office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 21, 1999.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 99–2015 Filed 1–27–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–R–0249]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: New collection; Title of Information Collection: Hospice Cost Report and Supporting Regulations in 42 CFR 413.20, and 413.24; Form No.: HCFA–R–0249 (OMB# 0938-new); Use: Medicare certified hospice programs must file an annual cost report with HCFA. This report contains information on overhead costs, assets, depreciation, and compensation which will be used for hospice rate evaluations.; Frequency: Annually; Affected Public: Not-for-profit institutions, and Business or other for-profit; Number of Respondents: 1,720; Total Annual Responses: 1,720; Total Annual Hours: 302,720.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: January 19, 1999.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 99–2028 Filed 1–27–99; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–8003]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Revision of a currently approved collection; *Title of Information Collection:* Home and Community-Based Services Waiver Requests and Supporting Regulations in 42 CFR 440.180, and 441.301–441.310; *Form No.:* HCFA–8003 (OMB# 0938–0449); *Use:* Under a Secretarial waiver, States may offer a wide array of home and community-based services to individuals who would otherwise require institutionalization. States requesting a waiver must provide certain assurances, documentation and cost & utilization estimates which are reviewed, approved and maintained for the purpose of identifying/verifying States' compliance with such statutory and regulatory requirements. The purpose of this request is to provide authority for the State to furnish such individuals with services in the home and community-based setting; *Frequency:* When a State requests a waiver or amendment to a waiver; *Affected Public:* State, Local or Tribal Government; *Number of Respondents:* 50; *Total Annual Responses:* 128; *Total Annual Hours:* 7,860.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: January 19, 1999.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 99–2029 Filed 1–27–99; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Draft Compliance Guidance for the Durable Medical Equipment, Prosthetics, Orthotics and Supply Industry

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

ACTION: Notice and comment period.

SUMMARY: This **Federal Register** notice seeks the comments of interested parties

on draft compliance program guidance developed by the Office of Inspector General for the durable medical equipment, prosthetics, orthotics and supplier (DMEPOS) industry. Through this notice, the OIG is setting forth (1) its general views on the value and fundamental principles of DMEPOS suppliers' compliance programs, and (2) the specific elements that each DMEPOS supplier should consider when developing and implementing an effective compliance program. This document presents basic procedural and structural guidance for designing a compliance program, that is, a set of guidelines to be considered by a DMEPOS supplier interested in implementing a compliance program.

DATES: To assure consideration, comments must be delivered to the address provided below by no later than 5 p.m. on March 1, 1999.

ADDRESSES: Please mail or deliver written comments to the following address: Office of Inspector General, Department of Health and Human Services, Attention: OIG–3N–CPG, Room 5246, Cohen Building, 330 Independence Avenue, S.W., Washington, D.C. 20201.

We do not accept comments by facsimile (FAX) transmission. In commenting, please refer to the file code OIG–3N–CPG. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 5541 of the Office of Inspector General at 330 Independence Avenue, S.W., Washington, D.C. 20201 on Monday through Friday of each week from 8 a.m. to 4:30 p.m.

FOR FURTHER INFORMATION CONTACT: Christine Saxonis, Office of Counsel to the Inspector General, (202) 619–2078.

SUPPLEMENTARY INFORMATION:

A. Background

The creation of compliance program guidance has become a major initiative of the OIG in its efforts to engage the private health care community in addressing and fighting fraud and abuse. Recently, the OIG has developed and issued compliance program guidance directed at various segments of the health care industry in the following areas:

- Clinical laboratories (62 FR 9435; March 3, 1997, as amended in 63 FR 45076; August 24, 1998),
- Hospitals (63 FR 8987; February 23, 1998),
- Home health agencies (63 FR 42410; August 7, 1998), and
- Third party medical billing companies (63 FR 70138; December 18, 1998).

The guidance can also be found on the OIG web site at http://www.dhhs.gov/progorg/oig. The guidance is designed to provide clear direction and assistance to specific sections of the health care industry that are interested in reducing and eliminating fraud and abuse within their organizations.

In an effort to formalize the process by which the OIG obtains public input on the guidances, on August 7, 1998, the OIG published a solicitation notice seeking information and recommendations for developing guidance for the DMEPOS industry (63 FR 42409). In response to that solicitation notice, the OIG received a number of comments from various parts of the industry and their representatives. We have carefully considered previous OIG publications, such as the Special Fraud Alerts and the recent findings and recommendations in reports issued by the OIG's Office of Audit Services and Office of Evaluation and Inspections, as well as the experience of past and recent fraud investigations conducted by the OIG's Office of Investigations and the Department of Justice. We have also consulted with the Health Care Financing Administration and the durable medical equipment regional carriers.

B. Elements Addressed in This Guidance

This draft of DMEPOS guidance contains the following 7 elements that the OIG has determined are fundamental to an effective compliance program:

- 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.

These elements are contained in the other guidances issued by the OIG. As is the case with the other guidances, the contents of the guidance should not be viewed as mandatory for providers or as an exclusive discussion of the advisable elements of a compliance program.

In an effort to ensure that all parties have an opportunity to provide input into the OIG's guidance, we are publishing this latest guidance in draft form, and welcome any comments from interested parties regarding this guidance, particularly with respect to the section concerning written policies and procedures. We will consider all comments received in a timely manner, incorporate any recommendations as appropriate, and prepare and publish a final version of the DMEPOS guidance later this year.

