

submitted and received by the time frame indicated above.

We anticipate that the DME guidance will contain the seven elements that we consider necessary for a comprehensive compliance program. These seven elements have been discussed in our previous guidances and include:

- The development of written policies and procedures;
- The designation of a compliance officer and other appropriate bodies;
- The development and implementation of effective training and education;
- The development and maintenance of effective lines of communication;
- The enforcement of standards through well-publicized disciplinary guidelines;
- The use of audits and other evaluation techniques to monitor compliance; and
- The development of procedures to respond to detected offenses and to initiate corrective action.

We would appreciate specific comments, recommendations and suggestions on (1) risk areas for the DME industry, and (2) aspects of the seven elements contained in previous guidances that may need to be modified to reflect the unique characteristics of the DME industry. Detailed justifications and empirical data supporting suggestions would be appreciated. We are also hopeful that any comments, recommendations and input be submitted in a format that addresses the above topics in a concise manner, rather than in the form of comprehensive draft guidance that mirrors previous guidance.

Dated: July 28, 1998.

June Gibbs Brown,

Inspector General.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Publication of the OIG Compliance Program Guidance for Home Health Agencies

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

ACTION: Notice.

SUMMARY: This **Federal Register** notice sets forth the recently issued Compliance Program Guidance for Home Health Agencies developed by the Office of Inspector General (OIG) in cooperation with, and with input from,

several provider groups and industry representatives. Many home health care providers have expressed interest in better protecting their operations from fraud and abuse through the adoption of a voluntary compliance program. The OIG has previously developed and published compliance program guidances focused on the clinical laboratory and hospital industries (62 FR 9435, March 3, 1997 and 63 FR 8987, February 23, 1998, respectively). We believe that the development of this compliance program guidance for the home health industry will continue as a positive step towards promoting a higher level of ethical and lawful conduct throughout the entire health care community.

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

SUPPLEMENTARY INFORMATION: The creation of compliance program guidances has become a major initiative of the OIG in its efforts to engage the health care community in combating fraud and abuse. In formulating compliance guidances, the OIG has worked closely with the Health Care Financing Administration, the Department of Justice and various sectors of the health care industry to provide clear guidance to those segments of the industry that are interested in reducing fraud and abuse within their organizations. The first of these compliance program guidances focused on clinical laboratories and was published in the **Federal Register** on March 3, 1997 (62 FR 9435). Building on basic elements of the first issuance, the second compliance program guidance developed by the OIG focused on the hospital industry and was published in the **Federal Register** on February 23, 1998 (63 FR 8987). The development of these types of compliance program guidance is based on our belief that a health care provider can use internal controls to more efficiently monitor adherence to applicable statutes, regulations and program requirements.

The OIG has identified seven fundamental elements to an effective compliance program. They are:

- Implementing written policies, procedures and standards of conduct;
- Designating a compliance officer and compliance committee;
- Conducting effective training and education;
- Developing effective lines of communication;
- Enforcing standards through well-publicized disciplinary guidelines;
- Conducting internal monitoring and auditing; and

- Responding promptly to detected offenses and developing corrective action.

Using these seven basic elements, the OIG has identified specific areas of home health operations that, based on prior Government enforcement efforts, have proven to be vulnerable to fraud and abuse. The development of this Compliance Program Guidance for Home Health Agencies has been further enhanced by input from various home health trade associations and others with expertise in the home health industry. Regardless of a home health agency's size and structure—whether large or small, urban or rural, for-profit or non-profit—the OIG believes that every home health agency can and should strive to accomplish the objectives and principles underlying all of the compliance policies and procedures set forth in this accompanying guidance. Like the previously-issued compliance guidances for hospitals and clinical laboratories, adoption of the Compliance Program Guidance for Home Health Agencies set forth below will be voluntary.

A reprint of the OIG's Compliance Program Guidance for Home Health Agencies follows.

Office of Inspector General's Compliance Program Guidance for Home Health Agencies

I. Introduction

The Office of Inspector General (OIG) of the Department of Health and Human Services (HHS) continues in its efforts to promote voluntarily developed and implemented compliance programs for the health care industry. The following compliance program guidance is intended to assist home health agencies¹ and their agents and subproviders (referred to collectively in this document as "home health agencies") develop effective internal controls that promote adherence to applicable Federal and State law, and the program requirements of Federal, State, and private health plans.² 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

¹ The term "home health agency" is applied in this document as defined in section 1861(o) of the Social Security Act, 42 U.S.C. 1395x(o).

² This Compliance Program Guidance for Home Health Agencies is not intended to address issues specific to suppliers of durable medical equipment, infusion therapy, and other services typically provided in the home setting.

home health agencies, which is to provide quality care to patients.

Within this document, the OIG first provides its general views on the value and fundamental principles of home health agency compliance programs, and then provides the specific elements that each home health agency 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 home health agency interested in implementing a compliance program.

The OIG recognizes the size-differential that exists between operations of the different home health agencies and organizations that compose the home health industry. Appropriately, this guidance is pertinent for all home health agencies, whether for-profit or non-profit, large or small, urban or rural. The applicability of the recommendations and guidelines provided in this document depends on the circumstances of each particular home health agency. However, regardless of a home health agency's size and structure, the OIG believes that every home health agency 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 home health agency 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 home health agency's business policies. In practice, the compliance program should effectively articulate and demonstrate the organization's commitment to ethical conduct. The existence of benchmarks that demonstrate implementation and achievements are essential to any effective compliance program. Eventually, a compliance program should become part of the fabric of routine home health agency operations.

Specifically, compliance programs guide a home health agency's governing body (e.g., Board of Directors or Trustees), Chief Executive Officer (CEO), managers, clinicians, billing personnel, and other employees in the efficient management and operation of a home health agency. They are especially critical as an internal control in the reimbursement and payment areas,

where claims and billing operations are often the source of fraud and abuse, and therefore, historically have been the focus of Government regulation, scrutiny, and sanctions.

It is incumbent upon a home health agency'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 home health agency's leadership as a measure of the organization's commitment to compliance. Indeed, many home health agencies have adopted mission statements articulating their commitment to high ethical standards. A formal compliance program, as an additional element in this process, offers a home health agency a further concrete method that may improve 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 home health agency'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 home health agency 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

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 Current Health Care Financing Administration (HCFA) reimbursement principles provide that certain of the costs associated with the creation of a voluntarily established compliance program may be allowable costs on certain types of home health agencies' cost reports. These allowable costs, of course, must at a minimum be *reasonable* and related to patient care. See generally 42 U.S.C. 1395x(v)(1)(A) (definition of reasonable cost); 42 CFR 413.9(a), (b)(2) (costs related to patient care). In contract, cost specifically associated with the implementation of a corporate integrity agreement

A. Benefits of a Compliance Program

In addition to fulfilling its legal duty to ensure that it is not submitting false or inaccurate claims to Government and private payors, a home health agency may gain numerous additional benefits by voluntarily implementing an effective compliance program. Such programs make good business sense because they help a home health agency fulfill its fundamental care-giving mission to patients and the community, and assist home health agencies in identifying weaknesses in internal systems and management. Other important potential benefits include the ability to:

- Concretely demonstrate to employees and the community at large the home health agency's strong commitment to honest and responsible provider and corporate conduct;
- Provide a more accurate view of employee and contractor behavior relating to fraud and abuse;
- Identify and prevent illegal and unethical conduct;
- Tailor a compliance program to a home health agency's specific needs;
- 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 related to fraud 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, nurses, and other health care professionals;
- Initiate immediate, appropriate, and decisive corrective action;
- Minimize, through early detection and reporting, the loss to the Government from false claims, and thereby reduce the home health agency's exposure to civil damages and penalties, criminal sanctions, and administrative remedies, such as program exclusion;⁵ and

in response to a Government investigation resulting in a civil or criminal judgment or settlement are unallowable, and are also made specifically and expressly unallowable in corporate integrity agreements and civil fraud settlements.

⁵ The 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. 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

- Enhance the structure of home health agency operations and gain consistency between separate business units.

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

The OIG recognizes that the implementation of a compliance program may not entirely eliminate fraud, abuse, and waste from the home health agency system. However, a sincere effort by home health agencies to comply with applicable Federal and State standards, as well as the requirements of private health care programs, through the establishment of an effective 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" home health agency compliance program. The OIG understands the variances and complexities within the home health industry and is sensitive to the differences among large national and regional multi-home health agency organizations, specialty home health agencies, small independent home health agencies, and other types of home health agency organizations and systems. However, elements of this guidance can be used by all home health agencies, regardless of size, location, or corporate structure, to establish an effective compliance program. Similarly, a hospital or corporation that owns a home health agency or provides home health services may incorporate these elements into its system-wide compliance or managerial structure. We recognize that some home health agencies 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 home health agency 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.

