health care provider who a hospice knows is submitting claims for services already covered by the Medicare Hospice Benefit;²⁵

²² A hospice must ensure that an individual (or authorized representative) is informed about the palliative nature of the care and services that may be provided if the individual desires to elect the Medicare Hospice Benefit. 42 CFR 418.62. The decision to elect the Medicare Hospice Benefit has significant consequences because the patient waives the right to receive standard Medicare benefits related to the terminal illness, including all treatment for the purposes of curing the terminal illness. See 42 U.S.C. 1395d(d). A patient's hospice election statement must include the following items of information: (1) identification of the particular hospice that will provide care to the individual; (2) the individual's or representative's acknowledgment that he or she has been given a full understanding of hospice care; (3) the individual's or representative's acknowledgment that he or she understands that certain Medicare services are waived by the election; (4) the effective date of the election; and (5) the signature of the individual or representative. See *Medicare Hospice Manual* § 210.

²³ Hospices should offer palliative care to all terminally ill individuals and their families who are eligible, regardless of age, gender, nationality, race, creed, sexual orientation, or disability.

²⁴ For a hospice patient to receive reimbursement for hospice services under Medicare, the patient must be "terminally ill." See 42 U.S.C. 1395d(a). An individual is considered to be "terminally ill" if the individual has a medical prognosis that the individual's life expectancy is six months or less if the illness runs its normal course. 42 CFR 418.3. In March 1995, Operation Restore Trust (ORT), a joint initiative, was established between the OIG, HCFA, and Administration on Aging. Among its projects, ORT assessed the medical eligibility for hospice services in the five largest States in terms of Medicare spending (New York, Florida, Illinois, Texas, and California). Through ORT activities, it was discovered that many beneficiaries receiving Medicare hospice benefits did not have a terminal illness as defined by Medicare. See OIG report A-05-96-00023—"Enhanced Controls Needed to Assure Validity of Medicare Hospice Enrollments." In addition, OIG investigators have encountered hospices that asked nurse employees to alter notes in patients' records or to otherwise misrepresent patients' medical conditions, in order to falsify the existence of a terminal condition. See also section II.A.3.a. and accompanying notes.

²⁵ When an individual makes an election to receive services covered by the Medicare Hospice Benefit, that individual waives the right to receive Medicare reimbursement for any treatment related to his or her terminal illness. Accordingly, a hospice should ensure it is not involved with a health care provider who the hospice knows submits claims for the following services that are unallowable for reimbursement under the Medicare Hospice Benefit: (1) standard Medicare benefits for treatment of the terminal illness; (2) treatment by another hospice not arranged for by the patient's hospice; and (3) care from another provider that duplicates care the hospice is required to furnish. See 42 U.S.C. 1395d(d). It is expected that the hospice provider will work with other providers to coordinate care and ensure appropriate billing if these situations occur.

- Under-utilization;²⁶
- Falsified medical records or plans of care;²⁷
- Untimely and/or forged physician certifications on plans of care;
- Inadequate or incomplete services rendered by the Interdisciplinary Group;²⁸
- Insufficient oversight of patients receiving more than six consecutive months of hospice care;²⁹
- Hospice incentives to actual or potential referral sources (e.g., physicians, nursing homes, hospitals, patients, etc.) that may violate the anti-kickback statute or other similar Federal or State statute or regulation,³⁰

²⁶ In other words, knowing denial of needed care in order to keep costs low. A hospice is accountable for the appropriate allocation and utilization of its resources in order to provide optimal care consistent with the needs of a patient, family, and/or lawful representative. When a patient is receiving hospice care, the hospice is paid a predetermined fee for each day during the length of care, no matter how much care the hospice actually provides. This means that a hospice may have a financial incentive to reduce the number of services provided to each patient, because the hospice will get paid the same amount regardless of the number of services provided. The OIG has received complaints about hospices neglecting patient needs and ignoring reasonable requests for treatment, including complaints about limited availability of durable medical equipment for patients as their medical condition decreases and failure to provide continuous care for periods of crisis due to staff shortages. The OIG has also been alerted to improper utilization of services that occurs when a hospice encourages a patient to revoke the Medicare Hospice Benefit for the purpose of obtaining expensive care under the standard Medicare benefits, only to re-elect the Medicare Hospice Benefit when expensive care is no longer necessary.

²⁷ OIG investigations have revealed that certain hospices have falsified or "re-created" patient medical records and plans of care to exaggerate the negative aspects regarding a hospice patient's condition to justify reimbursement. See section II.A.3.b. and accompanying notes.

²⁸ Each hospice is required to have an "Interdisciplinary Group" of personnel. See 42 U.S.C. 1395x(dd)(2)(B). See note 17. Failure of the Interdisciplinary Group to meet its responsibilities may result in substandard care. In addition, inadequate review of a hospice patient may result in improper reimbursement for services provided to a patient who fails to continue to be eligible for the Medicare Hospice Benefit.

²⁹ Since the enactment of the Balanced Budget Act of 1997, the Medicare Hospice Benefit is divided into the following benefit periods: (1) initial 90-day; (2) subsequent 90-day; and (3) unlimited number of 60-day benefit periods as long as the patient continues to meet program eligibility requirements. See 42 U.S.C. 1395d. At the beginning of each subsequent 60-day benefit period, either the attending physician or hospice physician must recertify that the patient is terminally ill. See 42 U.S.C. 1395f(a)(7). If the necessary oversight is not performed during the unlimited periods of care, a hospice may receive improper reimbursement for services provided to a patient who fails to continue to be eligible for the Medicare Hospice Benefit.

³⁰ Examples of arrangements that may run afoul of the anti-kickback statute include practices in which a hospice pays a fee to a physician for each plan of care certified, and provides nursing or

should be addressed and made part of all affected employees' training. The hospice must decide which additional educational programs should be limited to the different levels of employees, based on job functions and areas of responsibility.

¹⁹ A hospice can conduct focus groups composed of managers from various departments to solicit their concerns and ideas about compliance risks that may be then addressed by the hospice's policies and procedures. Such employee participation in the development of the hospice's compliance program can promote its credibility and foster employee acceptance of the program.

²⁰ The OIG periodically issues Special Fraud Alerts setting forth activities believed to raise legal and enforcement issues. For example, see OIG Special Fraud Alert—"Fraud and Abuse in Nursing Home Arrangements with Hospices" (March 1998); see also OIG Medicare Advisory Bulletin on Hospice Benefits (November 1995). Hospice compliance programs should require that the legal staff, compliance officer, or other appropriate personnel carefully consider any and all Special Fraud Alerts issued by the OIG that relate to hospices. Moreover, the compliance programs should address the ramifications of failing to cease and correct any conduct criticized in a Special Fraud Alert, if applicable to hospices, or to take reasonable action to prevent such conduct from reoccurring in the future. If appropriate, a hospice should take the steps described in section II.G. regarding investigations, reporting, and correction of identified problems.

²¹ Hospices may also want to consult the OIG's Work Plan when conducting the risk assessment. The OIG Work Plan details the various projects the OIG intends to address in the applicable fiscal year. It should be noted that the priorities in the Work Plan are subject to modification and revision as the year progresses and it does not represent a complete or final list of areas of concern to the OIG. The Work Plan is currently available on the Internet at <http://www.os.dhhs.gov/oig>.

including improper arrangements with nursing homes;³¹

- Overlap in the services that a nursing home provides, which results in insufficient care provided by a hospice to a nursing home resident;³²
- Improper relinquishment of core services and professional management responsibilities to nursing homes, volunteers, and privately-paid professionals;³³
- Providing hospice services in a nursing home before a written

administrative services for free or below fair market value to physicians, nursing homes, hospitals and other potential referral sources. See 42 U.S.C. 1320a-7b; 60 FR 40847 (1995). See also discussion in section II.A.4. and accompanying notes. In addition, a hospice that offers an incentive to an individual that such hospice knows or should know is likely to influence the individual to use a particular hospice may be subject to civil monetary penalties. See 42 U.S.C. 1320a-7a(a)(5).

³¹ The OIG has observed instances of potential kickbacks between hospices and nursing homes to unlawfully influence the referral of patients. In general, payments by a hospice to a nursing home for "room and board" provided to a Medicaid hospice patient should not exceed what the nursing home otherwise would have received if the patient had not been enrolled in hospice. (If a patient receiving Medicare hospice benefits in a nursing home is also eligible for Medicaid, Medicaid will pay the hospice at least 95 percent of the State's daily nursing home rate, and the hospice is then responsible for paying the nursing home for the patient's room and board.) Any additional payment must represent the fair market value of additional services actually provided to that patient that are not included in the Medicaid daily rate. See *Hospice Medicare Manual* § 204.2. See also section II.A.4. and accompanying notes.

³² There may be some overlap in the services that the nursing homes and hospices provide, thereby providing one or the other the opportunity to reduce services and costs. Recent OIG reports found that residents of certain nursing homes receive fewer services from their hospice than patients who receive hospice services in their own homes. Upon review, it was found that many nursing home hospice patients were receiving only basic nursing and aide visits that were provided by nursing home staff as part of room and board when hospice staff were not present. Other additional treatments provided by hospice staff, such as nursing and aide visits, were often clearly within the professional skills possessed by nursing home staff. The reports found that the nature of services provided by hospice staff, while appropriate and efficacious, appeared to differ little from services a nursing home would have provided if the patient was not enrolled in hospice. See OEI report OEI-05-95-00250—"Hospice Patients in Nursing Homes;" see also OIG report A-05-96-00023—"Enhanced Controls Needed to Assure Validity of Medicare Hospice Enrollments." Since hospices receive a fixed daily payment regardless of the number of services provided or the location of the patient, fewer services may result in higher profits per patient. See also section II.A.3.e. and accompanying notes.

³³ Certain of the hospice services, (i.e., "core services" such as nursing, medical, social, and counseling services) must be provided directly to the patient by employees of the hospice, while other non-core hospice services may be provided in accordance with contracts with other providers. However, the hospice must retain professional management for all contacted services. See 42 CFR 418.80.

agreement has been finalized, if required;³⁴

- Billing for a higher level of services than was necessary;³⁵
- Knowingly billing for inadequate or substandard care;
- Inadequate justification in the medical record when a patient revokes the Medicare Hospice Benefit;³⁶
- Billing for hospice care provided by unqualified or unlicensed clinical personnel;³⁷
- False dating of amendments to medical records;³⁸
- High-pressure marketing of hospice care to ineligible beneficiaries;³⁹

³⁴ A patient who resides in a skilled nursing facility or nursing facility may elect the Medicare Hospice Benefit if: (1) the residential care is paid for by (a) the beneficiary or private insurance, or (b) Medicaid (if the beneficiary is dual eligible); and (2) the hospice and facility have a written agreement under which the hospice takes full responsibility for the professional management of the individual's hospice care and the facility agrees to provide room and board. *Hospice Medicare Manual* § 204.2.

³⁵ Billing for unnecessary services involves knowingly seeking reimbursement for services that "are not reasonable and necessary for the palliation or management of terminal illness." See 42 U.S.C. 1395y(a)(1)(C). Because HCFA establishes different payment amounts for specific categories of covered hospice care, a hospice must ensure that it provides services to hospice patients that are reasonable and necessary. Otherwise, the hospice may be reimbursed for a higher level of services than was necessary, e.g., a hospice that provides and bills for continuous care where only routine home care is necessary. See also section II.A.3.d. and accompanying notes.