C. Draft Compliance Program Guidance for the DMEPO Industry

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 suppliers [1] of durable medical equipment,[2] prosthetics,[3] orthotics,[4] and supplies [5] (DMEPOS) and their agents and subcontractors (referred to collectively in this document as ''DMEPOS suppliers'') develop effective internal controls that promote adherence to applicable Federal and State law, and the program requirements of Federal, State and private health plans. The adoption and implementation of voluntary compliance programs significantly advance the prevention of fraud, abuse, and waste in these health care plans while at the same time further the fundamental mission of all DMEPOS suppliers, which is to provide quality items, service, and care to patients.

Within this document, the OIG first provides its general views on the value and fundamental principles of DMEPOS suppliers' compliance programs, and then provides the specific elements that each DMEPOS supplier should consider when developing and implementing an

[1] The term ''supplier'' is defined in this document as an entity or individual, including a physician or Part A provider, which sells or rents Part B covered items. See 42 CFR 424.57(a).

[2] The term ''durable medical equipment'' is applied in this document as defined in 42 U.S.C. 1395x(n).

[3] The term ''prosthetics'' and ''prosthetic devices'' are applied in this document as defined in 42 U.S.C. 1395 x (s)(9) and (s)(8), respectively.

[4] The term ''orthotics'' is applied in this document as defined in 42 U.S.C. 1395x(s)(9).

[5] The term ''supplies'' includes home dialysis supplies and equipment as described in 42 U.S.C. 1395x(s)(2)(f); surgical dressings and other devices as described in 42 U.S.C. 1395x(s)(5); immunosuppressive drugs as described in 42 U.S.C. 1395x(s)(2)(J); and any other items or services designated by the Health Care Financing Administration (HCFA).

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 DMEPOS supplier interested in implementing a compliance program.

The OIG recognizes the size-differential that exists between operations of the different DMEPOS suppliers and organizations that compose the DMEPOS supplier industry. Appropriately, this guidance is pertinent for all DMEPOS suppliers, regardless of size (in terms of employees and gross revenue); number of locations; type of equipment provided; or corporate structure. The applicability of the recommendations and guidelines provided in this document depends on the circumstances of each individual DMEPOS supplier. However, regardless of a DMEPOS supplier's size or structure, the OIG believes that every DMEPOS supplier 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 DMEPOS supplier 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 DMEPOS supplier's ethical and business policies. In practice, the compliance program should effectively articulate and demonstrate the DMEPOS supplier's commitment to ethical conduct. 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 DMEPOS supplier operations.

Specifically, compliance programs guide a DMEPOS supplier's owner(s), governing body (e.g., board of directors or trustees), chief executive officer (CEO), president, vice presidents, managers, sales representatives, billing personnel, and other employees in the efficient management and operation of a DMEPOS supplier. They are especially critical as an internal quality assurance 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 DMEPOS supplier's owner(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 DMEPOS supplier's leadership as a measure of the organization's commitment to compliance. Indeed, many DMEPOS suppliers have adopted mission statements articulating their commitment to high ethical standards. A formal compliance program, as an additional element in this process, offers a DMEPOS supplier a further concrete method that may improve quality of service 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 Federal, State and private health care program requirements.

Implementing an effective compliance program requires a substantial commitment of time, energy, and resources by senior management and the DMEPOS supplier's governing body.[6] Superficial programs that simply have the appearance of compliance without being wholeheartedly adopted and implemented by the DMEPOS supplier or programs that are hastily constructed and implemented without appropriate ongoing monitoring will likely be ineffective and could expose the DMEPOS supplier to greater liability than no program at all. Although it may require significant additional resources or reallocation of existing resources to implement an effective compliance program, the long term benefits of implementing the program significantly outweigh the costs. Undertaking a voluntary compliance program is a beneficial investment that advances both the DMEPOS supplier's organization and the stability and solvency of the Medicare program.

A. Benefits of a Compliance Program

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

- The formulation of effective internal controls to assure compliance with Federal and State statutes, rules, and regulations, and Federal, State and private payor health care program requirements, and internal guidelines;
- A concrete demonstration to employees and the community at large of the DMEPOS supplier's strong commitment to honest and responsible corporate conduct;
- The ability to obtain an accurate assessment of employee and contractor behavior relating to fraud and abuse;
- An increased likelihood of identification and prevention of criminal and unethical conduct;
- The ability to more quickly and accurately react to employees' operational compliance concerns and the capability to effectively target resources to address those concerns;
- Improvement of the quality, efficiency, and consistency of providing services;
- Increased efficiency on the part of employees;
- A centralized source for distributing information on health care statutes, regulations, policies, and other program directives regarding fraud and abuse and related issues;
- Improved internal communication;
- A methodology that encourages employees to report potential problems;
- Procedures that allow the prompt, thorough investigation of alleged misconduct by corporate officers, managers, sales representatives, employees, independent contractors, consultants, clinicians, and other health care professionals;
- Initiation of immediate, appropriate, and decisive corrective action;
- Early detection and reporting, minimizing the loss to the Government from false claims, and thereby reducing the DMEPOS supplier's exposure to civil damages and penalties, criminal sanctions, and administrative remedies, such as program exclusion;[7] and

[6] 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).