The OIG believes that input and support by representatives of the major home health trade associations is critical to the development and success

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).

of this compliance program guidance. Therefore, in drafting this guidance, the OIG received and considered input from various home health and medical associations, as well as professional practice organizations. 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 home health agencies conducted by OIG's Office of 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. New compliance practices may eventually be incorporated into this guidance if the OIG discovers significant enhancements to better ensure an effective compliance program.

The OIG recognizes that the development and implementation of compliance programs in home health agencies often raise sensitive and complex legal and managerial issues.⁶ 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 the Compliance Program Guidance for Hospitals that was published by the OIG in February 1998, the clinical laboratory compliance program guidance published by the OIG in February 1997,⁷ and our corporate integrity agreements.⁸ The elements represent a guide that can be tailored to fit the needs and financial realities of a particular home health agency.⁹ The OIG is cognizant that, with

⁶ Nothing stated within this document should be substituted for, or used in lieu of, competent legal advice from counsel.

⁷ See 63 FR. 8987 (1998) for the Compliance Program Guidance for Hospitals. See 62 FR 9435 (1997) for the clinical laboratory compliance program guidance. These documents are also located on the Internet at <http://www.dhhs.gov/progorg/oig>.

⁸ 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 3 to 5 years and require many of the elements included in this compliance program guidance.

⁹ This is particularly true in the context of the home health industry, which includes many small

regard to compliance programs, one model is not suitable to every home health agency. Nonetheless, the OIG believes that every home health agency, regardless of size or structure, can benefit from the principles espoused in this guidance.

The OIG believes that every effective compliance program must begin with a formal commitment by the home health agency'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.¹⁰ Further, we believe that every home health agency can implement most of our recommended elements that expand upon the seven steps of the Federal Sentencing Guidelines. We recognize that full implementation of all elements may not be immediately feasible for all home health agencies. However, as a first step, a good faith and meaningful commitment on the part of the home health agency 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 home health agency 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 that promote the home health agency's commitment to compliance (e.g., by including adherence to the compliance program as an element in evaluating managers and employees) and address specific areas of potential fraud, such as claims development and submission processes, cost reporting, and financial relationships with physicians 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 reports

independent home health agencies with limited financial resources and staff, as well as the larger multi-home health agency organizations and networks with extensive financial resources and staff.

¹⁰ 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.

directly to the CEO and the governing body;¹¹

(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 the adoption of procedures to protect the anonymity of complainants and to protect whistleblowers from retaliation;

(5) The development of a system to respond to allegations of improper/illegal activities and the enforcement of appropriate disciplinary action against employees who have violated internal compliance policies, applicable statutes, regulations, or Federal health care program requirements;¹²

(6) The use of audits and/or other evaluation techniques to monitor compliance and assist in the reduction of identified problem areas;

(7) The investigation and remediation of identified systemic problems and the development of policies addressing the non-employment or retention of sanctioned individuals.

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 home health agency. 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

¹¹ 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 home health agency may tailor the structure of those positions in consideration of the size and design of the home health agency, while endeavoring to address and accomplish all of the underlying objectives of a compliance officer and a corporate compliance committee.

¹² 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 purposes of this document, the term "Federal health care program requirements" refers to the statutes, regulations, rules, requirements, directive, and instructions governing Medicare, Medicaid, and all other Federal health care programs.

individuals who are affected by the particular policy at issue, including the home health agency's agents and independent contractors.¹³ In addition to these general corporate policies, it may be necessary to implement individual policies for independent components of the home health agency.

1. Standards of Conduct

Home health agencies should develop standards of conduct for all affected employees that include a clearly delineated commitment to compliance by the home health agency's senior management¹⁴ and its divisions, including affiliated providers operating under the home health agency's¹⁵ control and other health care professionals (e.g., physical therapists, occupational therapists, speech therapists, and medical social workers). Standards should articulate the home health agency's commitment to comply with all Federal and State 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 home health agency governing body members, officers, managers, employees, clinicians, and, where appropriate, contractors and other agents. 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

¹³ 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.

¹⁴ The OIG strongly encourages high-level involvement by the home health agency's governing body, chief executive officer, 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.

¹⁵ E.g., pharmacies, other home health agencies, and supplemental staffing entities.

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.¹⁶

When they first begin working for the home health agency, 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 home health agency in the employee's personnel file, and available for review by the compliance officer.

2. Risk Areas

The OIG believes that a home health agency'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 home health agency.¹⁷ Consequently, we recommend that the individual 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.¹⁸ Some of the special areas of OIG concern include:¹⁹

¹⁶ 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 should be addressed and made part of all affected employees' training. The home health agency must decide which additional educational programs should be limited to the different levels of employees, based on job functions and areas of responsibility.

¹⁷ A home health agency can conduct focus groups composed of managers from various departments to solicit their concerns and ideas about compliance risks that may be incorporated into the home health agency's policies and procedures. Such employee participation in the development of the home health agency's compliance program can enhance its credibility and foster employee acceptance of the program.

¹⁸ The OIG periodically issues Special Fraud Alerts setting forth activities believed to raise legal and enforcement issues. Home health agency 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 home health agencies. Moreover, the compliance programs should address the ramifications of failing to cease and correct any conduct criticized in such a special Fraud Alert, if applicable to home health agencies, or to take reasonable action to prevent such conduct from reoccurring in the future. If appropriate, a home health agency should take the steps described in section G.2. regarding investigations, reporting, and correction of identified problems.

¹⁹ The OIG's work plan is currently available on the Internet at <http://www.dhhs.gov/progorg/oig>.

- Billing for items or services not actually rendered;²⁰
- Billing for medically unnecessary services;²¹
- Duplicate billing;²²
- False cost reports;²³
- Credit balances—failure to refund;²⁴
- Home health agency incentives to actual or potential referral sources (*e.g.*,

The OIG Work Plan details the various projects of the Office of Audit Services, Office of Evaluation and Inspections, Office of Investigations, and Office of Counsel to the Inspector General that are planned to be addressed during each Fiscal Year.

²⁰Billing for services not actually rendered involves submitting a claim that represents the provider performed a service all or part of which was simply not performed. This form of billing fraud occurs in many health care entities, including home health agencies, hospitals, laboratories, and nursing homes, and represents a significant part of the OIG's investigative caseload.

²¹Billing for medically unnecessary services involves knowingly seeking reimbursement for a service that is not warranted by the patient's current and documented medical condition. See 42 U.S.C. § 1395y(a)(1)(A) ("no payment may be made under part A or part B [of Medicare] for any expenses incurred for items or services which * * * are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of the malformed body member"). Upon submission of an HCFA claim form (whether paper or electronic), a home health agency certifies that the services provided and billed were medically necessary for the health of the beneficiary, and were rendered in accordance with orders prescribed by the beneficiary's physician. See also discussion in section II.A.3.a and accompanying notes.

²²Duplicate billing occurs when the home health agency submits more than one claim for the same service or the bill is submitted to more than one primary payor at the same time. Although duplicate billing can occur due to simple error, knowing, duplicate billing—which is sometimes evidenced by systematic or repeated double billing—can create liability under criminal, civil, or administrative law, particularly if any overpayment is not promptly refunded.

²³The submission of false cost reports is usually limited to certain Medicare Part A providers, such as home health agencies, hospitals, and skilled nursing facilities, which are reimbursed in part on the basis of their self-reported operating costs. The OIG is aware of practices in which home health agencies maintain records that indicate salaries are paid to employees that do not exist, lump nonpatient-related expenses with patient-related ones in an attempt to bury the non-reimbursable costs, bill Medicare for patient visits with no records to substantiate that the services were performed, inappropriately shift certain costs to cost centers that are below their reimbursement cap, shift non-Medicare related costs to Medicare cost centers, and fail to properly disclose related organizations (see 42 CFR 413.17(b)), *e.g.*, entities that provide leased space or equipment, financial management consulting, and direct patient services and supplies.