³⁶ Fiscal intermediaries have informed the OIG that hospices rarely offer the reasons supporting the revocation of a patient's Medicare Hospice Benefit. Although a hospice may discharge a patient if it discovers that the patient is not terminally ill, hospices should not encourage a patient to revoke the benefit merely to avoid the obligation to pay for hospice services that have become too costly. See *Hospice Medicare Manual* § 210.

³⁷ Medicare conditions of participation require that hospices and all hospice employees must be licensed in accordance with applicable Federal, State, and local laws and regulations. 42 CFR 418.72.

³⁸ If additions or corrections need to be made to medical records, hospices should make such entries appropriately. For example, hospices might correct a medical record by drawing a single line through the erroneous entry, writing "error" next to the entry, initialing and dating the correction, and writing the correct information near the entry or writing where the correct information could be found.

³⁹ Hospices should not utilize prohibited or inappropriate conduct (e.g., offer free gifts or services to patients), designed to maximize business growth and patient retention, to carry out their initiatives and activities. Also, any marketing information offered by hospices should be clear, correct, non-deceptive, and fully informative. Through ORT, it was discovered that hospice marketing materials had placed considerable emphasis on the availability of hospice benefits for long term care patients, while downplaying or ignoring the terminal illness eligibility requirement. See OIG report A-05-96-00023—"Enhanced Controls Needed To Assure Validity of Medicare Hospice Enrollments." Hospices should not engage in marketing and sales strategies that offer incomplete or inadequate information about

- Improper patient solicitation activities, such as "patient charting;"⁴⁰
- Inadequate management and oversight of subcontracted services, which results in improper billing;⁴¹
- Sales commissions based upon length of stay in hospice;⁴²
- Deficient coordination of volunteers;⁴³
- Improper indication of the location where hospice services were delivered;⁴⁴

Medicare entitlement under the Medicare Hospice Benefit to induce beneficiaries to elect hospice and thereby waive aggressive treatment options that Medicare would otherwise cover. Marketing statements should not create the perception that the initial terminal prognosis is of limited importance and that hospice benefits may almost routinely be provided over an indefinite time period. Marketing materials should prominently feature the eligibility requirements for the Medicare Hospice Benefit.

⁴⁰ Hospices should not review medical records of nursing home patients in an attempt to recruit patients for hospice services based on their diagnoses. For instance, see OIG report A-05-96-00023—"Enhanced Controls Needed To Assure Validity of Medicare Hospice Enrollments."

⁴¹ The Balanced Budget Act of 1997, Pub. L. No. 105-33, amended the Social Security Act so that hospices will no longer be required to routinely provide all physician services directly by employing a physician. See 42 U.S.C. 1395x(dd)(2). Because the OIG has received reports of limited involvement displayed by contracted physicians, as opposed to hospice-employed physicians, hospices should consider having oversight mechanisms in place to ensure that hospice physicians are thoroughly reviewing re-certification documentation.

⁴² Through ORT activities, it was discovered that hospice sales staff often were paid on commission based on the length of a patient's stay in hospice. For example, commission amounts were determined by multiplying the total number of days of hospice patient care (patient days) within a sales representative's territory by a factor that reflected the level of achievement of assigned sales performance objectives. Such marketing tactics are encouraged the recruitment of long-term patients, many of whom the review found ineligible for the Medicare Hospice Benefit. The OIG recommends that hospices monitor sales commissions for potential vulnerabilities associated with improper patient recruiting. See OIG report A-05-96-00023—"Enhanced Controls Needed to Assure Validity of Medicare Hospice Enrollments."

⁴³ Hospices rely heavily on volunteer support. In fact, the Medicare Hospice Benefit is the only federally funded program that mandates the provision of volunteer services. Appropriately, hospices need to recognize and attend to compliance issues associated with volunteers (i.e., screening, training, disciplining, monitoring, etc.).

⁴⁴ Medicare payments for hospice services are made on a prospective basis and adjusted by an area wage index. Hospices must submit claims based on the geographic location at which the service is furnished and not the location of the hospice. Incorrect designation of the place of service for revenue codes 651 and 652 of the hospice claim may significantly alter reimbursement and result in overpayment for services performed (e.g., hospice office in a metropolitan area may be reimbursed more than a rural home where the services were performed).

- Failure to comply with applicable requirements for verbal orders for hospice services;⁴⁵
- Non-response to late hospice referrals by physicians;⁴⁶
- Knowing misuse of provider certification numbers, which results in improper billing;⁴⁷
- Failure to adhere to hospice licensing requirements and Medicare conditions of participation;⁴⁸ and
- Knowing failure to return overpayments made by Federal health care programs.⁴⁹

A hospice's prior history of noncompliance with applicable statutes, regulations, and Federal health care program requirements may indicate additional types of risk areas where the hospice may be vulnerable and that may require policies and procedures to prevent recurrence.⁵⁰ Additional risk

⁴⁵ Hospice staff must make an appropriate entry in the patient's medical record as soon as they receive a verbal certification of terminal illness and file written certifications in the medical record. See 42 CFR 418.22(d). State regulations may require that verbal and telephone orders from physicians should only be accepted by individuals authorized by State law to accept such orders. The OIG recommends that those authorized individuals accepting verbal and telephone orders should record, date, and sign these orders and the physician(s) who ordered the service or treatment should countersign them no later than the time period required by State regulations.

⁴⁶ We have received comments expressing concern over late hospice referrals by physicians. While the onus of a timely hospice referral may be on a physician, a hospice should not allow untimely referrals to go unrecognized with inadequate follow-up to the physicians. When hospice referrals are late, terminally ill patients may be unnecessarily denied access to the Medicare Hospice Benefit, hospices may have to admit a patient at the costliest stage of terminal illness, and quality of care may be affected because of patients being too far along to receive the optimum benefits of hospice care. Hospices need to work closely with physicians to educate and remind them as to the sensitivities and risks associated with untimely referrals.

⁴⁷ E.g., transfer of a patient from one hospice to another hospice owned by the same company to circumvent applicable reimbursement caps.

⁴⁸ See 42 CFR 418.50–418.100 for the Medicare conditions of participation that apply to hospices.

⁴⁹ An overpayment is the amount of money a hospice may have received in excess of the amount due and payable under a health care program. Examples of overpayments include, but are not limited to, instances where a hospice is: (1) paid twice for the same service either by Medicare or by Medicare and another insurer; or (2) paid for care rendered to patients who are not terminally ill or are otherwise ineligible for the Medicare Hospice Benefit. For instance, see *Hospice Medicare Manual* §307. The OIG strongly recommends that the hospice institute procedures to detect overpayments and to promptly remit such overpayments to the affected payor. See 42 U.S.C. 1320a–7(b)(3), which provides criminal penalties for failure to disclose an overpayment. See also 18 U.S.C. 669.

⁵⁰ Recurrence of misconduct similar to that which an organization has previously committed casts doubt on whether it took all reasonable steps to prevent such misconduct and is a significant factor in the assessment of whether a compliance program

areas should be assessed by hospices as well and incorporated into the written policies and procedures and training elements developed as part of their compliance programs.

3. Eligibility Requirements

Of the risk areas identified above, those pertaining to the Medicare eligibility requirements have been the frequent subject of investigations and audits. With respect to the reimbursement process, a hospice's written policies and procedures should reflect and reinforce current Federal health care requirements regarding the eligibility for Medicare reimbursement. The policies must create a mechanism for the billing or reimbursement staff to communicate effectively and accurately with the clinical staff. Policies and procedures should:

- Provide for complete and timely documentation of the specific clinical factors that qualify a patient for the Medicare Hospice Benefit;⁵¹
- Delineate who has authority to make entries in the patient record;
- Emphasize that patients should be admitted to hospice care only when appropriate documentation supports the applicable reimbursement eligibility criteria and only when such documentation is maintained, appropriately organized in a legible form, and available for audit and review. The documentation should record the activity leading to the record entry and the identity of the individual providing the service. Documentation should be consistent and any discrepancies discussed and reconciled. The hospice should consult with its physicians, clinical staff, and/or governing body to establish other appropriate documentation guidelines;
- Indicate that the diagnosis and procedure codes for hospice services reported on the reimbursement claim should be based on the patient's clinical condition as reflected in the medical record and other documentation, and should comply with all applicable official coding rules and guidelines. Any Health Care Financing Administration Common Procedure Coding System (HCPCS), International Classification of Disease (ICD), or

is effective. See United States Sentencing Commission Guidelines, *Guidelines Manual*, 8A1.2, Application Note 3(k)(iii).

⁵¹ Each patient's clinical record must contain: (1) the initial and subsequent assessments (including hospice admission history, certification, and recertification); (2) the plan of care; (3) identification data; (4) consent and authorization and election forms; (5) pertinent medical history; and (6) complete documentation of all services and events (including evaluations, treatments, progress notes, etc.) See 42 CFR 418.74.

revenue code (or successor codes) used by the billing staff should accurately describe the service that was ordered by the physician and performed by the hospice. The documentation necessary for accurate billing should be available to billing staff; and

- Provide that the compensation for hospice admission personnel, billing department personnel and billing consultants should not offer any financial incentive to bill for hospice care regardless of whether applicable eligibility criteria for reimbursement is met.

The written policies and procedures concerning proper billing should reflect the current reimbursement principles set forth in applicable regulations and should be developed in tandem with private payor and organizational standards. Particular attention should be paid to issues associated with patient election of the Medicare Hospice Benefit, certification of terminal illness of a patient, development and certification of a patient's interdisciplinary plan of care, and reasonableness and necessity of the level of hospice care provided.⁵²

a. Terminal Illness as an Eligibility Requirement

For a hospice patient to receive reimbursement for hospice services under Medicare,⁵³ the patient must be "terminally ill."⁵⁴ Hospices should create oversight mechanisms to ensure that the terminal illness of a Medicare beneficiary is verified⁵⁵ and the specific

⁵² The OIG has undertaken numerous audits, investigations, inspections, and national enforcement initiatives aimed at reducing potential and actual fraud, abuse, and waste. For example, see OIG report A–05–96–00023—"Enhanced Controls Needed to Assure Validity of Medicare Hospice Enrollments;" see also OIG Special Fraud Alert—"Fraud and Abuse in Nursing Home Arrangements with Hospices" (March 1998); OIG Medicare Advisory Bulletin on Hospice Benefits (November 1995).

⁵³ 42 U.S.C. 1395d(a) authorizes the reimbursement of hospice care.

⁵⁴ An individual is considered to be "terminally ill" if the individual has a medical prognosis that the individual's life expectancy is six months or less if the illness runs its normal course. 42 CFR 418.3. However, the fact that a hospice patient lives beyond this six month period, in and of itself, does not constitute grounds for a determination that the patient was never eligible for hospice care, or that the services provided to the patient were not reimbursable by Medicare.

⁵⁵ Medical reviews, audits, inspections, and investigations of hospices have concluded that hospices have billed Medicare for hospice services provided to patients who are not terminally ill, with diagnoses including arthritis, anorexia, debility, and failure to thrive. For instance, see OIG report OEI–04–93–00270—"Medicare Hospice Beneficiaries: Services and Eligibility." Through Operation Restore Trust activities and the increased program integrity actions by the Regional Home Health Intermediaries (RHHIs), it was discovered

factors qualifying the patient as terminally ill are properly documented.⁵⁶ Any determinative assessment of the terminal illness of a Medicare beneficiary should be completed prior to billing Medicare for hospice care. Physicians must certify that the beneficiary was terminally ill at the time when a patient was admitted for hospice services as well as at the beginning of subsequent hospice benefit periods.⁵⁷

The hospice's written policies and procedures should require, at a minimum, that:

- Before a patient is admitted for hospice services, the hospice physician and attending physician thoroughly review and certify the admitting diagnosis and prognosis;
- A patient's medical record contain complete and measurable documentation to support the certification made by the hospice physician or attending physician;⁵⁸
- The patient or lawful representative is informed of the determination of the patient's life limiting condition;
- The patient or lawful representative is aware that the goal of hospice is directed toward relief of symptoms, rather than the cure of the underlying disease;
- A patient's medical condition and status is completely reviewed during Interdisciplinary Group meetings; and
- The clinical progression/status of a patient's disease and medical condition are properly documented.