[7] 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. However, the burden is on the DMEPOS

Continued

• Enhancement of the structure of the DMEPOS supplier's operations and the consistency between: any related entities of the DMEPOS supplier; different departments within the DMEPOS supplier; the DMEPOS supplier's different locations; and the DMEPOS supplier's separate business units (e.g., franchises, subsidiaries).

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

The OIG recognizes that the implementation of a compliance program may not entirely eliminate fraud, abuse, and waste from the DMEPOS supplier system. However, a sincere effort by DMEPOS suppliers to comply with applicable Federal and State statutes, rules, and regulations and Federal, State and private payor health care program requirements, 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'' DMEPOS supplier compliance program.[8] The OIG understands the variances and complexities within the DMEPOS supplier industry and is sensitive to the differences among large national and regional DMEPOS supplier organizations, and small independent DMEPOS suppliers. However, elements of this guidance can be used by all DMEPOS suppliers, regardless of size (in terms of employees and gross revenue); number of locations; type of equipment provided; or corporate structure, to establish an effective compliance program. Similarly, a DMEPOS supplier or corporation that owns a DMEPOS supplier or provides DMEPOS supplies may incorporate these elements into its system-wide compliance or managerial structure.[9] We recognize that some DMEPOS suppliers 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 DMEPOS supplier can best establish internal controls and monitor its conduct to correct and prevent fraudulent activities. By no means should the contents of this guidance be viewed as an exclusive discussion of the advisable elements of a compliance program. On the contrary, the OIG strongly encourages DMEPOS suppliers to develop and implement compliance elements that uniquely address the individual DMEPOS supplier's risk areas.

The OIG believes that input and support by individuals and organizations that will utilize the tools set forth in this document is critical to the development and success of this compliance program guidance. In a continuing effort to collaborate closely with the private sector, the OIG placed a notice in the **Federal Register** soliciting recommendations and suggestions on what should be included in this compliance program guidance.[10] Further, we considered previous OIG publications, such as Special Fraud Alerts, advisory opinions,[11] the 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 DMEPOS suppliers 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 statutes, rules, regulations, policies, and procedures of the Federal, State and private health plans occur. The OIG understands DMEPOS suppliers will need adequate time to react to these modifications and expansions and to make any necessary changes to their voluntary compliance programs. 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 DMEPOS suppliers often raise sensitive and complex legal and managerial issues.[12] 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 other OIG compliance program guidances[13] and the OIG's corporate integrity agreements.[14] The OIG believes that every DMEPOS supplier can benefit from the principles espoused in this guidance, which can be tailored to fit the needs and financial realities of a particular DMEPOS supplier.

The OIG believes that every effective compliance program must begin with a formal commitment[15] by the DMEPOS supplier's governing body to include *all* of the applicable elements listed below, which are based on the seven steps of the Federal Sentencing Guidelines.[16] The OIG recognizes full implementation of all elements may not be immediately feasible for all DMEPOS suppliers. However, as a first step, a good faith and meaningful commitment on the part of

supplier to demonstrate the operational effectiveness of a compliance program. Further, the False Claims Act, 31 U.S.C. 3729–3733, provides that a person who has violated the Act, but who voluntarily discloses the violation to the Government within 30 days of detection, in certain circumstances will be subject to not less than double, as opposed to treble, damages. See 31 U.S.C. 3729(a). Thus, the ability to react quickly when violations of the law are discovered may materially help reduce the DMEPOS supplier's liability.

[8] This is particularly true in the context of DMEPOS suppliers, which include many small independent DMEPOS suppliers with limited financial resources and staff, as well as large DMEPOS supplier chains with extensive financial resources and staff.

[9] For Medicare, this would include any individual or entity that meets the supplier standards as described in 42 CFR 424.57 and has a National Supplier Clearinghouse Number.

[10] See 63 FR 42409 (August 7, 1998), Notice for Solicitation of Information and Recommendations for Developing OIG Compliance Program Guidance for the Durable Medical Equipment Industry.

[11] The OIG periodically issues advisory opinions responding to specific inquiries from members of the public and Special Fraud Alerts setting forth activities that raise legal and enforcement issues. Special Fraud Alerts and Advisory Opinions, as well as the regulations governing issuance of advisory opinions can be obtained on the Internet at: http://www.dhhs.gov/progorg/oig, in the **Federal Register**, or by contacting the OIG's Public Information Desk at (202) 619–1142.

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

[13] See 63 FR 70138 (December 18, 1998) for the Compliance Program Guidance for Third Party Medical Billing Companies; 63 FR 42410 (August 7, 1998) for the Compliance Program Guidance for Home Health Agencies; 63 FR 45076 (August 24, 1998) for the Compliance Program Guidance for Clinical Laboratories, as revised; 63 FR 8987 (February 23, 1998) for the Compliance Program Guidance for Hospitals. These documents are also located on the Internet at http://www.dhhs.gov/progorg/oig.

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

[15] A formal commitment may include a resolution by the board of directors, owner(s) or president, where applicable. A formal commitment should include the allocation of adequate resources to ensure that each of the elements is addressed.