²⁴A credit balance is an improper or excess payment made to a health care provider as a result of patient billing or claims processing errors. Examples of Medicare credit balances include instances where a provider is: (1) Paid twice for the same service either by Medicare or by Medicare and another insurer; or (2) paid for services planned but not performed or for non-covered services. See Home Health Agency Manual § 489. Home health agencies should institute procedures to provide for the timely and accurate reporting of Medicare and other Federal health care program credit balances.

physicians, hospitals, patients, etc.) that may violate the anti-kickback statute or other similar Federal or State statute or regulation;²⁵

- Joint ventures between parties, one of whom can refer Medicare or Medicaid business to the other;²⁶
- Stark physician self-referral law;²⁷
- Billing for services provided to patients who are not confined to their residence (or "homebound");²⁸
- Billing for visits to patients who do not require a qualifying service;²⁹
- Over-utilization³⁰ and under-utilization;³¹
- Knowing billing for inadequate or substandard care;
- Insufficient documentation to evidence that services were performed and to support reimbursement;
- Billing for unallowable costs of home health coordination;³²

²⁵Examples of arrangements that may run afoul of the anti-kickback statute include practices in which a home health agency pays a fee to a physician for each plan of care certified, provides items or services for free or below fair market value to beneficiaries of Federal health care programs, provides nursing or administrative services for free or below fair market value to physicians, hospitals and other potential referral sources, and provides salaries to a referring physician for services either not rendered or in excess of fair market value for services rendered. See 42 U.S.C. 1320a-7b; 60 FR 40, 847 (1995). See also discussion in section II.A.4. and accompanying notes.

²⁶Equally troubling to the OIG is the proliferation of business arrangements that may violate the anti-kickback statute. Such arrangements are generally established between those in a position to refer business, such as physicians, and those providing items or services for which a Federal health care program pays. Sometimes established as "joint ventures," these arrangements may take a variety of forms. The OIG currently has a number of investigations and audits underway that focus on such areas of concern.

²⁷Under the Stark physician self-referral law, if a physician (or an immediate family member of such physician) has a financial relationship with a home health agency, the physician may not make a referral to the home health agency for the furnishing of home health services for which payment may be made under the Federal health care programs. See 42 U.S.C. 1395nn.

²⁸See discussion in section II.A.3.b. and accompanying notes.

²⁹See discussion in section II.A.3.d. and accompanying notes.

³⁰Physicians often rely on home health agencies to determine the need, type, and frequency of home health services provided to a beneficiary. Since Medicare does not limit the number of visits or the length of home health coverage for an individual beneficiary, home health agencies have incentives to furnish as many visits as possible, which can lead to over-utilization. Although it is a physician that determines medical necessity, a home health agency has an obligation to ensure that services it provides are medically necessary, and should consult with physicians as appropriate for the requisite assurances.

³¹In other words, knowing denial of needed care in order to keep costs low.

³²Home health coordination is intended to manage and facilitate the transfer of patients from a hospital or skilled nursing facility to the care of a home health agency. Although some costs of

- Billing for services provided by unqualified or unlicensed clinical personnel;
- False dating of amendments to nursing notes;
- Falsified plans of care;³³
- Untimely and/or forged physician certifications on plans of care;
- Forged beneficiary signatures on visit slips/logs that verify services were performed;
- Improper patient solicitation activities and high-pressure marketing of uncovered or unnecessary services;³⁴
- Inadequate management and oversight of subcontracted services, which results in improper billing;
- Discriminatory admission and discharge of patients;
- Billing for unallowable costs associated with the acquisition and sale of home health agencies;
- Compensation programs that offer incentives for number of visits performed and revenue generated;³⁵
- Improper influence over referrals by hospitals that own home health agencies;
- Patient abandonment in violation of applicable statutes, regulations, and Federal health care program requirements;³⁶

performing this service may be allowable under Medicare, the costs of services performed by home health agency personnel that constitute patient solicitation or activities duplicative of an institution's discharge planning responsibilities are not allowable. These non-reimbursable activities, as well as the allowable costs of performing home health coordination, are more specifically described in the Provider Reimbursement Manual, Part I, § 2113. Further, the OIG's Home Health Fraud Alert of June 1995 specifically warned home health agencies that providing hospitals with discharge planners, home health coordinators, or home care liaisons in order to induce referrals can constitute a kickback.

³³See discussion in section II.A.3.c. and accompanying notes.

³⁴Home health agencies should not utilize prohibited or inappropriate conduct (*e.g.*, offer free gifts or services to patients) to carry out their initiatives and activities designed to maximize business growth and patient retention. Also, any marketing information offered by home health agencies should be clear, correct, non-deceptive, and fully informative.

³⁵The current nature of the home health benefit (*i.e.*, no limits on reimbursable home health visits in a cost-reimbursed system) and customary business pressures create risks associated with incentives (*e.g.*, payments benefits, etc.) for productivity and volume of services. Such risks include over-utilization and billing for services not provided in order to meet internal goals and budget benchmarks imposed by home health agency management.

³⁶Under the Medicare conditions of participation, a home health agency has the duty to fully inform a beneficiary in advance of termination of services when further care or treatment is necessary. See generally 42 U.S.C. 395bbb. Moreover, State licensure statutes and regulations may stipulate additional requirements (*e.g.*, the minimum time period of advance notice allowed) that home health agencies must follow when

- Knowing misuse of provider certification numbers, which results in improper billing;

- Duplication of services provided by assisted living facilities, hospitals, clinics, physicians, and other home health agencies;

- Knowing or reckless disregard of willing and able caregivers when providing home health services;³⁷

- Failure to adhere to home health agency licensing requirements and Medicare conditions of participation;³⁸ and

- Knowing failure to return overpayments made by Federal health care programs. A home health agency's prior history of noncompliance with applicable statutes, regulations, and Federal health care program requirements may indicate additional types of risk areas where the home health agency may be vulnerable and that may require necessary policy measures to be taken to prevent avoidable recurrence.³⁹ Additional risk areas should be assessed by home health agencies as well and incorporated into the written policies and procedures and training elements developed as part of their compliance programs.

3. Claim Development and Submission Process

Of the risk areas identified above, those pertaining to the claim development and submission process have been the frequent subject of administrative recoveries, as well as investigations and prosecutions under the civil False Claims Act and criminal statutes. Settlement of these cases often has required the defendants to execute corporate integrity agreements, in addition to paying significant civil

terminating the services provided to a patient. The risk of abandonment may arise when a home health agency attempts to keep costs of providing services low.

³⁷ According to Medicare reimbursement principles, where a family member or other person is or will be providing services that adequately meet a patient's needs, it is not reasonable and necessary for a home health agency to furnish such services. Therefore, if a home health agency has first hand knowledge of an able and willing person to provide the services being rendered by the home health agency, or a patient (or patient's family) objects to a home health agency providing such services, the home health agency should neither provide nor bill for such services. See Home Health Agency Manual § 203.2.

³⁸ See 42 U.S.C. 1395bbb for the Medicare conditions of participation that apply to home health agencies.

³⁹ "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 is effective. See United States Sentencing Commission Guidelines, *Guidelines Manual*, 8A1.2, Application Note 3(k)(iii).

damages and/or criminal fines and penalties. These corporate integrity agreements have provided the OIG with a mechanism to specify practices that help ensure compliance with applicable Federal and State statutes, and Federal health care program requirements. The following recommendations include a number of provisions from various corporate integrity agreements. As previously discussed, each home health agency should develop its own specific policies tailored to fit its individual needs.

With respect to the reimbursement process, a home health agency's written policies and procedures should reflect and reinforce current Federal health care requirements regarding the submission of claims and Medicare cost reports. 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 sufficient and timely documentation of all nursing and other home health services, including subcontracted services, *prior* to billing to ensure that only accurate and properly documented services are billed;

- Emphasize that a claim should be submitted only when appropriate documentation supports the claim 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, the identity of the individual providing the service, and any information needed to support medical necessity and other applicable reimbursement coverage criteria. The home health agency should consult with its medical director(s), clinical staff, and/or governing body to establish other appropriate documentation guidelines;

- Indicate that the diagnosis and procedure codes for home health services reported on the reimbursement claim should be based on the patient's medical record and other documentation, as well as comply with all applicable official coding rules and guidelines. Any Health Care Financing Administration Common Procedure Coding System (HCPCS), International Classification of Disease (ICD), Home Health Agency's Current Procedural Terminology (CPT), or 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 home health agency. The documentation necessary for

accurate billing should be available to billing staff;

- Provide that the compensation for billing department personnel and billing consultants should not offer any financial incentive to submit claims regardless of whether they meet applicable coverage criteria for reimbursement or accurately represent the services rendered; and

- Establish and maintain a process for pre-and post-submission review of claims⁴⁰ to ensure that claims submitted for reimbursement accurately represent medically necessary services actually provided, supported by sufficient documentation, and in conformity with any applicable coverage criteria for reimbursement.⁴¹

The written policies and procedures concerning proper billing should reflect the current reimbursement principles set forth in applicable regulations⁴² and should be developed in tandem with private payor and organizational standards. Particular attention should be paid to issues associated with medical necessity, homebound status of beneficiary, physician certification of plan of care, and qualifying services to establish coverage eligibility.⁴³

a. Medical necessity—Reasonable and necessary services. A home health agency's compliance program should provide that claims should only be

⁴⁰ The OIG recommends that, at a minimum, a valid statistical sample of claims should be reviewed before and after billing is submitted.