Hospices can further ensure compliance with the terminal illness requirement through discussions with Medicare beneficiaries and their

that many beneficiaries receiving Medicare hospice benefits did not have a terminal illness. In the review of hospice cases between 1992 and 1996, patients did not demonstrate significant clinical symptoms of their disease nor notable functional limitations one would expect to see in a person who has a terminal illness as defined by Medicare. See OIG report A-05-96-00023—"Enhanced Controls Needed to Assure Validity of Medicare Hospice Enrollments." Findings such as these have prompted a concern that some hospices may intentionally misrepresent a condition as terminal in order to secure Medicare reimbursement. See also note 24.

⁵⁶ See 42 CFR 418.22(d). If a question is raised as to whether a patient is terminally ill, the hospice will be requested to furnish its Medicare fiscal intermediary with the information necessary to establish that the patient is terminally ill.

⁵⁷ See 42 U.S.C. 1395f(a)(7). See also note 29.

⁵⁸ In order to verify a patient's terminal illness, Medicare fiscal intermediaries need to review physician input and rationale beyond a signature on the certification form (e.g., a recent medical history and physical if the physician does not actually examine the patient prior to admission to hospice; summary of physician review of the history and physical taken by hospice personnel; or physician documentation of his or her contribution to the Interdisciplinary Group meetings).

families, reminding them that they must satisfy the regulatory requirements for terminal illness status to be eligible for Medicare coverage. These discussions can take place at the beginning of hospice election and during appropriate times throughout a patient's hospice care, e.g., at time of recertification. Because the Medicare conditions of participation require hospices to give all beneficiaries an informed consent form that outlines their legal rights before furnishing them with hospice care,⁵⁹ providers can include reminders of terminal illness requirements in these forms.

The OIG recognizes that decisions to admit patients to hospices are often not based on medical factors alone. Such decisions are routinely influenced by non-medical factors that would generally be reflected in the plan of care. However, it is important to make a distinction between admitting a patient to a hospice program and certifying a patient for the Medicare Hospice Benefit. Based on an individual hospice's admission criteria, some patients may be admitted to hospice care prior to an estimated six months before death, as long as the hospice is paid fair market value for its services. Regardless, patients can be certified for the Medicare Hospice Benefit *only* when it is reasonable to conclude that a patient's life expectancy is six months or less if the illness runs its normal course. In other cases, alternative modes of reimbursement, often provided through community support, should be sought outside the Medicare Hospice Benefit.

b. Plan of Care

A hospice should take all reasonable steps to ensure that a written plan of care is established and maintained for each individual who receives hospice services, and that the care provided to that individual is in accordance with the plan.⁶⁰ The plan must be established by the patient's attending physician, the hospice physician, and the Interdisciplinary Group.⁶¹ Each patient's needs should be continuously assessed and all treatment options explored and evaluated in the context of the patient's symptoms.⁶² The hospice's written

⁵⁹ See 42 CFR 418.62.

⁶⁰ See 42 U.S.C. 1395f(a)(7); 42 CFR 418.58.

⁶¹ *Id.*

⁶² Some ORT audits found that hospice physicians, at times, rely partly on referring, attending physicians. Although the referring physician's opinion can and should be considered as part of the decision making process, the final determination of hospice eligibility is the responsibility of the hospice physician. For instance, see OIG report A-04-95-02111. If employees of a hospice believe that services

policies and procedures should require, at a minimum, that:

- Before the hospice bills for hospice care provided to a patient, the plan of care must be established by the hospice patient's attending physician,⁶³ the hospice physician, and the Interdisciplinary Group;
- The plan of care includes (i) An assessment of the hospice patient's needs and identification of services, including the management of discomfort and symptom relief, and (ii) the scope and frequency of services, in detail, needed to meet the patient's and family's needs;⁶⁴
- The plan of care must be reviewed and updated, at intervals specified in the plan, by the attending physician, hospice physician, and the Interdisciplinary Group;⁶⁵
- The hospice properly documents any review or update of a hospice patient's plan of care by the attending physician, the hospice physician and Interdisciplinary Group; and⁶⁶
- The hospice regularly reviews the appropriateness of Interdisciplinary Group services and level of services being provided, patient admission to hospice, patient length of stay, delays, and specific treatment modalities.

c. Utilization of Hospice Services

A hospice is accountable for the appropriate allocation and utilization of its resources in order to provide optimal care consistent with patient and family needs.⁶⁷ Accordingly, a hospice should monitor and evaluate its resource allocation regularly to identify and

ordered by a physician are excessive or otherwise inappropriate, the hospice cannot avoid liability for filing improper claims simply because a physician has certified the need for hospice care.

⁶³ For Medicare reimbursement purposes, a plan for furnishing hospice services must be certified by a physician who is a doctor of medicine, osteopathy, or podiatric medicine. See 42 CFR 410.20. The services of the hospice medical director(s) or the physician member of the Hospice Interdisciplinary Group must be performed by a doctor of medicine or osteopathy. See 42 CFR 418.202. The hospice should employ reasonable measures to verify that physicians who certify hospice services are appropriately licensed and no adverse actions, such as criminal conviction, debarment, or an exclusion, have been taken against them.

⁶⁴ 42 CFR 418.58(c).

⁶⁵ See 42 U.S.C. 1395f(a)(7)(B); 42 U.S.C. 1395x(dd)(2)(B).

⁶⁶ 42 CFR 418.58(b).

⁶⁷ Once a Medicare beneficiary elects hospice care, the hospice is responsible for furnishing directly, or arranging for, all supplies and services that relate to the beneficiary's terminal condition, except the services of an attending physician. Hospice beneficiaries have the right to receive covered medical, social, and emotional support services from the hospice directly, or through arrangements made by the hospice, and should not be forced to seek or pay for such care from non-hospice providers.

resolve problems with the utilization of services, facilities, and personnel. To achieve such monitoring, a hospice should schedule Interdisciplinary Group case reviews and conferences,⁶⁸ review specific problems that may arise with services provided, and use objective written criteria or treatment protocols to guide decisions about the utilization of hospice services provided. Utilization concerns may be an indication of a problem with the quality or quantity of services provided to a hospice patient or demonstrate a more fundamental concern as to the patient's eligibility for the Medicare Hospice Benefit in the first place. Therefore, a hospice should implement policies and procedures to identify, assess, and rectify any problems associated with:

- Appropriateness of Interdisciplinary Group services and level of services being provided;
- Appropriateness of patient admission to hospice;
- Regular review of patient length of stay;
- Delays in admission or in the provision of Interdisciplinary Group services; and
- Specific treatment modalities.

When utilization problems are identified, a hospice should implement corrective actions and preventative measures that may include ongoing monitoring, changes in the provision of services, and revisions of policies and procedures.

d. Levels of Hospice Care

A hospice's compliance program should provide that it should only seek reimbursement for services that the hospice has reason to believe are reasonable and necessary⁶⁹ for the palliation or management of terminal illness and were ordered by a physician or other appropriately licensed individual. The OIG recommends the hospice's compliance program communicate to physicians authorized to certify patients for hospice care and hospice personnel authorized to admit patients for hospice care that services will only be paid if ordered, certified, covered, reasonable, and necessary for the patient, given his or her clinical condition.

Although hospice services are reimbursed on a per diem basis and not per individual component of the services performed, the payment is

based upon the level of care provided.⁷⁰ Because HCFA establishes different payment amounts for specific categories of covered hospice care, a hospice must ensure that it provides for services to hospice patients that are reasonable and necessary. Otherwise, the hospice may be reimbursed for a higher level of services than was necessary, e.g., a hospice that provides and bills for continuous care where only routine home care is necessary.

As a preliminary matter, the OIG recognizes that licensed health care professionals must be able to order any services that are appropriate for the care of their patients. However, Medicare and other Government and private health care plans will only pay for those services otherwise covered that meet appropriate standards (i.e., in the case of Medicare, "reasonable and necessary" services). Providers may not bill for services that do not meet the applicable standards.⁷¹ The hospice is in a unique position to deliver this information to the health care professionals on its staff and to the physicians who certify hospice services. Upon request, a hospice must be able to provide documentation, such as physician orders and other patient medical records, to support the level of services provided to a hospice patient.⁷² The compliance officer should ensure that a clear, comprehensive summary of the definitions for the different levels of hospice care⁷³ and applicable rules of the various Government and private plans is prepared, disseminated, and explained to appropriate hospice personnel.

⁷⁰ Payment amounts are determined within each of the following categories: (1) Routine home care day; (2) continuous home care day (patient who receives hospice care that consists predominantly of nursing care on a continuous basis at home, is furnished only during brief periods of crisis and only as necessary to maintain the terminally ill patient at home); (3) inpatient respite care day (hospice patient receives care in an approved facility on a short-term basis for respite—not more than five consecutive days at a time); and (4) general inpatient care day (hospice patient receives general inpatient care in an inpatient facility for pain control or acute or chronic symptom management that cannot be managed in other settings). See 42 CFR 418.302.

⁷¹ Administrative civil monetary penalties, assessments, and exclusion, as well as remedies available under criminal and civil law, including the civil False Claims Act, may be imposed against any person who submits a claim for services "that [the] person knows or should know are not medically necessary." See, e.g., 42 U.S.C. 1320a-7a(a).

⁷² Medicare fiscal intermediaries have the authority to require hospices that furnish items or services under the program to submit documentation that substantiates services were actually provided and medically necessary. See *Medicare Intermediary Manual* § 3116.1.B.

⁷³ See note 70.

We recommend that hospices formulate policies and procedures that include periodic clinical reviews, both prior and subsequent to billing for services, as a means of verifying that patients are receiving only reasonable and necessary services. As part of such reviews, hospices should examine the level, frequency, and duration of the services they perform to determine, in consultation with a physician, whether patients' medical conditions justify the level of services provided and billed. A hospice may choose to incorporate this clinical review function into pre-existing quality assurance mechanisms or any other quality assurance processes that are part of its conditions of participation.⁷⁴

e. Services Provided to Hospice Patients in Nursing Homes

Hospice services may be appropriate and beneficial to terminally ill nursing home residents who wish to receive palliative care.⁷⁵ However, the OIG has found hospices that enroll nursing home patients in hospice care are particularly vulnerable to fraud and abuse.⁷⁶ Appropriately, a hospice should set sufficient oversight controls in place to ensure that care it provides to nursing home residents is appropriate, complete, and in accordance with applicable laws and Federal health care program requirements.

When a resident of a nursing home elects the Medicare Hospice Benefit, the hospice and the nursing home should jointly establish a coordinated plan of care that reflects the hospice philosophy, and is based on an assessment of the individual's needs and unique living situation in the nursing home. The coordinated plan should identify the care and services that the nursing home will provide to be responsive to the unique needs of the patient/resident and his or her expressed desire for hospice care.