[16] 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.

the DMEPOS supplier, especially the owner(s), governing body, president, vice presidents, CEO, and managing employees, will substantially contribute to the program's successful implementation. As the compliance program is implemented, that commitment should cascade down through the management to every employee of the DMEPOS supplier.

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 DMEPOS supplier'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, completing certificates of medical necessity (CMNs), and financial relationships with physicians and/or other persons authorized to order DMEPOS;

(2) The designation of a compliance officer and other appropriate bodies, (e.g., a corporate compliance committee), charged with the responsibility for operating and monitoring the compliance program, and who report directly to the CEO and the governing body; [17]

(3) The development and implementation of regular, effective education and training programs for all affected employees; [18]

(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 callers 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, State or private payor health care program requirements; [19]

(6) The use of audits and/or other risk evaluation techniques to monitor compliance, identify problem areas, and assist in the reduction of identified problem areas; [20] and

(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 individual DMEPOS supplier. These policies, standards, and practices should be developed under the direction and supervision of the compliance officer and the compliance committee (if such a committee is practicable for the DMEPOS supplier) and, at a minimum, should be provided to all individuals who are affected by the particular policy at issue, including the DMEPOS supplier's agents and independent contractors who may affect billing decisions.[21] In addition to these general corporate policies, it may be necessary to implement individual policies for the different components of the DMEPOS supplier.

1. Standards of Conduct. DMEPOS suppliers should develop standards of conduct for all affected employees that include a clearly delineated commitment to compliance by the DMEPOS supplier's senior management,[22] including any related entities or affiliated providers operating under the DMEPOS supplier's control,[23] and other health care professionals (e.g., nurses, licensed pharmacists, physicians, and respiratory therapists). The standards of conduct should function in the same fashion as a constitution, i.e., as a foundational document that details the fundamental principles, values, and framework for action within the DMEPOS supplier. The standards should articulate the DMEPOS supplier's commitment to comply with all Federal and State statutes, rules, regulations and Federal, State and private payor health care program requirements, with an emphasis on preventing fraud and abuse. They should explicitly state the organization's mission, goals, and ethical principles relative to compliance and clearly define the DMEPOS supplier's commitment to compliance and its expectations for all DMEPOS supplier owners, governing body members, president, vice presidents, corporate officers, managers, sales representatives, employees, and, where appropriate, independent contractors and other agents. These standards should promote integrity, support objectivity, and foster trust. Standards should not only address compliance with statutes and regulations, but should also set forth broad principles that guide employees in conducting business professionally and properly.

The standards should be distributed to, and comprehensible by, all affected employees (e.g., translated into other languages when necessary and written at appropriate reading levels). Further, to assist in ensuring that employees continuously meet the expected high standards set forth in the standards of conduct, any employee handbook delineating or expanding upon these standards should be regularly updated as applicable statutes, regulations, and Federal, State and private payor health care program requirements are modified and/or clarified.[24]

[17] The integral functions of the compliance officer and the corporate compliance committee in implementing an effective compliance program are discussed throughout this compliance program guidance. However, the OIG recognizes that the differences in the sizes and structures of DMEPOS suppliers will result in differences in the ways in which compliance programs are set up. The important thing is that the DMEPOS supplier structures its compliance program in such a way that the program is able to accomplish the key functions of the corporate compliance officer and the corporate compliance committee discussed within this document.

[18] Training and education programs for DMEPOS suppliers should be detailed and comprehensive. They should cover specific billing procedures, sales and marketing practices, as well as the general areas of compliance. See section II.C and accompanying notes.

[19] 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, directives, and instructions governing Medicare, Medicaid, and all other Federal health care programs.

[20] For example, spot-checking the work of coding and billing personnel periodically should be an element of an effective compliance program.

[21] 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(d).

[22] The OIG strongly encourages high-level involvement by the DMEPOS supplier's owner(s), governing body, chief executive officer, president, vice presidents, as well as other personnel, as appropriate, in the development of standards of conduct. Such involvement should help communicate a strong and explicit organizational commitment to compliance goals and standards.

[23] E.g., pharmacies, billing services, and manufacturers.

[24] The OIG recognizes that not all statutes, rules, regulations, standards, policies, and procedures need to be communicated to all employees.

Continued

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

2. Written Policies for Risk Areas. As part of its commitment to compliance, DMEPOS suppliers should establish a comprehensive set of written policies and procedures that take into consideration the particular statutes, rules, regulations and program instructions applicable to each function of the DMEPOS supplier.[25] In contrast to the standards of conduct, which are designed to be a clear and concise collection of fundamental standards, the written policies should articulate specific procedures personnel should follow.

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.[26] Some of the special areas of OIG concern include:[27]

- Billing for items or services not provided;[28]
- Billing for medically unnecessary services;[29]
- Duplicate billing;[30]
- Billing for items or services not ordered;[31]
- Using a billing agent whose compensation is based on the dollar amounts billed or based on the actual collection of payment;[32]
- Upcoding;[33]
- Billing patients for denied charges without a signed written notice;[34]
- Unbundling items or supplies;[35]
- Billing for new equipment and providing used equipment;[36]
- Continuing to bill for rental items after they are no longer medically necessary;[37]
- Resubmission of denied claims with different and incorrect information in an attempt to be reimbursed;[38]
- Refusing to submit a claim to Medicare;[39]
- Inadequate management and oversight of contracted services, which results in improper billing;[40]

Charge limitations;[41]

- Providing and/or billing substantially excessive amounts of DMEPOS items or supplies;[42]

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 DMEPOS supplier must decide whether additional educational programs should be targeted to specific categories of employees based on job functions and areas of responsibility.