⁴¹ *E.g.*, plan of care is dated and signed by a physician, beneficiary is homebound, skilled service is required, finite and predictable endpoint exists and is documented for skilled nursing services in excess of 35 hours of per week, etc. 42 U.S.C. 1395m(x); 42 CFR 424.22; Home Health Agency Manual § 204.

⁴² The official reimbursement coverage guidelines for participating providers in the Medicare program are promulgated by HCFA in the Provider Reimbursement Manual and the Home Health Agency Manual. Generally, to qualify for the home health benefit covered by Medicare, individuals must be confined to their residences (be "homebound"), be under a physician's care, and need part-time or intermittent skilled nursing care and/or physical or speech therapy. See Home Health Agency Manual § 204 entitled "Conditions the Patient Must Need to Qualify for Coverage of Home Health Services."

⁴³ The OIG undertaken numerous audits, investigations, inspections, and national enforcement initiatives aimed at reducing potential and actual fraud, abuse, and waste. For example, OIG audit reports, which have focused on issues such as home health agency billing for services not authorized by a physician, not medically necessary, not eligible for reimbursement, not rendered, and for unallowable general and administrative costs, continue to reveal abusive, wasteful or fraudulent behavior by some home health agencies. Our report on the practices of problem providers, our Operation Restore Trust Audit Report of July 1997, and our special fraud alert on home health fraud, illustrate how certain home health agency billing and business practices may result in fraudulent and abusive behavior.

submitted for services that the home health agency has reason to believe are medically necessary and were ordered by a physician⁴⁴ or other appropriately licensed individual.

As a preliminary matter, the OIG recognizes that licensed health care professionals must be able to order any services that are appropriate for the treatment of their patients. However, Medicare and other Government and private health care plans will only pay for those services otherwise covered that meet appropriate medical necessity 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.⁴⁵ The home health agency is in a unique position to deliver this information to the health care professionals on its staff and to the physicians who refer patients. Upon request, a home health agency must be able to provide documentation, such as physician orders and other patient medical records, to support the medical necessity of a service that the home health agency has provided.⁴⁶ The compliance officer should ensure that a clear, comprehensive summary of the "medical necessity" definitions and applicable rules of the various Government and private plans is prepared, disseminated, and explained to appropriate home health agency personnel.⁴⁷

We recommend that home health agencies 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 medically necessary services. As part of such reviews, home health agencies should examine the frequency and duration of the services

⁴⁴ For Medicare reimbursement purposes, a plan for furnishing home health services must be certified by a physician who is a doctor of medicine, osteopathy, or podiatric medicine, and who does not have a significant ownership interest in, or a significant financial or contractual relationship with, the home health agency. See 42 CFR 424.22.

⁴⁵ Civil monetary penalties and administrative sanctions, 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 42 U.S.C. 1320a-7(a).

⁴⁶ Medicare fiscal intermediaries and carriers have the authority to require home health agencies, which furnish items or services under the program, to submit documentation that substantiates services are actually provided and medically necessary. See Medicare Intermediary Manual § 3116.1.B.

⁴⁷ As it applies to private plan requirements, this compliance function may be delegated to supervisory personnel with suitable oversight by the compliance officer.

they perform to determine, in consultation with a physician, whether patients' medical conditions justify the number of visits provided and billed. Home health agencies may choose to incorporate this clinical review function into pre-existing quality assurance mechanisms or any other quality assurance processes that may become part of the conditions of participation for home health agencies.

Additionally, home health agencies should implement policies and procedures to verify that beneficiaries have actually received the appropriate level and number of services billed. The OIG believes that a home health agency has a duty to sufficiently monitor services its employees provide to patients for confirmation that all services were provided as claimed.⁴⁸ To satisfy such an objective, home health agencies may choose to periodically contact (*i.e.*, via mail, telephone, or in person) a random sample of patients and interview the clinical staff involved.

b. Homebound beneficiaries. For a home health agency to receive reimbursement for home health services under either Medicare Part A or Part B, the beneficiary must be "confined to the home."⁴⁹ Home health agencies should create oversight mechanisms to ensure that the homebound status of a Medicare beneficiary is verified and the specific factors qualifying the patient as homebound are properly documented.⁵⁰ Any determinative assessment of the homebound status of a Medicare

⁴⁸ A home health agency may consider including attestations on nursing note forms to be signed by caregivers for the purpose of reinforcing the importance of accurate documentation of services performed and billed.

⁴⁹ Title XVIII of the Social Security Act, § 1861(m), 42 U.S.C. 1395x(m), authorizes the provision of home health services to patients who are confined to their home (or homebound). In general, a patient will be considered to be homebound if the patient has a condition due to an illness or injury that restricts the patient's ability to leave his or her place of residence except with the aid of supportive devices such as crutches, canes, wheelchairs, and walkers, or the assistance of another person or if leaving home is medically contraindicated. The condition of these patients should be such that there exists a normal inability to leave the home and, consequently, leaving home would require a considerable and taxing effort. See Home Health Agency Manual § 204.1. HHS plans to submit a report to Congress by October 1, 1998, recommending criteria that should be applied, and the method of applying such criteria, in the determination of whether an individual is homebound for Medicare reimbursement purposes. See Balanced Budget Act of 1997, Pub. L. 105-33, § 4614. Any new criteria developed by HHS should be incorporated into the public applicable policies and procedures of a home health agency.

⁵⁰ Recent audits, investigations, and studies of home health agencies have concluded that many home health agencies have billed Medicare for services provided to beneficiaries who are not homebound. See note 43.

beneficiary should be completed prior to billing Medicare for home health services provided to the beneficiary.⁵¹ As with other conditions for Medicare coverage, a physician must certify that the beneficiary was confined to the home at the time when services were provided.⁵²

One means by which home health agencies may verify the homebound status of a Medicare beneficiary is the inclusion of written prompts on nursing note forms. These prompts can direct the home health agency's clinicians (*e.g.*, registered nurse or licensed practical nurse) to adequately assess and document the homebound status of a Medicare beneficiary based upon clinical expertise, consultation with the beneficiary, and orders of the attending physician.⁵³ Carefully designed prompts on nursing note forms may help ensure the complete and appropriate documentation necessary to substantiate the homebound status of a Medicare beneficiary for reimbursement purposes.

Home health agencies can further ensure compliance with the homebound requirement by distributing written notices to Medicare beneficiaries, reminding them that they must satisfy the regulatory requirements for homebound status to be eligible for Medicare coverage. Since the Medicare conditions of participation require home health agencies to give all beneficiaries a written notice of their legal rights before furnishing them with home health services, providers can include reminders of homebound requirements in these notices.⁵⁴

c. Physician certification of the plan of care. A home health agency should take all reasonable steps to ensure that claims for home health services are ordered and authorized by a physician.⁵⁵ The home health agency's

⁵¹ If a question is raised as to whether a patient is confined to the home, the home health agency will be requested to furnish its Medicare fiscal intermediary with the information necessary to establish that the patient is homebound. Home Health Agency Manual § 204.1.

⁵² 42 CFR 424.22(a)(1)(ii).

⁵³ These prompts can be in the form of directions (*e.g.*, "Consult with the patient and physician as to the patient's ability to leave the home.") or questions (*e.g.*, "Does the patient ever leave the home, and if so, where does the patient go and how often? Does the patient require supportive devices to leave the home?").

⁵⁴ See 42 CFR 484.10(a)(1).