In general, a hospice should involve nursing home personnel in assisting with the administration of a patient's prescribed therapies included in the plan of care only to the extent that the

⁷⁴ See 42 CFR 418.66.

⁷⁵ See note 34.

⁷⁶ In some cases reviewed in nursing homes, records have shown that patients did have a terminal condition, but were stable with little sign of deterioration or decline. OIG medical reviewers have found that while the hospice benefit may eventually have been appropriate, at the time of election, patients were stable and the election of hospice was premature. See OEI report OEI-05-95-00250: "Hospice Patients in Nursing Homes;" see also OIG report A-05-96-00023—"Enhanced Controls Needed to Assure Validity of Medicare Hospice Enrollments." For other examples of potential fraud and abuse in the hospice/nursing home context, see notes 31-34.

⁶⁸ Interdisciplinary Group conferences are regularly scheduled periodic meetings of the Interdisciplinary Group to review the most current patient/family assessment, evaluate needs, and update the plan of care.

⁶⁹ See note 35.

hospice would routinely utilize the services of a hospice patient's family/caregiver in implementing the plan of care.⁷⁷ To satisfy the applicable Medicare conditions of participation in the nursing home context, hospices should implement policies and procedures to ensure that:

- The hospice makes all covered services available to meet the needs of a patient and does not routinely discharge patients in need of costly inpatient care;⁷⁸
- The hospice retains professional responsibility for services (e.g., personal care, nursing, medication for relieving pain control) furnished by nursing home staff;⁷⁹
- All the care furnished by a nursing home is in accordance with the plan of care;⁸⁰
- The hospice and the nursing home must communicate with each other when any changes are indicated to the plan of care, and each provider must be aware of the other's responsibilities in implementing the plan of care and complete those respective functions;⁸¹
- Evidence of the coordinated plan of care must be present in the clinical records of both providers;⁸²
- Substantially all the core services are routinely provided directly by hospice employees⁸³ and the hospice does not rely on employees of the inpatient facility to furnish needed nursing, physician, counseling, or medical social services;⁸⁴ and
- The hospice keeps its forms and documentation of services separate from the nursing home's forms and documentation.⁸⁵

4. Anti-Kickback and Self-Referral Concerns

The hospice should have policies and procedures in place with respect to compliance with Federal and State anti-kickback statutes.⁸⁶ Such policies should provide that:

- All of the hospices's contracts and arrangements with actual or potential referral sources are reviewed by counsel and comply with all applicable statutes and regulations;⁸⁷

- The hospice does not submit or cause to be submitted to the Federal health care programs claims for patients who were referred to the hospice pursuant to contracts or financial arrangements that were designed to induce such referrals in violation of the anti-kickback statute or similar Federal or State statute or regulation; and

- The hospice does not offer or provide gifts, free services, or other incentives to patients, relatives of patients, physicians, nursing facilities, hospitals, contractors, or other potential referral sources for the purpose of inducing referrals in violation of the anti-kickback statute or similar Federal or State statute or regulation.⁸⁸

In particular, arrangements between nursing homes and hospices are vulnerable to fraud and abuse because nursing home operators have control over the specific hospice or hospices they will permit to provide hospice services to their residents.⁸⁹ Moreover, hospice patients residing in nursing homes may be particularly desirable from a hospice's financial standpoint.⁹⁰ Therefore, with respect to arrangements with nursing homes, a hospice should develop policies and procedures to prevent the following practices from occurring, which may constitute potential kickbacks:

- Hospice offering free or below fair market value goods to induce a nursing home to refer patients to the hospice;
- Hospice paying "room and board" payments to the nursing home in amounts in excess of what the nursing

home would have received directly from Medicaid had the patient not been enrolled in hospice;⁹¹

- Hospice referring its patients to a nursing home to induce the nursing home to refer its patients to the hospice;
- Hospice providing free (or below fair market value) care to nursing home patients, for whom the nursing home is receiving Medicare payment under the Medicare Skilled Nursing Facility Benefit, with the expectation that after the patient exhausts the skilled nursing facility benefit, the patient will receive hospice services from that hospice; and
- Hospice providing staff at its expense to the nursing home to perform duties that otherwise would be performed by the nursing home.

Further, the policies and procedures should specifically reference and take into account the OIG's safe harbor regulations, which clarify those payment practices that would be immune from prosecution under the anti-kickback statute, as well as the OIG's civil monetary penalty and exclusion authorities.⁹²

5. Retention of Records

Hospice compliance programs should provide for the implementation of a records system. This system should establish policies and procedures regarding the creation, distribution, retention, storage, retrieval, and destruction of documents.⁹³ The two categories of documents developed under this system should include: (1) All records and documentation (e.g., medical records, and billing and claims documentation) required either by Federal or State law for participation in Federal health care programs⁹⁴ or any other applicable Federal and State laws and regulations (e.g., document retention requirements to maintain State licensure); and (2) all records necessary to protect the integrity of the hospice's compliance process and confirm the effectiveness of the program. The second category includes: (a) Documentation that employees were adequately trained; (b) reports from the hospice's hotline, including the nature and results of any investigation that was conducted; (c) documentation of

⁸⁷ Although hospices may contract with physicians, see note 41, hospices and physicians must still tailor such agreements to avoid violation of the anti-kickback statute or similar Federal or State statute or regulation and to comply with applicable Medicare conditions of participation. See 42 CFR 418.56 and 418.86.

⁸⁸ See 42 U.S.C. 1320a-7b(b); 60 FR 40847 (1995).

⁸⁹ While an exclusive or semi-exclusive arrangement with a nursing home to provide hospice services to residents can promote efficiency and safety by permitting the nursing home operator to coordinate care, screen hospice caregivers, and maintain control of the premises, such an arrangement may have substantial monetary value to a hospice. In these circumstances, some nursing home operators and/or hospices may request or offer illegal remuneration to influence a nursing home's decision to do business with a particular hospice.

⁹⁰ First, a nursing home's population represents a sizable pool of potential hospice patients. Second, nursing home hospice patients may generate higher gross revenues per patient than patients residing in their own homes, because nursing home residents receiving hospice care have, on average, longer lengths of stay than hospice patients residing in their own homes.

⁹¹ See note 31.

⁹² See 42 CFR 1001.952.

⁹³ This records system should be tailored to fit the individual needs and financial resources of the hospice.

⁹⁴ For example, Medicare requires that hospices must establish and maintain a clinical record for every individual receiving care and services. The record must be complete, promptly and accurately documented, readily accessible and systematically organized to facilitate retrieval. Any entries are to be made and signed by the person providing the services. See 42 CFR 418.74.

⁷⁷ *Hospice Certification Manual* § 2082.B.

⁷⁸ See 42 CFR 418.50.

⁷⁹ See 42 CFR 418.56.

⁸⁰ See 42 CFR 418.58.

⁸¹ *Hospice Certification Manual* § 2082.A.

⁸² *Hospice Certification Manual* § 2082.A.

⁸³ See 42 CFR 418.80.

⁸⁴ In limited circumstances, HCFA may approve a waiver of the requirement for core nursing services to be provided by a hospice that is located in a non-urbanized area. See 42 CFR 418.83.

⁸⁵ A hospice may consider creating some type of payroll tracking or time study in an effort to properly differentiate services between the hospice and the nursing home.

⁸⁶ The hospice's in-house counsel or compliance officer should, among other things, obtain copies of all relevant OIG regulations, Special Fraud Alerts, and advisory opinions (these documents are located on the Internet at <http://www.os.dhhs.gov/oig>), and ensure that the hospice's policies reflect the guidance provided by the OIG.

corrective action, including disciplinary action taken and policy improvements introduced, in response to any internal investigation or audit; (d) modifications to the compliance program; (e) self-disclosures; and (f) the results of the hospice's auditing and monitoring efforts.⁹⁵

6. Compliance as an Element of a Performance Plan

Compliance programs should require that the promotion of, and adherence to, the elements of the compliance program be a factor in evaluating the performance of all employees, who should be periodically trained in new compliance policies and procedures. In addition, all managers and supervisors should:

- Discuss with all supervised employees and relevant contractors the compliance policies and legal requirements pertinent to their function;
- Inform all supervised personnel that strict compliance with these policies and requirements is a condition of employment; and
- Disclose to all supervised personnel that the hospice will take disciplinary action up to and including termination for violation of these policies or requirements.

In addition to making performance of these duties an element in evaluations, a compliance program should include a policy for sanctioning managers and supervisors who fail to adequately instruct their subordinates or fail to detect noncompliance with applicable policies and legal requirements, where reasonable diligence on the part of the manager or supervisor would have led to the discovery of any problems or violations and given the hospice the opportunity to correct them earlier.

The OIG believes all hospices should ensure that its employees understand the importance of compliance. If a small hospice does not have a formal performance evaluation structure, it should informally convey the employee's compliance responsibilities and the importance of these responsibilities in a written job description or orientation checklist. The applicable documentation should include a dated signature, with an indication that the employee has received it and will be responsible for adherence to the responsibilities expressed.

⁹⁵The creation and retention of such documents and reports may raise a variety of legal issues, such as patient privacy and confidentiality. These issues are best discussed with legal counsel.

B. Designation of a Compliance Officer and a Compliance Committee

1. Compliance Officer

Every hospice should designate a compliance officer to serve as the focal point for compliance activities. This responsibility may be the individual's sole duty or added to other management responsibilities, depending upon the size and resources of the hospice and the complexity of the task. Designating a compliance officer with the appropriate authority is critical to the success of the program, necessitating the appointment of a high-level official in the hospice with direct access to the hospice's president or CEO, governing body, all other senior management, and legal counsel.⁹⁶ The officer should have sufficient funding and staff to perform his or her responsibilities fully. Coordination and communication are the key functions of the compliance officer with regard to planning, implementing, and monitoring the compliance program.

The compliance officer's primary responsibilities should include:

- Overseeing and monitoring the implementation of the compliance program;⁹⁷
- Reporting on a regular basis to the hospice's governing body, CEO, and compliance committee (if applicable) on the progress of implementation, and assisting these components in establishing methods to improve the hospice's efficiency and quality of services, and to reduce the hospice's vulnerability to fraud, abuse, and waste;
- Periodically revising the program in light of changes in the organization's needs, and in the law and policies and procedures of Government and private payor health plans;
- Reviewing employees' certifications that they have received, read, and understood the standards of conduct;
- Developing, coordinating, and participating in a multifaceted

⁹⁶The OIG believes that it is not advisable for the compliance function to be subordinate to the hospice's general counsel, or comptroller or similar hospice financial officer. Free standing compliance functions help to ensure independent and objective legal reviews and financial analyses of the institution's compliance efforts and activities. By separating the compliance function from the key management positions of general counsel or chief financial officer (where the size and structure of the hospice make this a feasible option), a system of checks and balances is established to more effectively achieve the goals of the compliance program.