[25] A DMEPOS supplier 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 DMEPOS supplier's policies and procedures. Such employee participation in the development of the DMEPOS supplier's compliance program can enhance its credibility and foster employee acceptance of the program.

[26] DMEPOS supplier compliance programs should require that the legal staff, compliance officer, or other appropriate personnel carefully consider any and all Special Fraud Alerts and advisory opinions issued by the OIG that relate to DMEPOS suppliers. See note 11. Moreover, the compliance programs should address the ramifications of failing to cease and correct any conduct criticized in such a Special Fraud Alert or advisory opinion, if applicable to DMEPOS suppliers, or to take reasonable action to prevent such conduct from reoccurring in the future. If appropriate, a DMEPOS supplier should take the steps described in section G regarding investigations, reporting, and correction of identified problems.

[27] The OIG's work plan is currently available on the Internet at: http://www.dhhs.gov/progorg/oig. 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.

[28] Billing for items or services not provided involves submitting a claim representing the DMEPOS supplier provided an item or service or part of an item or service that the patient did not receive.

[29] Billing for medically unnecessary services involves 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 a HCFA claim form (whether paper or electronic), a DMEPOS supplier certifies that the services provided and billed were medically necessary for the health of the beneficiary, and were provided in accordance with orders by the beneficiary's treating physician or other authorized person. In limited instances, HCFA does allow DMEPOS suppliers to submit claims when the DMEPOS supplier believes the item or service may be denied. Such instances include, but are not limited to: when a beneficiary has signed a written notice (see *Medicare Carriers Manual*, section 7300.5) (See also section II.A.3.i for further discussion on written notices); and when the beneficiary requests the DMEPOS supplier to submit the claim (see *Medicare Carriers Manual*, section 3043). In the first instance, the DMEPOS supplier should include modifier ''GA'' on the claim, which indicates the beneficiary has signed a written notice. In the latter instance, the DMEPOS supplier should use modifier ''ZY.'' Civil monetary penalties and administrative sanctions 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–7a(a). Remedies may also be available under criminal and civil law, including the False Claims Act. See discussion in section II.A.3.a and accompanying notes.

[30] Duplicate billing occurs when more than one claim for payment is submitted for the same patient, for the same service, for the same date of service (by the same or different DMEPOS suppliers), or the same claim is submitted to more than one primary payor. Although duplicate billing can occur due to simple error, fraudulent duplicate billing is evidenced by systematic or repeated double billing, and creates liability under criminal, civil, or administrative law, particularly if any overpayment is not promptly refunded.

[31] Billing for items or services not ordered involves seeking reimbursement for services provided but not ordered by the treating physician or other authorized person.

[32] DMEPOS supplier billing agents may only receive payment based on a fixed fee, and not based upon a percentage of revenue. See 42 U.S.C. 1395u(b)(6); 42 CFR 424.73; *Medicare Carriers Manual*, section 3060; 3060.10.

[33] Upcoding involves selecting a code to maximize reimbursement when such a code is not the most appropriate descriptor of the service (e.g., billing for a more expensive piece of equipment when a less expensive piece of equipment is provided).

[34] This includes, but is not limited to, billing the patient for items or services denied by the payor on assigned claims, where there has been no written notice signed by the patient, the written notice has been inappropriately obtained or the written notice was drafted inappropriately. See *Medicare Carrier Manual*, section 7300.5A, regarding the requirements for written notice.

[35] Unbundling items or supplies involves billing for individual components when a specific HCPCs code provides for the components to be billed as a unit (e.g., providing a wheelchair and billing the individual parts of the wheelchair, rather than the wheelchair as a whole).

[36] The DMEPOS supplier must indicate on the Medicare claim form, through the use of modifiers, whether the item provided is new or used. The modifier for providing new equipment is ''NU.'' The modifier for providing used equipment is ''UE.'' A knowing failure to correctly document the item provided would constitute falsifying information on the claim form and would constitute a violation of the False Claims Act. See 31 U.S.C. 3729.

[37] Once a rental item is no longer medically necessary, the DMEPOS supplier is required to discontinue billing the payor for it. In addition, the OIG recommends the DMEPOS supplier pick up such equipment from the patient in a timely manner.

[38] This practice involves the DMEPOS supplier improperly changing information on a previously denied claim and continuing to resubmit the claim in an attempt to receive payment.

[39] This practice involves a DMEPOS supplier not submitting a claim to the Medicare program on behalf of the beneficiary. Irrespective of whether or not a DMEPOS supplier accepts assignment, it is obligated to submit the claim on behalf of the beneficiary. See 42 U.S.C 1395w–4(g)(4).

[40] DMEPOS suppliers should create internal mechanisms to ensure that the use of contractors does not lead to improper billing practices.

[41] DMEPOS suppliers should ensure their billing personnel are informed of the different payment rules of all Federal, State, and private health care programs they bill. DMEPOS suppliers should be aware that billing for items or services furnished substantially in excess of the DMEPOS supplier's usual charges may result in exclusion. See 42 U.S.C. 320a–7(b)(6)(A). See also OIG Ad. Op. 98–8 (1998) regarding this issue.