⁵⁵ As a condition for payment of home health services by Medicare, a physician must certify that a plan for furnishing the services has been established and is periodically reviewed by a physician. 42 CFR 424.22(a) and (b); Home Health Agency Manual § 204.2 (If employees of a home health agency believe that services ordered by a physician are excessive or otherwise inappropriate, the home health agency cannot avoid liability for filing improper claims simply because a physician

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

- Before the home health agency bills for services provided to a beneficiary, the plan of care⁵⁶ must be established, dated, and signed by a qualified physician;⁵⁷

- The plan of care must be periodically reviewed by a physician in order for the beneficiary to continue to qualify for Medicare coverage of home health benefits;⁵⁸

- Home health services are only billed if the home health agency is acting upon a physician's certification attesting that the services provided to a patient are medically necessary and meet the requirements for home health services to be covered by Medicare;⁵⁹

- When consulted, the home health agency assists the physician in determining the medical necessity of home health services and formulating an appropriate and certified plan of care;⁶⁰

has ordered the services. Medicare, through certifications that are incorporated into the claim forms (paper or electronic) and ratified by home health agencies upon submission, imposes a duty to investigate the truth, accuracy, and completeness of claims before they are submitted. To illustrate, the HCFA-1500 claim form states that the person submitting the form certifies "the services shown on the[*e*] form were medically necessary for the health of the patient."

⁵⁶The Home Health Agency Manual uses the term "plan of care" to refer to the medical treatment plan established by the treating physician with the assistance of the home health care nurse. Among other things, the plan of care must contain all pertinent diagnoses, including the patient's mental status, the types of services, supplies, and equipment required, the frequency of visits to be made, prognosis, rehabilitation potential, functional limitations, activities permitted, nutritional requirements, and all medications and treatments. See Home Health Agency Manual § 204.2. The plan of care is presented in writing on the HCFA-485 form entitled "Home Health Certification and Plan of Treatment."

⁵⁷The home health agency should employ reasonable measures to verify that the physician is appropriately licensed and no adverse actions, such as criminal conviction, debarment, or an exclusion, have been taken against the physician.

⁵⁸The plan of care must be reviewed and signed by the physician who established the plan of care, in consultation with the home health agency professional personnel, at least every 62 days. Each review of a patient's plan of care must contain the signature of the physician and the date of review. 42 C.F.R. § 424.22(a), (b); Home Health Agency Manual § 204.2.F.

⁵⁹The physician must certify that: (1) The patient is confined to the home; (2) the patient is in need of intermittent skilled nursing care, physical therapy and/or speech therapy or continues to need occupational therapy; (3) the patient is under the care of the physician while the services are or were furnished; and (4) a plan of care has been established and is periodically reviewed by the physician. See Home Health Agency Manual § 204.5 and the HCFA-485 form.

⁶⁰In practice, home health agencies often accept the responsibility of assessing a beneficiary's status and completing the HCFA-485 plan of care form for approval by a physician. In the July 1997 OIG Audit

- The home health agency properly documents any assessment it has made of a beneficiary's home health needs, which may be used by a physician in developing and authorizing a plan of care; and

- The home health agency reminds or educates physicians, as appropriate, about the scope of their duty to certify patients for home health services to be reimbursed by Medicare.⁶¹

d. Lack of qualifying service. In addition to addressing the issues associated with other reimbursement coverage criteria, a home health agency's policies and procedures should ensure that all claims satisfy the requisite need of a qualifying service.⁶² Since reimbursement coverage of services by other disciplines may depend on the need and the provision of the qualifying service,⁶³ it is critical

Report (A-04-96-02121) entitled, "Results of the Operation Restore Trust Audit of Medicare Home Health Services in California, Illinois, New York, and Texas" (hereinafter "OIG ORT Report"), the OIG concluded that physicians did not always review or actively participate in developing the plans of care they signed, especially for less complex cases. The report found that physicians relied heavily on home health agencies to make determinations as to homebound status, as well as the need, type, and frequency of home health services without physician participation. Since such lack of physician involvement may likely result in non-covered services, it is advisable that home health agencies undertake all reasonable efforts to procure sufficient physician consultation to ensure that an appropriate plan of care is established for medically necessary services.

⁶¹This can be accomplished through provider education and liaison activities with physicians and physician support personnel. See Provider Reimbursement Manual § 2113.4

⁶²Among other criteria, to receive Medicare reimbursement for home health services, a beneficiary must have a need for skilled nursing care on an intermittent basis, physical therapy, speech-language pathology services, or a continuing need for occupational therapy. See Home Health Agency Manual § 205. To qualify as skilled nursing services, the services must require the skills of a registered nurse or a licensed practical (vocational) nurse under the supervision of a registered nurse, must be reasonable and necessary to the treatment of the patient's illness or injury, and must be intermittent (as discussed in Home Health Agency Manual, § 206.7). Where a service can be safely and effectively performed (or self-administered) by the average nonmedical person without the direct supervision of a licensed nurse, the service cannot be regarded as a skilled service even if a skilled nurse actually provides the service. Home Health Agency Manual § 205.1 A.2.

⁶³If an eligible beneficiary requires a qualifying service, Medicare also covers visits by home health aides, medical social workers, and occupational therapists, as well as medical supplies needed and used. Hands-on personal care services, such as bathing, feeding, and assistance with medications, are services customarily performed by home health aides in conjunction with a qualifying service. However, a beneficiary who needs only this type of personal or custodial care does not qualify for the home health benefit. Consequently, with no allowable skilled services, the home health aide services are also not medically necessary or reasonable. See Home Health Agency Manual § 206.2.

for a home health agency to enlist measures to prevent billing for dependent services after any qualifying service has ceased.⁶⁴ Any procedures or practices that a home health agency may implement in response to this identified risk will most likely correspond with other policy measures taken by the home health agency to ensure medical necessity.

e. Cost reports. In addition to submitting claims for specific services, home health agencies submit annual cost reports to Medicare for reimbursement of administrative, overhead, and other general costs. With regard to cost report issues, the written policies should include procedures that seek to ensure full compliance with applicable statutes, regulations, and Federal health care program requirements. Among other things, the home health agency's procedures should ensure that:

- Costs are not claimed unless they are reimbursable, reasonable, and are based on appropriate and accurate documentation;

- Allocations of costs to various cost centers are accurately made and supportable by verifiable and auditable data;

- Unallowable costs are not claimed for reimbursement;⁶⁵

- Accounts containing both allowable and unallowable costs are analyzed to determine the unallowable amount that should not be claimed for reimbursement;

- Costs are properly classified;⁶⁶

- Medicare fiscal intermediary prior year audit adjustments are implemented and are either not claimed for reimbursement or if claimed for reimbursement, are clearly identified as protested amounts on the cost report;

- All related parties are identified on the cost report and all related party charges are reduced to the cost to the related party;

- Allocations from a home health agency chain's home office cost statement to individual home health agency cost reports are accurately made

⁶⁴Recent audits conducted by the OIG have revealed several instances where home health agencies have submitted substantial numbers of claims for home health aide visits to beneficiaries that did not require any skilled qualifying service. See OIG ORT Report.

⁶⁵For administrative, overhead, and other general costs to be allowable under Medicare, regulations require that they be reasonable, necessary for the maintenance of the health care entity, and related to patient care. 42 CFR 413.9; see also Provider Reimbursement Manual, Chapter 21.

⁶⁶*E.g.*, time must be accurately split between reimbursable home health coordination and non-reimbursable patient solicitation activities (see note 32), and between visits to Medicare beneficiaries and visits to non-Medicare beneficiaries.

and supportable by verifiable and auditable data;

- Management fees are reasonable and necessary, and do not include unallowable costs, such as certain acquisition costs associated with the purchase of a home health agency (e.g., good will, non-competes);
- Any return of overpayments, including those resulting from an internal review or audit, are appropriately reflected in cost reports, i.e., a repayment of an overpayment received in a prior year may necessitate changes or amendments to the cost report applicable to the prior year; and
- Procedures are in place and documented for notifying promptly the Medicare fiscal intermediary (or any other applicable payor, e.g., TRICARE (formerly CHAMPUS) and Medicaid) in writing of errors discovered after the submission of the home health agency cost report, and, where applicable, after the submission of a home health agency chain's home office cost statement.

f. Services provided to patients who reside in assisted living facilities. Home health agencies should formulate effective policies and procedures to evaluate home health services provided to individuals who reside in assisted living facilities (also called residential care facilities, personal care homes, group homes, etc.) to determine whether the services are appropriate for reimbursement.⁶⁷ To avoid the submission of improper claims for services to such individuals, the adoption of the following measures is advisable upon a request to provide home health services to a resident of an assisted living facility:

- Contact the appropriate State licensing authority to determine any applicable State licensure and service requirements for the specific facility involved;
- Make reasonable attempts to verify the specific license, if any, held by the facility, e.g., view the license certificate hanging on the facility's wall;
- Request to view the service agreement between the facility and the resident during the initial assessment