⁹⁷For multi-hospice organizations or hospital-owned hospices, the OIG encourages coordination with each hospice owned by the corporation or hospital through the use of a headquarter's compliance officer, communicating with parallel positions in each facility, regional office, or business line, as appropriate.

educational and training program that focuses on the elements of the compliance program, and seeks to ensure that all relevant employees and management are knowledgeable of, and comply with, pertinent Federal and State standards;

- Ensuring that independent contractors and agents who furnish physician, nursing, or other health care services to the clients of the hospice, or billing services to the hospice, are aware of the requirements of the hospice's compliance program with respect to eligibility, billing, and marketing, among other things;

- Coordinating personnel issues with the hospice's Human Resources/Personnel office (or its equivalent) to ensure that (i) the National Practitioner Data Bank⁹⁸ has been checked with respect to all medical staff and independent contractors (as appropriate) and (ii) the List of Excluded Individuals/Entities⁹⁹ has been checked with respect to all employees, medical staff, and independent contractors (as appropriate);¹⁰⁰

- Assisting the hospice's financial management in coordinating internal compliance review and monitoring activities, including annual or periodic reviews of departments;

- Independently investigating and acting on matters related to compliance, including the flexibility to design and coordinate internal investigations (e.g., responding to reports of problems or suspected violations) and any resulting corrective action (e.g., making necessary improvements to hospice policies and practices, taking appropriate disciplinary action, etc.) with all hospice departments, subcontracted providers, and health care professionals

⁹⁸The National Practitioner Data Bank is a data base that contains information about medical malpractice payments, sanctions by boards of medical examiners or State licensing boards, adverse clinical privilege actions, and adverse professional society membership actions. Health care entities can have access to this data base to seek information about their own medical or clinical staff, as well as prospective employees or physician contractors.

⁹⁹The List of Excluded Individuals/Entities is an OIG-produced report available on the Internet at <http://www.os.dhhs.gov/oig>. It is updated on a regular basis to reflect the status of health care providers who have been excluded from participation in the Medicare and Medicaid programs. In addition, the General Services Administration maintains a monthly listing of debarred contractors on the Internet at <http://www.arnet.gov/eplis>.

¹⁰⁰The compliance officer may also have to ensure that the criminal backgrounds of employees have been checked depending upon State requirements or hospice policy. See note 132.

under the hospice's control,¹⁰¹ and any other agents if appropriate; and

- Continuing the momentum of the compliance program and the accomplishment of its objectives long after the initial years of implementation.¹⁰²

The compliance officer must have the authority to review all documents and other information that are relevant to compliance activities, including, but not limited to, patient medical records, billing records, and records concerning the marketing efforts of the facility and the hospice's arrangements with other parties, including employees, physicians, professionals on staff, relevant independent contractors, suppliers, agents, and supplemental staffing entities. This policy enables the compliance officer to review contracts and obligations (seeking the advice of legal counsel, where appropriate) that may contain referral and payment provisions that could violate the anti-kickback statute and other legal or regulatory requirements.

A small hospice may not have the need or the resources to hire or appoint a full time compliance officer. However, each hospice should have a person in its organization (this person may have other functional responsibilities) who can oversee the hospice's compliance with applicable statutes, rules, regulations, and policies. The structure and comprehensiveness of the hospice's compliance program will help determine the responsibilities of each individual compliance officer.

2. Compliance Committee

The OIG recommends that a compliance committee be established to advise the compliance officer and assist in the implementation of the compliance program.¹⁰³ When

¹⁰¹ *E.g.*, attending physicians, pharmacies, durable medical equipment suppliers, hospitals, nursing homes, home health agencies, and supplemental staffing entities.

¹⁰² Periodic on-site visits of hospice operations, bulletins with compliance updates and reminders, distribution of audiotapes or videotapes on different risk areas, lectures at management and employee meetings, circulation of recent health care articles covering fraud and abuse, and innovative changes to compliance training are various examples of approaches and techniques the compliance officer can employ for the purpose of ensuring continued interest in the compliance program and the hospice's commitment to its policies and principles.

¹⁰³ The compliance committee benefits from having the perspectives of individuals with varying responsibilities in the organization, such as operations, finance, audit, human resources, and clinical management (*e.g.*, hospice physician), as well as employees and managers of key operating units. These individuals should have the requisite seniority and comprehensive experience within their respective departments to implement any

developing an appropriate team of people to serve as the hospice's compliance committee, including the compliance officer, a hospice should consider a variety of skills and personality traits that are expected from those in such positions.¹⁰⁴ Once a hospice chooses the people that will accept the responsibilities vested in members of the compliance committee, the hospice needs to train these individuals on the policies and procedures of the compliance program, as well as how to discharge their duties.

The committee's functions should include:

- Analyzing the legal requirements with which it must comply, and specific risk areas;
- Assessing existing policies and procedures that address these risk areas for possible incorporation into the compliance program;
- Working with appropriate hospice departments to develop standards of conduct and policies and procedures to promote compliance with legal and ethical requirements;
- Recommending and monitoring, in conjunction with the relevant departments, the development of internal systems and controls to carry out the organization's standards, policies, and procedures as part of its daily operations;
- Determining the appropriate strategy/approach to promote compliance with the program and detection of any potential violations, such as through hotlines and other fraud reporting mechanisms;
- Developing a system to solicit, evaluate, and respond to complaints and problems; and
- Monitoring internal and external audits and investigations for the purpose of identifying troublesome issues and deficient areas experienced by the hospice, and implementing corrective and preventive action.

The committee may also address other functions as the compliance concept becomes part of the overall hospice operating structure and daily routine.

C. Conducting Effective Training and Education

The proper education and training of corporate officers, managers, employees,

necessary changes to hospice policies and procedures as recommended by the committee.

¹⁰⁴ A health care provider should expect its compliance committee members and compliance officer to demonstrate high integrity, good judgment, assertiveness, and an approachable demeanor, while eliciting the respect and trust of employees of the hospice and having significant professional experience working with billing, clinical records, documentation, and auditing principles.

volunteers, nurses, physicians, and other health care professionals, and the continual retraining of current personnel at all levels, are significant elements of an effective compliance program. As part of their compliance programs, hospices should require personnel to attend specific training on a periodic basis, including appropriate training in Federal and State statutes, regulations, and guidelines, and the policies of private payors, and training in corporate ethics, which emphasizes the organization's commitment to compliance with these legal requirements and policies.¹⁰⁵

These training programs should include sessions highlighting the organization's compliance program, summarizing fraud and abuse laws, Federal health care program requirements, claim development and submission processes, patient rights, and marketing practices that reflect current legal and program standards. The organization must take steps to communicate effectively its standards and procedures to all affected employees, physicians, independent contractors, and other significant agents, *e.g.*, by requiring participation in training programs and disseminating publications that explain specific requirements in a practical manner.¹⁰⁶ Managers of specific departments or groups can assist in identifying areas that require training and in carrying out such training.¹⁰⁷ Training instructors may come from outside or inside the organization, but must be qualified to present the subject matter involved and experienced enough in the issues presented to adequately field questions and coordinate discussions among those being trained. New employees should be trained early in their employment.¹⁰⁸ Training programs and materials should be designed to take into account the skills, experience, and knowledge of the individual trainees. The compliance

¹⁰⁵ Specific compliance training should complement any "inservice" training sessions that a hospice may regularly schedule to provide an ongoing program for the training of employees as required by its conditions of participation. 42 CFR 418.64.

¹⁰⁶ Some publications, such as OIG's Special Fraud Alerts, audit and inspection reports, and advisory opinions, as well as the annual OIG work plan, are readily available from the OIG and could be the basis for standards, educational courses, and programs for appropriate hospice employees.

¹⁰⁷ Significant variations in the functions and responsibilities of different departments or groups may create the need for training materials that are tailored to compliance concerns associated with particular operations and duties.

¹⁰⁸ Certain positions, such as those that involve the billing of hospice services or patient admission to hospice care, create a greater organizational legal exposure, and therefore require specialized training.

officer should document any formal training undertaken by the hospice as part of the compliance program.

A variety of teaching methods, such as interactive training, and training in several different languages, particularly where a hospice has a culturally diverse staff, should be implemented so that all affected employees are knowledgeable of the institution's standards of conduct and procedures for alerting senior management to problems and concerns.¹⁰⁹ In addition to specific training in the risk areas identified in section II.A.2, above, primary training for appropriate corporate officers, managers, and other hospice staff should include such topics as:

- Government and private payor reimbursement principles;
- General prohibitions on paying or receiving remuneration to induce referrals;
- Improper alterations to clinical records;¹¹⁰
- Providing hospice services with proper authorization;
- Patient rights and patient education;
- Compliance with Medicare conditions of participation; and
- Duty to report misconduct.

Clarifying and emphasizing these areas of concern through training and educational programs are particularly relevant to a hospice's marketing and financial personnel, in that the pressure to meet business goals may render these employees vulnerable to engaging in prohibited practices.

The OIG suggests that all relevant levels of personnel be made part of various educational and training programs of the hospice.¹¹¹ Employees should be required to have a minimum number of educational hours per year, as appropriate, as part of their employment responsibilities.¹¹² For

¹⁰⁹ Post-training tests can be used to assess the success of training provided and employee comprehension of the hospice's policies and procedures.

¹¹⁰ This practice involves the hospice altering the attending physician's or other authorized physician's diagnosis in order to receive reimbursement for hospice care. A hospice should not claim the patient has a particular medical condition in order to qualify for reimbursement for which it would not otherwise qualify.

¹¹¹ In addition, where feasible, the OIG recommends that a hospice afford outside contractors the opportunity to participate in the hospice's compliance training and educational programs, or develop their own programs that complement the hospice's standards of conduct, compliance requirements, and other rules and practices.

¹¹² Currently, the OIG is monitoring a significant number of corporate integrity agreements that require many of these training elements. The OIG usually requires a minimum of one to three hours annually for basic training in compliance areas.

example, for certain employees involved in the hospice admission functions, periodic training in applicable reimbursement coverage and eligibility requirements should be required. In hospices with high employee turnover, periodic training updates are critical.

The OIG recognizes that the format of the training program will vary depending upon the resources of the hospice. For example, a small hospice may want to create a video for each type of training session so new employees can receive training in a timely manner.¹¹³

The OIG recommends that attendance and participation in training programs be made a condition of continued employment and that failure to comply with training requirements should result in disciplinary action, including possible termination, when such failure is serious. Adherence to the provisions of the compliance program, such as training requirements, should be a factor in the annual evaluation of each employee. The hospice should retain adequate records of its training of employees, including attendance logs and material distributed at training sessions.

D. Developing Effective Lines of Communication

1. Access to the Compliance Officer

An open line of communication between the compliance officer and hospice employees is equally important to the successful implementation of a compliance program and the reduction of any potential for fraud, abuse, and waste. Written confidentiality and non-retaliation policies should be developed and distributed to all employees to encourage communication and the reporting of incidents of potential fraud.¹¹⁴ The compliance committee should also develop independent reporting paths for an employee to report fraud, waste, or abuse so that employees can feel comfortable reporting outside the normal chain of

Additional training is required for specialty fields such as billing and marketing.

¹¹³ If videos are utilized for compliance training, the OIG suggests that a hospice make an individual available to field questions from video trainees. In addition, those hospices that use video training should strongly consider requiring trainees to complete post training comprehension tests to ensure that trainees actively paid attention to the video.

¹¹⁴ The OIG believes that whistleblowers should be protected against retaliation, a concept embodied in the provisions of the False Claims Act. See 31 U.S.C. 3730(h). In many cases, employees sue their employers under the False Claims Act's *qui tam* provisions out of frustration because of the company's failure to take action when a questionable, fraudulent, or abusive situation was brought to the attention of senior corporate officials.

command and supervisors or other personnel cannot divert such reports.¹¹⁵

The OIG encourages the establishment of a procedure so that hospice personnel may seek clarification from the compliance officer or members of the compliance committee in the event of any confusion or question with regard to a hospice policy, practice, or procedure. Questions and responses should be documented and dated and, if appropriate, shared with other staff so that standards, policies, practices, and procedures can be updated and improved to reflect any necessary changes or clarifications. The compliance officer may want to solicit employee input in developing these communication and reporting systems.