[42] This practice, which constitutes overutilization, involves providing and/or billing for substantially more items or supplies than are reasonable and necesssary for the needs of each individual patient. Such practices may lead to exclusion from Federal health care programs. See 42 U.S.C. 1320a–7(b)(6)(B).

• Providing and/or billing for an item or service that does not meet the quality and standard of the DMEPOS item claimed (e.g., item provided is in violation of Food and Drug Administration (FDA) regulations and standards); [43]

• Capped rentals; [44]

• Failure to monitor medical necessity on an on-going basis; [45]

• Dispensing certain items or supplies prior to receiving a physician's order and/or appropriate CMN; [46]

• Falsifying information on the claim form, CMN, and/or accompanying documentation; [47]

• Completing portions of CMNs reserved for completion only by treating physician or other authorized person; [48]

• Altering medical records; [49]

• Manipulating the patient's diagnosis in order to receive payment; [50]

• Failing to maintain medical necessity documentation; [51]

• Inappropriate use of place of service codes; [52]

• Inappropriate use of cover letters; [53]

• Improper use of ZX modifier; [54]

• Providing incentives to actual or potential referral sources (e.g., physicians, hospitals, patients, etc.) that may violate the anti-kickback statute or other similar Federal or State statute or regulation; [55]

• Compensation programs that offer incentives for items or services ordered and revenue generated; [56]

• Routine waiver of deductibles and coinsurance; [57]

• Joint ventures between parties, one of whom can refer Medicare or Medicaid business to the other; [58]

• Situations where conflict of interest may result due to referrals by physicians that own or have compensation arrangements with DMEPOS supply companies; [59]

• Billing for items or services furnished pursuant to a prohibited referral under the Stark physician self-referral law; [60]

• Improper telemarketing practices; [61]

• Improper patient solicitation activities and high-pressure marketing of non-covered or unnecessary services; [62]

• Co-location of DMEPOS items and supplies with the referral source; [63]

[43] This practice involves providing and/or billing for an item or service that does not meet the definition and/or requirement of the item or service ordered by the treating physician or other authorized person. Generally, such items are inferior in quality, and therefore, do not meet the definition of what was ordered and/or billed. Sometimes this may mean that products were never determined to be safe and effective by the FDA, as required by law. This practice may lead to billing for items that are not reasonable and necessary. DMEPOS suppliers should ensure that the items or services they furnish meet professionally recognized minimum standards of health care.

[44] See discussion in section II.A.3.k and accompanying notes.

[45] In order for a patient to continue to receive items or supplies (e.g., rental equipments, supplies for an on-going condition), the patient must meet the medical necessity criteria for that specific item or supply on an on-going basis. The items or supplies furnished by the DMEPOS supplier should be replaced or adjusted, in a timely manner, to reflect changes in the patient's condition.

[46] This practice involves the DMEPOS supplier dispensing to the patient, and/or billing the payor for, items or supplies that have not yet been ordered by the treating physician or other authorized person. Medicare requires written physician orders for certain items before dispensing. See 42 CFR 410.38.

[47] This practice involves supplying false information to be included on the claim form, the CMN, or other accompanying documentation. The information reported on these documents should accurately reflect the patient's information, including medical information, and the items or services ordered by the treating physician or other authorized person and provided by the DMEPOS supplier.

[48] This practice involves not completing the CMN in compliance with Medicare regulations (i.e., sections B and D should never be completed by the supplier). Instructions for completing the CMN can be found on the back of the form. See section 3312 of the *Medicare Carriers Manual,* which provides instructions on how to complete the CMN and the civil monetary penalties (CMPs) that may be assessed for improper completion of the CMN. See also 42 U.S.C. 1395m(j)(2); section II.A.3.c and accompanying notes for further discussion on CMNs.

[49] This practice involves the DMEPOS supplier falsifying information on the medical records to justify reimbursement for an item or service.

[50] This practice involves the DMEPOS supplier incorrectly altering the diagnosis in order to receive reimbursement for the particular item or service. A DMEPOS supplier should not claim the patient has a particular medical condition in order to qualify for an item for which he or she would not otherwise qualify.

[51] This practice involves failing to ensure that the medical necessity documentation requirements for the item or service billed are properly met (e.g., failing to maintain the original physician orders or CMNs or failing to ensure that CMNs contain adequate and correct information). See section 4105.2 of the *Medicare Carriers Manual* for evidence of medical necessity. See also sections II.A.3.b and II.A.3.c regarding physician orders and CMNs, respectively.

[52] This practice involves indicating on the claim form that the place of service is a location other than where the service was provided. For example, the patient resides in a skilled nursing facility (SNF) and the DMEPOS supplier submits a claim with the place of service being the patient's home. Provided that the DMEPOS items or services are ordered, provided, reasonable and necessary given the clinical condition of the patient, the items or services may be covered if the beneficiary resides at home. However, such items may not be covered if the beneficiary resides in a SNF. See *Medicare Carriers Manual,* section 2100.3 for the definition of a beneficiary's home.

[53] This practice involves sending the treating physician or other authorized person a cover letter attached to the CMN that contains information that the physician is supposed to include on the CMN or otherwise may lead the physician to order medically unnecessary equipment or supplies for the specified patient. Cover letters should only be used to describe what is being ordered and how it is to be administered. See discussion in section II.A.3.m.