⁶⁷ Individuals who reside in assisted living facilities may be eligible for Medicare coverage of home health services. See Home Health Agency Manual § 204.1B. However, if it is determined that the services furnished by the home health agency are duplicative of services furnished by an assisted living facility, such as when provision of such care is required of the facility under State licensure requirements, claims for such services are unallowable under 42 U.S.C. 1395y(a)(1)(A) and should not be submitted. Services to people who already have access to appropriate care from a willing caregiver would not be considered reasonable and necessary to the treatment of the individual's illness or injury. See Home Health Agency Manual § 203.2. See also note 37.

visit to determine the extent and type of the services that the facility is contractually obligated to provide to the resident; and

- Provide home health services to the resident only to the extent that they are appropriate and not duplicative of those services provided or required to be provided by the facility.⁶⁸

The OIG strongly recommends that a home health agency contact the appropriate State licensing authority if there is reason to believe a State-licensed facility is failing to provide care that is required by its licensure, regardless of whether claims for services provided to residents of such facilities would otherwise be reimbursable by Medicare or another Federal health care program.

g. Prospective payment system. The Balanced Budget Act of 1997 provides for the establishment of a prospective payment system (PPS) for all costs of home health services. Upon the commencement of such system, all services covered and paid on a reasonable cost basis under the Medicare home health benefit, including medical supplies, will be paid for on the basis of a computed prospective payment amount.⁶⁹ Once HHS institutes the PPS, home health agencies should guard against new types of fraud, abuse, and waste that might arise in such a reimbursement system. Potential risks may include failure to report or mischaracterization of a change in patient conditions used to establish the PPS charge, denial of medically necessary care resulting in under-utilization, and duplicate billing of charges subsumed within the PPS payment. Accordingly, home health agencies should prepare to implement policies and procedures to properly address any potential risk areas associated with the PPS.

4. Anti-Kickback and Self-Referral Concerns

The home health agency should have policies and procedures in place with respect to compliance with Federal and

⁶⁸ Audits and investigations by both the OIG and Medicare fiscal intermediaries have revealed several instances where home health aids of home health agencies have provided personal care services, such as meal preparation, room cleaning, and bathing, to Medicare beneficiaries who reside in assisted living facilities required by State license to provide such services. In addition to the customary liability assumed by a home health agency for submitting claims for such duplicative and unallowable services, a home health agency may violate the anti-kickback statute for providing these services at no charge to an assisted living facility, an entity that is responsible to perform the services and is a potential source of referrals.

⁶⁹ See Balanced Budget Act of 1997, Pub. L. 105-33, § 4603.

State anti-kickback statutes, as well as the Stark physician self-referral law.⁷⁰ Such policies should provide that:

- All of the home health agency's contracts and arrangements with actual or potential referral sources are reviewed by counsel and comply with all applicable statutes and regulations;⁷¹
- The home health agency does not submit or cause to be submitted to the Federal health care programs claims for patients who were referred to the home health agency pursuant to contracts or financial arrangements that were designed to induce such referrals in violation of the anti-kickback statute, Stark physician self-referral law, or similar Federal or State statute or regulation; and
- The home health agency does not offer or provide gifts, free services, or other incentives to patients, relatives of patients, physicians, hospitals, contractors, assisted living facilities, or other potential referral sources for the purpose of inducing referrals in violation of the anti-kickback statute, Stark physician self-referral law, or similar Federal or State statute or regulation.⁷²

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.⁷³

5. Retention of Records

Home health agency 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.⁷⁴ The three categories of documents developed under this system should include: (1) All records and documentation (e.g., clinical and

⁷⁰ Towards this end, the home health agency'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.dhhs.gov/progorg/oig>), and ensure that the home health agency's policies reflect the guidance provided by the OIG.

⁷¹ In addition to the anti-kickback statutes and the Stark physician self-referral law provisions, 42 CFR 424.22 expressly prohibits a home health agency from providing services certified or recertified by any physician who has a significant ownership interest in, or a significant financial or contractual relationship with, that home health agency.

⁷² See 42 U.S.C. 1320a-7b(b); 60 FR 40847 (1995).

⁷³ See 42 CFR 1001.952.

⁷⁴ This records system should be tailored to fit the individual needs and financial resources of the home health agency.

medical records, and billing and claims documentation) required either by Federal or State law for participation in Federal health care programs⁷⁵ or any other applicable Federal and State laws and regulations (e.g., document retention requirements to maintain State licensure); (2) all records, documentation, and verifiable and auditable data that support the home health agency's Medicare cost report, and, where applicable, the home health agency chain's home office cost statement; and (3) all records necessary to protect the integrity of the home health agency's compliance process and confirm the effectiveness of the program. The third category includes: documentation that employees were adequately trained; reports from the home health agency's hotline, including the nature and results of any investigation that was conducted; documentation of corrective action, including disciplinary action taken and policy improvements introduced, in response to any internal investigation or audit; modifications to the compliance program; self-disclosures; and the results of the home health agency's auditing and monitoring efforts.⁷⁶

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 involved in the claims and cost report development and submission processes 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 home health agency 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,

⁷⁵ For example, as a condition of participation, Medicare requires that home health agencies retain records regarding their claims to Medicare for a minimum of 5 years after the month the cost report to which the records apply is filed with the fiscal intermediary. See 42 CFR 484.48(a).

⁷⁶ The 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.

the compliance officer or home health agency management should include in the home health agency's compliance program a policy that managers and supervisors will be sanctioned for failing to adequately instruct their subordinates or for failing 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 home health agency the opportunity to correct them earlier.

B. Designation of a Compliance Officer and a Compliance Committee

1. Compliance Officer

Every home health agency 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 home health agency 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 home health agency with direct access to the home health agency's president or CEO, governing body, all other senior management, and legal counsel.⁷⁷ 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;⁷⁸
- Reporting on a regular basis to the home health agency's governing body,

⁷⁷ The OIG believes that it is not advisable for the compliance function to be subordinate to the home health agency's general counsel, or comptroller or similar home health agency 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 home health agency make this a feasible option), a system of checks and balances is established to more effectively achieve the goals of the compliance program.

⁷⁸ For multi-home health agency organizations or hospital-owned home health agencies, the OIG encourages coordination with each home health agency 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.

CEO, and compliance committee (if applicable) on the progress of implementation, and assisting these components in establishing methods to improve the home health agency's efficiency and quality of services, and to reduce the home health agency'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 payer health plans;

- Reviewing employees' certifications that they have received, read, and understood the standards of conduct;

- Developing, coordinating, and participating in a multifaceted 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 nursing or other health care services to the clients of the home health agency, or billing services to the home health agency, are aware of the requirements of the home health agency's compliance program with respect to coverage, billing, and marketing, among other things;

- Coordinating personnel issues with the home health agency's Human Resources/Personnel office (or its equivalent) to ensure that the National Practitioner Data Bank⁷⁹ and Cumulative Sanction Report⁸⁰ have been checked with respect to all employees, medical staff, and independent contractors (as appropriate);⁸¹

- Assisting the home health agency's financial management in coordinating internal compliance review and

⁷⁹ The 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.

⁸⁰ The Cumulative Sanction Report is an OIG-produced report available on the Internet at <http://www.dhhs.gov/progorg/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>.

⁸¹ The compliance officer may also have to ensure that the criminal backgrounds of employees have been checked depending upon State requirements or home health agency policy. See note 105.

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 home health agency policies and practices, taking appropriate disciplinary action, etc.) with all home health agency departments, subcontracted providers, and health care professionals under the home health agency's control,⁸² and any other agents if appropriate;

- Developing policies and programs that encourage managers and employees to report suspected fraud and other improprieties without fear of retaliation; and

- Continuing the momentum of the compliance program and the accomplishment of its objectives long after the initial years of implementation.⁸³

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 records, billing records, and records concerning the marketing efforts of the facility and the home health agency's arrangements with other parties, including employees, professionals on staff, relevant independent contractors, suppliers, agents, supplemental staffing entities, and physicians. 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, as well as the Stark physician self-referral prohibition and other legal or regulatory requirements.

2. Compliance Committee

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

⁸² E.g., physical therapists, occupational therapists, speech therapists, medical social workers, and supplemental staffing entities.

⁸³ Periodic on-site visits of home agency 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 article 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 home health agency's commitment to its policies and principles.

compliance program.⁸⁴ When developing an appropriate team of people to serve as the home health agency's compliance committee, including the compliance officer, a home health agency should consider a variety of skills and personality traits that are expected from those in such positions.⁸⁵ Once a home health agency chooses the people that will accept the responsibilities vested in members of the compliance committee, the home health agency 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 organization,⁸⁶ regulatory environment, the legal requirements with which it must comply,⁸⁷ and specific risk areas;
- Assessing existing policies and procedures that address these risk areas for possible incorporation into the compliance program;

- Working with appropriate home health agency 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;⁸⁸

⁸⁴ 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., Medical Director), 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 necessary changes to home health agency policies and procedures as recommended by the committee. A compliance committee for a home health agency that is part of a hospital might benefit from the participation of officials from other departments in the hospital, such as the accounting and billing departments.