2. Hotlines and Other Forms of Communication

The OIG encourages the use of hotlines,¹¹⁶ e-mails, written memoranda, newsletters, suggestion boxes, and other forms of information exchange to maintain these open lines of communication.¹¹⁷ If the hospice establishes a hotline, the telephone number should be made readily available to all employees and independent contractors, possibly by circulating the number on wallet cards or conspicuously posting the telephone number in common work areas.¹¹⁸ Employees should be permitted to report matters on an anonymous basis. Matters reported through the hotline or other communication sources that suggest substantial violations of compliance policies, Federal health care program requirements, regulations, or statutes should be documented and investigated promptly to determine their veracity. A log should be maintained by the compliance officer that records such calls, including the nature of any investigation and its results.¹¹⁹ Such

¹¹⁵ Hospices can also consider rewarding employees for appropriate use of established reporting systems.

¹¹⁶ The OIG recognizes that it may not be financially feasible for a smaller hospice to maintain a telephone hotline dedicated to receiving calls about compliance issues. These companies may want to explore alternative methods, e.g., outsourcing the hotline or establishing a written method of confidential disclosure.

¹¹⁷ In addition to methods of communication used by current employees, an effective employee exit interview program could be designed to solicit information from departing employees regarding potential misconduct and suspected violations of hospice policy and procedures.

¹¹⁸ Hospices should also post in a prominent, available area the HHS-OIG Hotline telephone number, 1-800-447-8477 (1-800-HHS-TIPS), in addition to any company hotline number that may be posted.

¹¹⁹ To efficiently and accurately fulfill such an obligation, the hospice should create an intake form for all compliance issues identified through

information should be included in reports to the governing body, the CEO, and compliance committee.¹²⁰ Further, while the hospice should always strive to maintain the confidentiality of an employee's identity, it should also explicitly communicate that there may be a point where the individual's identity may become known or may have to be revealed in certain instances.

The OIG recognizes that assertions of fraud and abuse by employees who may have participated in illegal conduct or committed other malfeasance raise numerous complex legal and management issues that should be examined on a case-by-case basis. The compliance officer should work closely with legal counsel, who can provide guidance regarding such issues.

The OIG recognizes that protecting anonymity may be infeasible for small hospices. However, the OIG believes all hospice employees, when seeking answers to questions or reporting potential instances of fraud and abuse, should know to whom to turn to for attention and should be able to do so without fear of retribution.

E. Auditing and Monitoring

An ongoing evaluation process is critical to a successful compliance program. The OIG believes that an effective program should incorporate thorough monitoring of its implementation and regular reporting to senior hospice or corporate officers.¹²¹ Compliance reports created by this ongoing monitoring, including reports of suspected noncompliance, should be maintained by the compliance officer and shared with the hospice's senior management and the compliance committee. The extent and frequency of the audit function may vary depending on factors such as the size and available resources, prior history of noncompliance, and the risk factors that a particular hospice confronts.

Although many monitoring techniques are available, one effective

reporting mechanisms. The form could include information concerning the date that the potential problem was reported, the internal investigative methods utilized, the results of the investigation, the corrective action implemented, the disciplinary measures imposed, and any identified overpayments and monies returned.

¹²⁰ Information obtained over the hotline may provide valuable insight into management practices and operations, whether reported problems are actual or perceived.

¹²¹ Even when a hospice or group of hospices is owned by a larger corporate entity, the regular auditing and monitoring of the compliance activities of an individual hospice must be a key feature in any annual review. Appropriate reports on audit findings should be periodically provided and explained to a parent organization's senior staff and officers.

tool to promote and ensure compliance is the performance of regular, periodic compliance audits by internal or external auditors who have expertise in Federal and State health care statutes, regulations, and Federal health care program requirements. The audits should focus on the hospice's programs or divisions, including external relationships with third-party contractors, specifically those with substantive exposure to Government enforcement actions. At a minimum, these audits should be designed to address the hospice's compliance with laws governing kickback arrangements, claim development and submission, reimbursement, eligibility, and marketing. The audits and reviews should inquire into the hospice's compliance with the Medicare conditions of participation and the specific rules and policies that have been the focus of particular attention on the part of the Medicare fiscal intermediaries or carriers, and law enforcement, as evidenced by educational and other communications from OIG Special Fraud Alerts, OIG audits and evaluations, and law enforcement's initiatives.¹²² In addition, the hospice should focus on any areas of concern that are specific to the individual hospice and have been identified by any entity, whether Federal, State, or internal.

Monitoring techniques may include sampling protocols that permit the compliance officer to identify and review variations from an established baseline.¹²³ Significant variations from the baseline should trigger a reasonable inquiry to determine the cause of the deviation. If the inquiry determines that the deviation occurred for legitimate, explainable reasons, the compliance officer and hospice management may want to limit any corrective action or take no action. If it is determined that the deviation was caused by improper procedures, misunderstanding of rules, including fraud and systemic problems, the hospice should take prompt steps to correct the problem. Any overpayments discovered as a result of such deviations should be returned promptly to the

¹²² See also section II.A.2.

¹²³ The OIG recommends that when a compliance program is established in a hospice, the compliance officer, with the assistance of department managers, should take a "snapshot" of their operations from a compliance perspective. This assessment can be undertaken by outside consultants, law or accounting firms, or internal staff, with authoritative knowledge of health care compliance requirements. This "snapshot," often used as part of benchmarking analyses, becomes a baseline for the compliance officer and other managers to judge the hospice's progress in reducing or eliminating potential areas of vulnerability.

affected payor, with appropriate documentation and a sufficiently detailed explanation of the reason for the refund.¹²⁴

An effective compliance program should also incorporate periodic (at least annual) reviews of whether the program's compliance elements have been satisfied, e.g., whether there has been appropriate dissemination of the program's standards, training, ongoing educational programs, and disciplinary actions, among other elements.¹²⁵ This process will verify actual conformance by all departments with the compliance program and may identify the necessity for improvements to be made to the compliance program, as well as the hospice's operations. Such reviews could support a determination that appropriate records have been created and maintained to document the implementation of an effective program.¹²⁶ However, when monitoring discloses that deviations were not detected in a timely manner due to program deficiencies, proper modifications must be implemented. Such evaluations, when developed with the support of management, can help ensure compliance with the hospice's policies and procedures.

As part of the review process, the compliance officer or reviewers should consider techniques such as:

- Visits and interviews of patients at their residences;
- Analysis of utilization patterns;
- Testing clinical and hospice admission staff on their knowledge of reimbursement coverage criteria (e.g., present hypothetical scenarios of situations experienced in daily practice and assess responses);
- Assessment of existing relationships with physicians, nursing homes,¹²⁷ hospitals, and other potential referral sources;
- Unannounced mock audits and investigations;
- Reevaluation of deficiencies cited in past surveys for Medicare conditions of participation;
- Examination of hospice complaint logs;

¹²⁴ In addition, when appropriate, as referenced in section G.2, below, reports of fraud or systemic problems should also be made to the appropriate governmental authority.

¹²⁵ One way to assess the knowledge, awareness, and perceptions of the hospice's employees is through the use of a validated survey instrument (e.g., employees questionnaires, interviews, of focus groups).

¹²⁶ Such records should include, but not be limited to, logs of hotline calls, logs of training attendees, training agenda materials, and summaries of corrective action taken and improvements made to hospice policies as a result of compliance activities.

¹²⁷ See section II.A.3.e.

- Checking personnel records to determine whether any individuals who have been reprimanded for compliance issues in the past are among those currently engaged in improper conduct;

- Questionnaires developed to solicit impressions of a broad cross-section of the hospice's employees and staff;

- Evaluation of the timeliness of physician referrals and physician signatures for hospice certifications;

- Reviews of clinical documentation (e.g., terminal illness certification, plan of care, nursing notes, etc.), financial records, and other source documents that support claims for reimbursement;

- Validation of qualifications of hospice physicians and other hospice staff, including verification of applicable state license renewals;

- Evaluation of written materials and documentation outlining the hospice's policies and procedures; and

- Trend analyses, or longitudinal studies, that uncover deviations, positive or negative, in specific areas over a given period.

The reviewers should:

- Have the qualifications and experience necessary to adequately identify potential issues with the subject matter that is reviewed;

- Be objective and independent of line management to the extent reasonably possible;¹²⁸

- Have access to existing audit and health care resources, relevant personnel, and all relevant areas of operation;

- Present written evaluative reports on compliance activities to the CEO, governing body, and members of the compliance committee on a regular basis, but no less often than annually; and

- Specifically identify areas where corrective actions are needed.

Just as a hospice is required by its conditions of participation to conduct "an ongoing, comprehensive, integrated, self-assessment of the quality and appropriateness of care provided,"¹²⁹ the OIG believes that a hospice should monitor its compliance with the Federal health care program requirements in the same fashion. Furthermore, just as a hospice is required by its conditions of participation to use its quality assurance findings to correct identified problems and revise hospice policies if necessary to improve patient care,¹³⁰ the OIG believes that a hospice's management should take whatever steps are

necessary to correct identified compliance problems and prevent them from recurring. In certain cases, subsequent reviews or studies would be advisable to ensure that the recommended corrective actions have been implemented successfully.

While conducting its monitoring and auditing efforts, as well as its daily operations, a hospice should document its efforts to comply with applicable statutes, regulations, and Federal health care program requirements. For example, where a hospice, in its efforts to comply with a particular statute, regulation or program requirement, requests advice from a Government agency (including a Medicare fiscal intermediary or carrier) charged with administering a Federal health care program, the hospice should document and retain a record of the request and any written or oral response. This step is extremely important if the hospice intends to rely on that response to guide it in future decisions, actions, or claim reimbursement requests or appeals. A log of oral inquiries between the hospice and third parties will help the organization document its attempts at compliance. In addition, the hospice agency should maintain records relevant to the issue of whether its reliance was "reasonable" and whether it exercised due diligence in developing procedures and practices to implement the advice.

The extent of a hospice's audit should depend on the hospice's identified risk areas and resources. If the hospice comes under Government scrutiny in the future, the Government will assess whether or not the hospice developed a comprehensive audit based upon identified risk areas and resources. If the Government determines the hospice failed to develop an adequate audit program, given its resources, the Government will be less likely to afford the hospice favorable treatment under the Federal Sentencing Guidelines.

F. Enforcing Standards Through Well-Publicized Disciplinary Guidelines

1. Discipline Policy and Actions

An effective compliance program should include guidance regarding disciplinary action for corporate officers, managers, employees, and other health care professionals who have failed to comply with the hospice's standards of conduct, policies and procedures, Federal health care program requirements, or Federal and State laws, or those who have otherwise engaged in wrongdoing, which have the potential to impair the hospice's status as a reliable, honest, and trustworthy health care provider.

The OIG believes that the compliance program should include a written policy statement setting forth the degrees of disciplinary actions that may be imposed upon corporate officers, managers, employees, physicians, and other health care professionals for failing to comply with the hospice's standards and policies and applicable statutes and regulations. Intentional or reckless noncompliance should subject transgressors to significant sanctions. Such sanctions could range from oral warnings to suspension, termination, or financial penalties, as appropriate. Each situation must be considered on a case-by-case basis to determine the appropriate sanction. The written standards of conduct should elaborate on the procedures for handling disciplinary problems and those who will be responsible for taking appropriate action. Some disciplinary actions can be handled by department or agency managers, while others may have to be resolved by a senior hospice administrator. Disciplinary action may be appropriate where a responsible employee's failure to detect a violation is attributable to his or her negligence or reckless conduct. Personnel should be advised by the hospice that disciplinary action will be taken on a fair and equitable basis. Managers and supervisors should be made aware that they have a responsibility to discipline employees in an appropriate and consistent manner.