[54] This practice involves the improper use of the ZX modifier, relating to maintaining medical necessity documentation. See discussion in section II.A.3.l.

[55] Examples of arrangements that may run afoul of the anti-kickback statute include practices in which a DMEPOS supplier pays a fee to a physician for each CMN the physician signs, provides free gifts to physicians for signing CMNs, and/or provides items or services for free or below fair market value to providers or beneficiaries of Federal health care programs. *See* 42 U.S.C. 1320a–7b(b); 60 FR 40847 (August 10, 1995). See also discussion in section II.A.4. and accompanying notes.

[56] Compensation programs that offer incentives for items or services ordered or the revenue they generate may lead to the ordering of medically unnecessary items or supplies and/or the ''dumping'' of such items or supplies in a facility or in a beneficiary's home (e.g., mail order supply companies that continue to send the patient supplies when the supplies are no longer medically necessary).

[57] See discussion in section II.A.3.j and accompanying notes.

[58] Equally 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, such as a DMEPOS supplier, 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. The OIG has also issued a Special Fraud Alert on Joint Venture Arrangements. This Special Fraud Alert can be found at 59 FR 65372 (December 19, 1994) or on the Internet at: http://www.dhhs.gov/progorg/oig.

[59] See 42 U.S.C. 1395nn.

[60] Under the Stark physician self-referral law, if a physician (or an immediate family member of such physician) has a financial relationship with a DMEPOS supplier, the physician may not make a referral to the DMEPOS supplier and the DMEPOS supplier may not bill for furnishing DMEPOS items or supplies for which payment may be made under the Federal health care programs. See 42 U.S.C. 1395nn.

[61] See 42 U.S.C. 1395m(a)(17) or Pub.L. 103–432, section 132(a) for the prohibition on telemarketing. See also discussion in section II.A.5 and accompanying notes.

[62] DMEPOS suppliers should not utilize prohibited or inappropriate conduct to carry out their initiatives and activities designed to maximize business growth and patient retention. Many cases against DMEPOS suppliers have involved the DMEPOS supplier giving the beneficiary free gifts such as angora underwear, microwaves and air conditioners in exchange for providing and billing for unnecessary items. Any marketing information offered by DMEPOS suppliers should be clear, correct, non-deceptive, and fully informative. See discussion in section II.A.5 and accompanying notes.

[63] In this situation, a physician allows a DMEPOS supplier to stock space (space may or may not be rented by the DMEPOS supplier) in a physician's office with DMEPOS items and supplies. When such items and supplies are dispensed to the patient, Medicare is then billed. DEMPOS suppliers should check the policy of the individual durable medical equipment regional carrier(s) (DMERC) they bill with regard to this arrangement. Although such arrangements are not prohibited by a national policy, the OIG believes that such arrangements may potentially raise anti-kickback and self-referral issues.

• Non-compliance with the Federal, State and private payor supplier standards; [64]

• Providing false information on the Medicare DMEPOS supplier enrollment form; [65]

• Not providing corrected information on the DMEPOS supplier enrollment form in a timely manner; [66]

• Misrepresentation of a person's status as an agent or representative of Medicare; [67]

• Knowing misuse of supplier number, which results in improper billing; [68]

• Failing to meet individual payor requirements; [69]

• Performing tests on a beneficiary that a DMEPOS supplier is not authorized to perform; [70]

• Failing to refund overpayments to a health care program; [71]

• Failing to refund overpayments to patients; [72]

• Lack of communication between the DMEPOS supplier, the physician, and the patient; [73]

• Lack of communication between different departments within the DMEPOS supplier; [74] and

• Employing persons excluded from participation in Federal health care programs. [75]

A DMEPOS supplier's prior history of noncompliance with applicable statutes, regulations, and Federal, State or private health care program requirements may indicate additional types of risk areas where the DMEPOS supplier may be vulnerable and that may require necessary policy measures to be taken to prevent avoidable recurrence.[76] Additional risk areas should be assessed by DMEPOS suppliers and incorporated into the written policies and procedures and training elements developed as part of their compliance program.

3. *Claims Development and Submission*. a. *Medical Necessity*. A DMEPOS supplier's compliance program should ensure that services are billed only if they were ordered by the treating physician or other authorized person, have been provided, are covered, and are reasonable and necessary given the clinical condition of the patient.[77] DMEPOS suppliers must keep the treating physician's or other authorized person's original signed and dated order or CMN on file for all DMEPOS items and services.[78] Because the DMEPOS supplier is in a unique position to inform its clients who write orders and refer patients, the DMEPOS supplier may want to send a written notice to such clients concerning the necessary paperwork requirements.