⁸⁵ 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 home health agency and having significant professional experience working with billing, clinical records, documentation, and auditing principles.

⁸⁶ E.g., understanding the practical implications of the fraud and abuse provisions of the Balanced Budget Act of 1997, Pub. L. 105-33, and the Health Insurance Portability and Accountability Act of 1996, Pub. L. 104-191.

⁸⁷ This includes, but is not limited to, compliance with the Medicare conditions of participation. See 42 U.S.C. 1395bbb.

⁸⁸ With respect to multi-home health agency organizations and hospital-owned home health agencies, this may include fostering coordination

- 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 home health agency, and implementing corrective and preventive action.

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

C. Conducting Effective Training and Education

The proper education and training of corporate officers, managers, employees, nurses, 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, home health agencies 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.⁸⁹

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

and communication between those employees responsible for compliance at the corporation or hospital and those responsible for compliance at the home agencies.

⁸⁹ Specific compliance training should complement any "in-service" training sessions that a home health agency may regularly schedule to reinforce adherence to policies and practices of the particular home health agency.

requirements in a practical manner.⁹⁰ Managers of specific departments or groups can assist in identifying areas that require training and in carrying out such training.⁹¹ 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.⁹² Training programs and materials should be designed to take into account the skills, experience, and knowledge of the individual trainees. The compliance officer should document any formal training undertaken by the home health agency as part of the compliance program.

A variety of teaching methods, such as interactive training, and training in several different languages, particularly where a home health agency 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.⁹³ Targeted training should be provided to corporate officers, managers, and other employees whose actions affect the accuracy of the claims submitted to the Government, such as employees involved in the billing, cost reporting, and marketing processes. Given the complexity and interdependent relationships of many departments, proper coordination and supervision of this process by the compliance officer is important. 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

home health agency 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;
- Providing home health services with proper authorization;
- Proper documentation of services rendered, including the correct coding of official ICD and CPT coding rules and guidelines;
- 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 home health agency'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 home health agency.⁹⁴ Employees should be required to have a minimum number of educational hours per year, as appropriate, as part of their employment responsibilities.⁹⁵ For example, for certain employees involved in the billing functions, periodic training in applicable reimbursement coverage and documentation of clinical records should be required.⁹⁶ In home health agencies with high employee turnover, periodic training updates are critical.

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 home health agency should retain adequate records of its training of employees, including attendance logs and material distributed at training sessions.

Finally, the OIG recommends that home health agency compliance programs address the need for periodic professional education courses that may be required by statute and regulation for certain home health agency employees.

D. Developing Effective Lines of Communication

1. Access to the Compliance Officer

An open line of communication between the compliance officer and home health agency 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.⁹⁷ 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 command and supervisors or other personnel cannot divert such reports.⁹⁸

The OIG encourages the establishment of a procedure so that home health agency 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 home health agency 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

⁹⁰ 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 home health agency employees.

⁹¹ 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.

⁹² Certain positions, such as those that involve the billing of home health services, create a greater organizational legal exposure, and therefore require specialized training. One recommendation would be for a home health agency to attempt to fill such positions with individuals who have the appropriate educational background and training.

⁹³ Post-training tests can be used to assess the success of training provided and employee comprehension of the home health agency's policies and procedures.

⁹⁴ In addition, where feasible, the OIG recommends that a home health agency afford outside contractors the opportunity to participate in the home health agency's compliance training and educational programs, or develop their own programs that complement the home health agency's standards of conduct, compliance requirements, and other rules and practices.

⁹⁵ 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 1 to 3 hours annually for basic training in compliance areas. Additional training is required for specialty fields such as billing and marketing.

⁹⁶ Appropriate billing depends upon the quality and completeness of the clinical documentation. Therefore, OIG believes that active clinical staff participation in educational programs focusing on billing and documentation should be emphasized by the home health agency. Clinical staff should be reminded that thorough, precise, and timely documentation of services provided services the interests of the patient, as well as the interests of the billing department.

⁹⁷ 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.

⁹⁸ Home health agencies can also consider rewarding employees for appropriate use of established systems.

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,⁹⁹ e-mails, written memoranda, newsletters, suggestion boxes, and other forms of information exchange to maintain these open lines of communication.¹⁰⁰ If the home health agency 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.¹⁰¹ 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.¹⁰² Such information should be included in reports to the governing body, the CEO, and compliance committee.¹⁰³ Further, while the home health agency 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.

⁹⁹The OIG recognizes that it may not be financially feasible for a smaller home health agency to maintain a telephone hotline dedicated to receiving calls about compliance issues.

¹⁰⁰In 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 home health agency policy and procedures.

¹⁰¹Home health agencies 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.

¹⁰²To efficiently and accurately fulfill such an obligation, the home health agency should create an intake form for all compliance issues identified through 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.

¹⁰³Information obtained over the hotline may provide valuable insight into management practices and operations, whether reported problems are actual or perceived.

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.

E. 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 home health agency'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 home health agency'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, and other health care professionals for failing to comply with the home health agency'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 home health agency 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 home health agency 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 home health agency 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 home health agency. 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, home health agencies should conduct a reasonable and prudent background investigation, including a reference check,¹⁰⁴ as part of every such employment application. The application should specifically require the applicant to disclose any criminal conviction,¹⁰⁵ as defined by 42 U.S.C. 1320a-7(i), or exclusion action. Pursuant to the compliance program, home health agency policies should prohibit the employment of individuals who have been recently convicted of a criminal offense related to health care¹⁰⁶ or who are listed as debarred, excluded, or otherwise ineligible for participation in Federal health care programs.¹⁰⁷ In addition, pending the

¹⁰⁴See note 80.

¹⁰⁵Slightly over a quarter of the States require, and several home health agencies voluntarily conduct, criminal background checks for prospective employees of home health agencies. 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 home health. See United States General Accounting Office's September 27, 1996, *Letter Report* entitled "Long-Term Care: Some States Apply Criminal Background Checks to Home Care Workers," GAO/PEMD-96-5.

¹⁰⁶Since providers of home health services have frequent, relatively unsupervised access to potentially vulnerable people and their property, a home health agency should also strictly scrutinize whether it should employ individuals who have been convicted of crimes of neglect, violence, or financial misconduct.

¹⁰⁷Likewise, home health agency compliance programs should establish standards prohibiting 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.¹⁰⁸ With regard to current employees or independent contractors, if resolution of the matter results in conviction, debarment, or exclusion, the home health agency should terminate its employment or other contract arrangement with the individual or contractor.

F. 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 home health agency or corporate officers.¹⁰⁹ Compliance reports created by this ongoing monitoring, including reports of suspected noncompliance, should be maintained by the compliance officer and shared with the home health agency'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 home health agency confronts.

Although many monitoring techniques are available, one effective 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 home health agency's programs or divisions, including external relationships with third-party contractors, specifically those with substantive exposure to Government enforcement actions. At a

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 80.

¹⁰⁸ 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.

¹⁰⁹ Even when a home health agency or group of home health agencies is owned by a larger corporate entity, the regular auditing and monitoring of the compliance activities of an individual home health agency 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.

minimum, these audits should be designed to address the home health agency's compliance with laws governing kickback arrangements, the physician self-referral prohibition, claim development and submission, reimbursement, cost reporting, and marketing. The audits and reviews should inquire into the home health agency'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.¹¹⁰ In addition, the home health agency should focus on any areas of concern that are specific to the individual home health agency 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.¹¹¹ 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 home health agency 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 home health agency should take prompt steps to correct the problem. Any overpayments discovered as a result of such deviations should be returned promptly to the affected payor, with appropriate documentation and a sufficiently detailed explanation of the reason for the refund.¹¹²

Monitoring techniques may also include a review of any reserves the

¹¹⁰ See also section II.A.2.

¹¹¹ The OIG recommends that when a compliance program is established in a home health agency, 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 home health agency's progress in reducing or eliminating potential areas of vulnerability.

¹¹² 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.

home health agency has established for payments that it may owe to Medicare, Medicaid, or other Federal health care programs. Any reserves discovered that include funds that should have been paid to such programs, or funds set aside for potential reimbursement of a known overpayment to the home health agency, should be paid promptly, regardless of whether demand has been made for such payment.