It is vital to publish and disseminate the range of disciplinary standards for improper conduct and to educate officers and other hospice employees regarding these standards. The consequences of noncompliance should be consistently applied and enforced, in order for the disciplinary policy to have the required deterrent effect. All levels of employees should be potentially subject to the same types of disciplinary action for the commission of similar offenses. The commitment to compliance applies to all personnel levels within a hospice. The OIG believes that corporate officers, managers, supervisors, clinical staff, and other health care professionals should be held accountable for failing to comply with, or for the foreseeable failure of their subordinates to adhere to, the applicable standards, laws, and procedures.

2. New Employee Policy

For all new employees who have discretionary authority to make decisions that may involve compliance with the law or compliance oversight, hospices should conduct a reasonable and prudent background investigation,

¹²⁸The OIG recognizes the hospices that are small in size and have limited resources may not be able to use internal reviewers who are not part of line management or hire outside reviewers.

¹²⁹42 CFR 418.66.

¹³⁰*Id.*

including a reference check,¹³¹ as part of every such employment application. The application should specifically require the applicant to disclose any criminal conviction,¹³² as defined by 42 U.S.C. 1320a-7(i), or exclusion action. Pursuant to the compliance program, hospice policies should prohibit the employment of individuals who have been recently convicted of a criminal offense related to health care¹³³ or who are listed as debarred, excluded, or otherwise ineligible for participation in Federal health care programs.¹³⁴ In addition, pending the resolution of any criminal charges or proposed debarment or exclusion, the OIG recommends that an individual who is the subject of such actions should be removed from direct responsibility for or involvement in any Federal health care program. That individual's salary should not be paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds.¹³⁵ With regard to current employees or independent contractors, if resolution of the matter results in conviction, debarment, or exclusion, the hospice should terminate its employment or other contract arrangement with the individual or contractor.

G. Responding to Detected Offenses and Developing Corrective Action Initiatives

1. Violations and Investigations

Violations of a hospice's compliance program, failures to comply with applicable Federal or State law, and other types of misconduct threaten a hospice's status as a reliable, honest and trustworthy provider capable of participating in Federal health care

¹³¹ See note 99.

¹³² States may mandate, and many hospices voluntarily conduct, criminal background checks for prospective employees of hospices. Identification of a criminal background of an applicant, who may have been recently convicted of serious crimes that relate to the proposed employment duties, could be grounds for denying employment. Further, criminal background screening may deter those individuals with criminal intent from entering the field of hospice.

¹³³ Because providers of hospice care have frequent, relatively unsupervised access to potentially vulnerable people and their property, a hospice should also strictly scrutinize whether it should employ individuals who have been convicted of crimes of neglect, violence, or financial misconduct.

¹³⁴ Likewise, hospice compliance programs should establish standards prohibiting the execution of contracts with companies that have been recently convicted of a criminal offense related to health care or that are listed by a Federal agency as debarred, excluded, or otherwise ineligible for participation in Federal health care programs. See note 99.

¹³⁵ Prospective employees who have been officially reinstated into the Medicare and Medicaid programs by the OIG may be considered for employment upon proof of such reinstatement.

programs. Detected but uncorrected misconduct can seriously endanger the mission, reputation, and legal status of the hospice. Consequently, upon reports or reasonable indications of suspected noncompliance, it is important that the compliance officer or other management officials immediately investigate the conduct in question to determine whether a material violation of applicable law or the requirements of the compliance program has occurred, and if so, take decisive steps to correct the problem.¹³⁶ As appropriate, such steps may include an immediate referral to criminal and/or civil law enforcement authorities, a corrective action plan,¹³⁷ a report to the Government,¹³⁸ and the return of any overpayments, if applicable.

Where potential fraud or False Claims Act liability is not involved, the OIG recommends that normal repayment channels should be used for returning overpayments to the Government as they are discovered. However, even if the overpayment detection and return process is working and is being monitored by the hospice's audit or billing divisions, the OIG still believes that the compliance officer needs to be made aware of these overpayments, violations, or deviations that may reveal trends or patterns indicative of a systemic problem.

Depending upon the nature of the alleged violations, an internal investigation will probably include interviews and a review of relevant documents. Some hospices should consider engaging outside counsel, auditors, or health care experts to assist in an investigation. Records of the investigation should contain documentation of the alleged violation,

¹³⁶ Instances of noncompliance must be determined on a case-by-case basis. The existence, or amount, of a *monetary* loss to a health care program is not solely determinative of whether or not the conduct should be investigated and reported to governmental authorities. In fact, there may be instances where there is no readily identifiable monetary loss at all, but corrective action and reporting are still necessary to protect the integrity of the applicable program and its beneficiaries, *e.g.*, where services required by a plan of care were not provided.

¹³⁷ Advice from the hospice's in-house counsel or an outside law firm may be sought to determine the extent of the hospice's liability and to plan the appropriate course of action.

¹³⁸ The OIG currently maintains a provider self-disclosure protocol that encourages providers to report suspected fraud. The concept of voluntary self-disclosure is premised on a recognition that the Government alone cannot protect the integrity of the Medicare and other Federal health care programs. Health care providers must be willing to police themselves, correct underlying problems, and work with the Government to resolve these matters. The self-disclosure protocol can be located on the OIG's website at: <http://www.os.dhhs.gov/oig>.

a description of the investigative process (including the objectivity of the investigators and methodologies utilized), copies of interview notes and key documents, a log of the witnesses interviewed and the documents reviewed, the results of the investigation, *e.g.*, any disciplinary action taken, and the corrective action implemented. While any action taken as the result of an investigation will necessarily vary depending upon the hospice and the situation, hospices should strive for some consistency by utilizing sound practices and disciplinary protocols.¹³⁹ Further, after a reasonable period, the compliance officer should review the circumstances that formed the basis for the investigation to determine whether similar problems have been uncovered or modifications of the compliance program are necessary to prevent and detect other inappropriate conduct or violations.

If an investigation of an alleged violation is undertaken and the compliance officer believes the integrity of the investigation may be at stake because of the presence of employees under investigation, those subjects should be removed from their current work activity until the investigation is completed (unless an internal or Government-led undercover operation known to the hospice is in effect). In addition, the compliance officer should take appropriate steps to secure or prevent the destruction of documents or other evidence relevant to the investigation. If the hospice determines that disciplinary action is warranted, it should be prompt and imposed in accordance with the hospice's written standards of disciplinary action.

2. Reporting

If the compliance officer, compliance committee, or management official discovers credible evidence of misconduct from any source and, after a reasonable inquiry, has reason to believe that the misconduct may violate criminal, civil, or administrative law, then the hospice should promptly report the existence of misconduct to the appropriate Federal and State authorities¹⁴⁰ within a reasonable

¹³⁹ The parameters of a claim review subject to an internal investigation will depend on the circumstances surrounding the issue(s) identified. By limiting the scope of an internal audit to current billing, a hospice may fail to discover major problems and deficiencies in operations, as well as be subject to certain liability.

¹⁴⁰ Appropriate Federal and State authorities include the Office of Inspector General of the Department of Health and Human Services, the Criminal and Civil Divisions of the Department of

period, but not more than sixty (60) days¹⁴¹ after determining that there is credible evidence of a violation.¹⁴² Prompt reporting will demonstrate the hospice's good faith and willingness to work with governmental authorities to correct and remedy the problem. In addition, reporting such conduct will be considered a mitigating factor by the OIG in determining administrative sanctions (e.g., penalties, assessments, and exclusion), if the reporting provider becomes the target of an OIG investigation.¹⁴³

When reporting misconduct to the Government, a hospice should provide all evidence relevant to the alleged violation of applicable Federal or State law(s) and potential cost impact. The compliance officer, under advice of counsel, and with guidance from the governmental authorities, could be requested to continue to investigate the reported violation. Once the investigation is completed, the compliance officer should be required to notify the appropriate governmental authority of the outcome of the investigation, including a description of the impact of the alleged violation on the operation of the applicable health care programs or their beneficiaries. If the investigation ultimately reveals that criminal, civil, or administrative violations have occurred, the appropriate Federal and State authorities¹⁴⁴ should be notified immediately.

Justice, the U.S. Attorney in relevant districts, and the other investigative arms for the agencies administering the affected Federal or State health care programs, such as the State Medicaid Fraud Control Unit, the Defense Criminal Investigative Service, the Department of Veterans Affairs, and the Office of Personnel Management (which administers the Federal Employee Health Benefits Program).

¹⁴¹ In contrast, to qualify for the "not less than double damages" provision of the False Claims Act, the report must be provided to the Government within thirty (30) days after the date when the hospice first obtained the information. 31 U.S.C. 3729(a).

¹⁴² The OIG believes that some violations may be so serious that they warrant immediate notification to governmental authorities, prior to, or simultaneous with, commencing an internal investigation, e.g., if the conduct: (1) is a clear violation of criminal law; (2) has a significant adverse effect on the quality of care provided to program beneficiaries (in addition to any other legal obligations regarding quality of care); or (3) indicates evidence of a systemic failure to comply with applicable laws or an existing corporate integrity agreement, regardless of the financial impact on Federal health care programs.

¹⁴³ The OIG has published criteria setting forth those factors that the OIG takes into consideration in determining whether it is appropriate to exclude a health care provider from program participation pursuant to 42 U.S.C. 1320a-7(b)(7) for violations of various fraud and abuse laws. See 62 FR 67392 (December 24, 1997).

¹⁴⁴ See note 140.

As previously stated, the hospice should take appropriate corrective action, including prompt identification of any overpayment to the affected payor and the imposition of proper disciplinary action. If potential fraud or violations of the False Claims Act are involved, any repayment of the overpayment should be made as part of the discussion with the Government following a report of the matter to law enforcement authorities. Otherwise, normal repayment channels should be used for repaying identified overpayments.¹⁴⁵ Failure to disclose overpayments within a reasonable period of time could be interpreted as an intentional attempt to conceal the overpayment from the Government, thereby establishing an independent basis for a criminal violation with respect to the hospice, as well as any individuals who may have been involved.¹⁴⁶ For this reason, hospice compliance programs should emphasize that overpayments obtained from Medicare or other Federal health care programs should be promptly disclosed and returned to the payor that made the erroneous payment.

The OIG believes all hospices, regardless of size, should ensure they are reporting the results of any overpayments or violations to the appropriate entity and taking the appropriate corrective action to remedy the identified deficiency.

III. Assessing the Effectiveness of a Compliance Program

Because the Government views the existence of a compliance program as a mitigating factor when determining culpability regarding allegations of fraud and abuse only if the compliance program is "effective," how a hospice may assess its compliance program becomes quite significant. A hospice, as well as any other type of health care provider, should consider the attributes of each individual element of its compliance program to assess the program's "effectiveness" as a whole. Examining the comprehensiveness of policies and procedures implemented to satisfy these elements is merely the first

¹⁴⁵ A hospice should consult with its Medicare fiscal intermediary or HCFA for any further guidance regarding normal repayment channels. The hospice's Medicare fiscal intermediary or HCFA may require certain information (e.g., alleged violation or issue causing overpayment, description of the internal investigative process with methodologies used to determine any overpayments, disciplinary actions taken, and corrective actions taken, etc.) to be submitted with return of any overpayments, and that such repayment information be submitted to a specific department or individual. Interest will be assessed, when appropriate. See 42 CFR 405.376.

¹⁴⁶ See 42 U.S.C. 1320a-7b(a)(3).

step. Evaluating how a compliance program performs during a provider's day-to-day operations becomes the critical indicator.¹⁴⁷

As previously stated, a compliance program should require the development and distribution of written compliance policies, standards, and practices that identify specific areas of risk and vulnerability to a hospice. One way to judge whether these policies, standards, and practices measure up is to observe how an organization's employees react to them. Do employees consistently experience recurring pitfalls because they lack guidance on certain issues not adequately covered in company policies? Are employees flagrantly disobeying an organization's standards of conduct because they observe no sincere buy-in from senior management? Do employees have trouble understanding policies and procedures because they are written in legalese or at difficult reading levels? Does an organization routinely experience systematic billing failures because employees are ill-instructed how to implement written policies and practices? Written compliance policies, standards, and practices are only as good as an organization's commitment to apply them in practice.

Every hospice should designate a compliance officer or contact to serve as the focal point of compliance activities, and, if appropriate, a compliance committee to advise and assist the compliance officer. An organization needs to seriously consider whoever fills such integral roles and periodically monitor how the individuals chosen satisfy their responsibilities. Does a compliance officer have sufficient professional experience working with billing, clinical records, documentation, and auditing principles to perform assigned responsibilities fully? Has a compliance officer or compliance committee been negligent in ensuring an organization's compliance due to inadequate funding, staff, and authority necessary to carry out their jobs? Did adding the compliance officer function to a key management position with other significant duties compromise the goals of the compliance program (e.g., chief financial officer who discounts certain overpayments identified to improve the company's bottom line profits)? Since a compliance officer and

¹⁴⁷ Evaluation may be accomplished through techniques such as employee surveys, management assessments, and periodic review of benchmarks established for audits, investigations, disciplinary action, overpayments, and employee feedback. All elements of an organization's compliance program can be evaluated, including policies, training, practices, and compliance personnel.

a compliance committee can potentially have a significant impact on how effectively a compliance program is implemented, those functions should not be taken for granted.

As evidenced throughout this guidance, the proper education and training of corporate officers, managers, health care professionals, and other applicable employees of a provider, and the continual retraining of current personnel at all levels, are significant elements of an effective compliance program. Accordingly, such efforts should be routinely evaluated. Are employees trained frequently enough? Do employees fail post-training tests that evaluate knowledge of compliance? Do training sessions and materials adequately summarize important aspects of the organization's compliance program, such as fraud and abuse laws, Federal health care program requirements, and claim development and submission processes? Are training instructors qualified to present the subject matter and experienced enough to duly field questions? When thorough compliance training is periodically conducted, employees receive the reinforcement they need to ensure an effective compliance program.

An open line of communication between the compliance officer and a provider's employees is equally important to the success of a compliance program. In today's intensive regulatory environment, the OIG believes that a provider cannot possibly have an effective compliance program if it receives minimal or no feedback from its employees regarding compliance matters. For instance, if a compliance officer does not receive appropriate inquiries from employees: Do policies and procedures fail to adequately guide employees to whom and when they should be communicating compliance matters? Do employees fear retaliation if they report misconduct? Are employees reporting issues not related to compliance through the wrong channels? Do employees have bad-faith, ulterior motives for reporting? Regardless of the means that a provider employs, whether it be telephone hotline, email, or suggestion boxes, employees should seek clarification from compliance staff in the event of any confusion or question dealing with compliance policies, practices, or procedures.

An effective compliance program should include guidance regarding disciplinary action for corporate officers, managers, health care professionals, and other employees who have failed to adhere to an organization's standards of conduct,

Federal health care program requirements, or Federal or State laws. The number and caliber of disciplinary actions taken by an organization can be insightful. Have appropriate sanctions been applied to compliance misconduct? Are sanctions applied to all employees consistently, regardless of an employee's level in the corporate hierarchy? Have double-standards in discipline bred cynicism among employees? When disciplinary action is not taken seriously or applied haphazardly, such practices reflect poorly on senior management's commitment to foster compliance as well as the effectiveness of an organization's compliance program in general.

Another critical component of a successful compliance program is an ongoing monitoring and auditing process. The extent and frequency of the audit function may vary depending on factors such as the size and available resources, prior history of noncompliance, and risk factors of a particular hospice. The hallmark of effective monitoring and auditing efforts is how an organization determines the parameters of its reviews. Do audits focus on all pertinent departments of an organization? Does an audit cover compliance with all applicable laws and Federal health care program requirements? Are results of past audits, pre-established baselines, or prior deficiencies reevaluated? Are the elements of the compliance program monitored? Are auditing techniques valid and conducted by objective reviewers? The extent and sincerity of an organization's efforts to confirm its compliance often proves to be a revealing determinant of a compliance program's effectiveness.

As was expressed in the last section of this guidance, it is essential that the compliance officer or other management officials immediately investigate reports or reasonable indications of suspected noncompliance. If a material violation of applicable law or compliance program requirements has occurred, a provider must take decisive steps to correct the problem. Providers who do not thoroughly investigate misconduct leave themselves open to undiscovered fraud, waste, and abuse. When a provider learns of certain issues, does it knowingly disregard associated legal exposure? Is there a consistent and methodical approach to the correlation between compliance issues identified and the corrective action necessary to remedy? Are isolated overpayment matters properly resolved through normal repayment channels? Is credible evidence of misconduct that may violate

criminal, civil, or administrative law promptly reported to the appropriate Federal and State authorities? If any step in this process of responding to detected offenses is circumvented or improperly handled, such conduct would most likely demonstrate an ineffective compliance program, as well as potentially result in criminal, civil, or administrative liability.

Documentation is the key to demonstrating the effectiveness of a provider's compliance program. For example, documentation of the following should be maintained: audit results; logs of hotline calls and their resolution; corrective actions plans; due diligence efforts regarding business transactions; records of employee training, including the number of training hours; disciplinary action; and modification and distribution of policies and procedures. Given that the OIG is encouraging self-disclosure of overpayments and billing irregularities, maintaining a record of disclosures and refunds to the health care programs is strongly endorsed. A documented practice of refunding of overpayments and self-disclosing incidents of non-compliance with Federal health care program requirements can serve as evidence of a meaningful compliance effort by a hospice.

Hospices, as well as all health care providers, should acknowledge that it is their responsibility to formulate policies, procedures, and practices that are tailored to their own operations, and that are comprehensive enough to ensure compliance with all applicable Federal health care program requirements. An organization is in the best position to validate the suitability of its compliance efforts based upon its own particular circumstances.

IV. Conclusion

Through this document, the OIG has attempted to provide a foundation to the process necessary to develop an effective and cost-efficient hospice compliance program. As previously stated, however, each program must be tailored to fit the needs and resources of an individual hospice, depending upon its particular corporate structure, mission, and employee composition. The statutes, regulations, and guidelines of the Federal and State health insurance programs, as well as the policies and procedures of the private health plans, should be integrated into every hospice's compliance program.

The OIG recognizes that the health care industry in this country, which reaches millions of beneficiaries and expends about a trillion dollars annually, is constantly evolving. The

time is right for hospices to implement a strong voluntary health care compliance program. As stated throughout this guidance, compliance is a dynamic process that helps to ensure that hospices and other health care providers are better able to fulfill their commitment to ethical behavior, as well as meet the changes and challenges being imposed upon them by Congress and private insurers. Ultimately, it is OIG's hope that a voluntarily created compliance program will enable hospices to meet their goals, improve the quality of patient care, and substantially reduce fraud, waste, and abuse, as well as the cost of health care to Federal, State, and private health insurers.

Dated: July 14, 1999.

June Gibbs Brown,

Inspector General.

[FR Doc. 99-18590 Filed 7-20-99; 8:45 am]

BILLING CODE: 4150-04-P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-4441-N-34]

Notice of Submission of Proposed Information Collection to OMB: Emergency Comment Request; HUD's Year 2000 Status Survey—A Special Year Data Gathering Request

AGENCY: Office of the Assistance Secretary for Administration, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for emergency review and approval, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: *Comments Due Date:* July 28, 1999.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments must be received within seven (7) days from the date of this Notice. Comments should refer to the proposal by name and should be sent to: Joseph F. Lackey, Jr., HUD Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Wayne Eddins, Reports Management Officer, Department of Housing and Urban Development, 451 Seventh Street, SW, Washington, DC 20410, telephone (202) 708-2374. This is not a toll-free

number. Copies of available documents submitted to the OMB may be obtained from Mr. Eddins.

SUPPLEMENTARY INFORMATION: This Notice informs the public that the Department of Housing and Urban Development (HUD) has submitted to OMB, for emergency processing, an information collection package with respect to Year 2000 (Y2K) compliancy efforts for HUD properties operated by Public Housing Authorities and Multi-Family owner/agents. The survey specifically addresses the status of embedded chips in HUD facilities.

Emergency processing of this request is necessary due to the imminent nature of Y2K issues and the potential vulnerability of HUD facilities to experience Y2K-induced failures.

This notice is soliciting comments from members of the public and affecting agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

This Notice also lists the following information:

Title of Proposal: HUD's Year 2000 Status Survey—A Special Year Data Gathering Request on Embedded Microchips.

OMB Control Number, if applicable: 2507-__.

Description of the need for the information and proposed use: The House Committee on Banking and Financial Services has requested that HUD—Real Estate Assessment Center (REAC) provide information on the status of Y2K compliancy efforts for HUD properties operated by Public Housing Authorities and Multi-Family owner/agents. The Committee is specifically interested in the status of embedded chips in HUD facilities. The Y2K Embedded Chip survey will enable HUD—REAC to respond to the House Committee's request for information.

Agency form numbers, if applicable: form HUD-95000 (6/23/99).

Members of affected public: Public Housing Authorities and Multi-Family owner/agents.

Estimation of the total numbers of hours needed to prepare the information collection including number of respondents, frequency of response, and hours of response:

It is estimated that the survey will take approximately 60 minutes to complete. Approximately 33,200 Public Housing Authorities and Multi-Family owner/agents will be requested to complete the survey.

Status of the proposed information collection: Awaiting OMB approval.

Authority: The Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35, as amended.

Dated: July 15, 1999.

David S. Cristy,

Director, IRM Policy and Management Division.

[FR Doc. 99-18512 Filed 7-20-99; 8:45 am]

BILLING CODE 4210-01-M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-4441-N-33]

Submission for OMB Review: Repayment Agreement

AGENCY: Office of the Assistant Secretary for Administration, HUD.

ACTION: Notice.

SUMMARY: Information on the HUD-56146 is being collected under Public Law 479 which empowers the Secretary for HUD to collect or compromise all obligations assigned to or held by the Secretary and all legal or equitable rights accruing to HUD in connection with the payment of a HUD-insured loan until such time as such obligations may be referred to the Attorney General of the United States for suit or collections.

DATES: *Comments Due Date:* August 20, 1999.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB approval number (2502-0483) and should be sent to: Joseph F. Lackey, Jr., OMB Desk Officer, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Wayne Eddins, Reports Management Officer, Department of Housing and Urban Development, 451 7th Street, Southwest, Washington, DC 20410, telephone (202) 708-1305. This is not a toll-free number. Copies of the proposed