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.¹¹³ 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 home health agency's operations. Such reviews could support a determination that appropriate records have been created and maintained to document the implementation of an effective program.¹¹⁴ 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 home health agency'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 homes;
- Analysis of utilization patterns;
- Testing clinical and billing staff on their knowledge of reimbursement coverage criteria and official coding guidelines (*e.g.*, present hypothetical scenarios of situations experienced in daily practice and assess responses);
- Assessment of existing relationships with physicians, hospitals, and other potential referral sources;
- Unannounced mock surveys, audits, and investigations;
- Reevaluation of deficiencies cited in past surveys for Medicare conditions of participation;

¹¹³ One way to assess the knowledge, awareness, and perceptions of the home health agency's employees is through the use of a validated survey instrument (*e.g.*, employee questionnaires, interviews, or focus groups).

¹¹⁴ 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 home health agency policies as a result of compliance activities.

- Examination of home health agency complaint logs;
- 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;
- Interviews with personnel involved in management, operations, claim development and submission, patient care, and other related activities;
- Questionnaires developed to solicit impressions of a broad cross-section of the home health agency's employees and staff;
- Interviews with physicians who order services provided by the home health agency;
- Reviews of clinical documentation (e.g., plan of care, nursing notes, etc.), financial records, and other source documents that support claims for reimbursement and Medicare cost reports;
- Validation of qualifications of physicians who order services provided by the home health agency;
- Evaluation of written materials and documentation outlining the home health agency'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;¹¹⁵
- 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.

With these reports, home health agency management can take whatever steps are necessary to correct past problems and prevent them from recurring. In certain cases, subsequent reviews or studies would be advisable to ensure that the recommended corrective

¹¹⁵ The OIG recognizes that home health agencies 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 outsider reviewers.

actions have been implemented successfully.

The home health agency should document its efforts to comply with applicable statutes, regulations, and Federal health care program requirements. For example, where a home health agency, 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 home health agency should document and retain a record of the request and any written or oral response. This step is extremely important if the home health agency 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 home health agency and third parties will help the organization document its attempts at compliance. In addition, the home health 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.

G. Responding to Detected Offenses and Developing Corrective Action Initiatives

1. Violations and Investigations

Violations of a home health agency's compliance program, failures to comply with applicable Federal or State law, and other types of misconduct threaten a home health agency's status as a reliable, honest and trustworthy provider capable of participating in Federal health care programs. Detected but uncorrected misconduct can seriously endanger the mission, reputation, and legal status of the home health agency. 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.¹¹⁶ As appropriate, such

¹¹⁶ 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.

steps may include an immediate referral to criminal and/or civil law enforcement authorities, a corrective action plan,¹¹⁷ a report to the Government,¹¹⁸ 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 home health agency'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 home health agencies 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, 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 home health agency and the situation, home health agencies should strive for some consistency by utilizing sound practices and disciplinary protocols.¹¹⁹

¹¹⁷ Advice from the home health agency's in-house counsel or an outside law firm may be sought to determine the extent of the home health agency's liability and to plan the appropriate course of action.

¹¹⁸ The OIG currently maintains a voluntary disclosure program 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 OIG's voluntary self-disclosure program has four prerequisites: (1) The disclosure must be on behalf of an entity and not an individual; (2) the disclosure must be truly voluntary (i.e., no pending proceeding or investigation); (3) the entity must disclose the nature of the wrongdoing and the harm to the Federal health care programs; and (4) the entity must not be the subject of a bankruptcy proceeding before or after the self-disclosure.

¹¹⁹ The parameters of a claim review subject to an internal investigation will depend on the

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 home health agency 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 home health agency determines that disciplinary action is warranted, it should be prompt and imposed in accordance with the home health agency'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 home health agency should promptly report the existence of misconduct to the appropriate Federal and State authorities¹²⁰ within a reasonable period, but not more than sixty (60) days¹²¹ after determining that there is credible evidence of a violation.¹²² Prompt reporting will

circumstances surrounding the issue(s) identified. By limiting the scope of an internal audit to current billing, a home health agency may fail to discover major problems and deficiencies in operations, as well as be subject to certain liability.

¹²⁰ 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 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, and the Department of Veterans Affairs and the Office of Personnel Management (which administers the Federal Employee Health Benefits Program).

¹²¹ 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 home health agency first obtained the information. 31 U.S.C. 3729(a).

¹²² The OIG believes that some violations may be so serious that they warrant immediate notification

demonstrate the home health agency'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.¹²³

When reporting misconduct to the Government, a home health agency 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 authorities¹²⁴ should be notified immediately.

As previously stated, the home health agency 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.¹²⁵ Failure to disclose

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.

¹²³ 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 (1997).

¹²⁴ See note 120.

¹²⁵ A home health agency should consult with its Medicare fiscal intermediary or HCFA for any

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 home health agency, as well as any individuals who may have been involved.¹²⁶ For this reason, home health agency compliance programs should emphasize that overpayments obtained from Medicare and other Federal health care programs should be promptly disclosed and returned to the payor that made the erroneous payment.

III. Conclusion

Through this document, the OIG has attempted to provide a foundation to the process necessary to develop an effective and cost-efficient home health agency compliance program. As previously stated, however, each program must be tailored to fit the needs and resources of an individual home health agency, 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 home health agency'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. In particular, the home health industry is currently responding to recent legislative changes that have created additional program participation requirements and is gearing up for the changes underway in the areas of home health reimbursement and payment methodologies. However, the time is right for home health agencies to implement a strong voluntary compliance program concept in health care. As stated throughout this guidance, compliance is a dynamic process that helps to ensure that home health agencies and other health care providers are better able to fulfill their commitment to ethical behavior, as well as meet the changes and challenges

further guidance regarding normal repayment channels. The home health agency'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.

¹²⁶ See U.S.C. 130a-7b(a)(3).

being imposed upon them by Congress and private insurers. Ultimately, it is OIG's hope that a voluntarily created compliance program will enable home health agencies 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 31, 1998.

June Gibbs Brown,
Inspector General.

[FR Doc. 98-20966 Filed 8-6-98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel Cooperative Trials in Diagnostic Imaging.

Date: August 11-12, 1998.

Time: 7:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Ramada Inn, 1775 Rockville Pike, Rockville, MD 20852.

Contact Person: Ray Bramhall, Scientific Review Administrator, Special Review, Referral and Resources Branch, Division of Extramural Activities, National Cancer Institute, National Institutes of Health, 6130 Executive Blvd., Rockville, MD 20892, (301) 496-3428.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399,

Cancer Control, National Institutes of Health, HHS)

Dated: July 31, 1998.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 98-21240 Filed 8-6-98; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel Prostate, Lung Colorectal and Ovarian Cancer Screening Trial Expansion.

Date: August 10, 1998.

Time: 12:00 PM to 2:00 PM.

Agenda: To review and evaluate contract proposals.

Place: 6130 Executive Blvd. 6th Floor, Rockville, MD 20852.

Contact Person: Wilna A. Woods, Deputy Chief, Special Review, Referral and Research Branch, Division of Extramural Activities, National Cancer Institute, National Institutes of Health, Rockville, MD 20852, (301) 496-7903.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control; 93.392, Cancer Construction, National Institutes of Health, HHS)

Dated: August 4, 1998.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 98-21246 Filed 8-6-98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center For Research Resources; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Center for Research Resources Special Emphasis Panel, American Type Culture Collection (ATCC) Contract Evaluation.

Date: September 2, 1998.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate contract proposals.

Place: The Bethesda Ramada, Ambassador One, 8400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: D.G. Patel, PHD, Scientific Review Administrator, Office of Review, National Center For Research Resources, 6705 Rockledge Drive, MSC 7965, Room 6018, Bethesda, MD 20892-7965, 301-435-0824.

Name of Committee: National Center for Research Resources Special Emphasis Panel Small Business Innovation Research.

Date: October 8, 1998.

Time: 10 a.m. to 12 p.m.

Agenda: To review and evaluate contract proposals.

Place: 6705 Rockledge Drive, Suite 6018, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: D.G. Patel, PHD, Scientific Review Administrator, Office of Review, National Center for Research Resources, 6705 Rockledge Drive, MSC 7965, Room 6018, Bethesda, MD 20892-7965, 301-435-0824.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine, 93.306; 93.333, Clinical Research, 93.333; 93.371, Biomedical Technology; 93.389, Research Infrastructure, National Institutes of Health, HHS)

Dated: July 31, 1998.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 98-21241 Filed 8-6-98; 8:45 am]

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