As a preliminary matter, the OIG recognizes that physicians and other authorized persons must be able to order any items or services 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 the appropriate medical necessity standards (e.g., ordered, provided, covered, reasonable, necessary, and criteria established by medical review policies). DMEPOS suppliers should not knowingly bill for services that do not meet the applicable medical necessity standards.[79] Upon a payor's request, the DMEPOS supplier must be able to provide documentation, such as original orders, proof of delivery, completed original certificates of medical necessity, written confirmation of verbal orders and any other documentation, to support the medical necessity of an item or service that the DMEPOS supplier has provided. [80]

Although DMEPOS suppliers do not and cannot treat patients or make medical necessity determinations, there are steps that a DMEPOS supplier can take to help maximize the likelihood that they only bill for services that are ordered, provided, covered, reasonable and necessary for each individual patient. The OIG recommends that DMEPOS supplier personnel understand the coverage and payment criteria of each payor they bill. To help aid supplier personnel, the DMEPOS supplier's compliance officer may want to create a clear, comprehensive summary of the ''medical necessity'' or coverage criteria and applicable rules of the various Government and private plans. This summary should be disseminated and explained to the appropriate DMEPOS supplier personnel.

We also recommend that DMEPOS suppliers formulate internal control mechanisms through their written policies and procedures. Such policies and procedures should include periodic claim reviews, both prior and subsequent to billing for items and services. Such a procedure will verify that patients are receiving and the DMEPOS supplier is billing for items and/or services that are ordered,

[64] See 42 CFR 424.57 for the Medicare supplier standards. DMEPOS suppliers may have the appropriate personnel acknowledge they have reviewed and will abide by these standards. In addition, DMEPOS suppliers should ensure they are meeting individual state and private payor supplier standards.

[65] Criminal penalties may be imposed against an individual who knowingly and willfully makes or causes to be made any false statements or representations of a material fact in any application for any benefit or payment under a Federal health care program. See 42 U.S.C. 1320a–7b(a)(1).

[66] By signing the DMEPOS supplier enrollment application, the DMEPOS supplier certifies it will notify the Medicare contractor of any changes in its enrollment information within 30 days of the effective date of the change.

[67] It is unlawful for a DMEPOS supplier to represent itself as a Medicare representative. See 42 U.S.C. 1320b–10.

[68] This practice may involve, but is not limited to, using another DMEPOS supplier's billing number.

[69] DMEPOS suppliers should be aware of the requirements of any payor they bill, especially in those situations where there is a primary and secondary payor.

[70] E.g., Medicare does not permit DMEPOS suppliers to perform oxygen tests (e.g., oximetry tests and arterial blood gas tests) to qualify patients for oxygen and oxygen supplies. See section 60–4 of the *Medicare Coverage Issues Manual*. See also discussion in section II.A.3.o.

[71] An overpayment is the amount of money the DMEPOS supplier has received in excess of the amount due and payable under a health care program. Examples of overpayments include, but are not limited to, instances where a DMEPOS supplier is: (1) paid twice for the same service, for the same beneficiary; or (2) paid for services that were provided but not ordered by the treating physician or other authorized person. DMEPOS suppliers should institute procedures to detect overpayments and to promptly remit such overpayments to the affected payor. See 42 U.S.C. 1320a–7b(a)(3), which provides criminal penalties for failure to disclose an overpayment.

[72] If the patient is also due money when a DMEPOS supplier identifies an overpayment to a health care program, the DMEPOS supplier should make a prompt refund to the patient. See 42 U.S.C. 1395m(j)(4) on limitation of patient liability for non-assigned claims that are denied due to medical necessity. See also 42 U.S.C. 1395pp(h) on limitation of patient liability for assigned claims that are denied due to medical necessity.

[73] A lack of communication between the DMEPOS supplier, physician, and patient may result in the DMEPOS supplier inappropriately billing for items or supplies (e.g., supplies for an on-going condition or rental equipment that are no longer medically necessary).

[74] A lack of communication between the different departments of the DMEPOS supplier may result in the DMEPOS supplier filing incorrect claims and/or equipment delivery problems.

[75] This involves hiring or contracting with individuals or entities who have been excluded from participation in Federal health care programs or any other Federal prucurement or non-prucurement program. See section II.E.2.

[76] ''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).

[77] See note 29.

[78] See *Medicare Carriers Manual*, section 3312. See also *Medicare Carrier Manual*, section 4105.2 regarding what information must be included on the physician's order.

[79] See note 29.

[80] In order to ensure correct reimbursement, the payor may conduct a post-payment audit of the DMEPOS supplier's claims. Such audits may require that the DMEPOS supplier submit documentation that substantiates that the items or services were ordered by the treating physician or other authorized person, provided, covered, reasonable and necessary. See 42 CFR 424.5(a)(6).

provided, covered, reasonable and necessary. DMEPOS suppliers may choose to incorporate this claims review function into pre-existing quality assurance mechanisms.

b. *Physician Orders.* The DMEPOS supplier's written policies and procedures should state that the DMEPOS supplier will not bill for an item or service unless and until it has been ordered by the treating physician or any other authorized person. For all Medicare reimbursed DMEPOS items or services, the DMEPOS supplier must receive a written order from the patient's physician. When the DMEPOS supplier receives a verbal order, the supplier should document the verbal order and must have the treating physician confirm it in writing prior to billing.

The written policies and procedures should also state for items requiring a written order prior to delivery, that the order must be received by the DMEPOS supplier before it delivers the equipment to the patient and before it bills the payor.[81]

c. *Certificate of Medical Necessity.*[82] For some DMEPOS items and services, the DMEPOS supplier must receive a signed CMN from the treating physician or other authorized person. Currently, CMNs are required for Medicare reimbursement for fourteen items.[83] The original CMN must be retained in the DMEPOS supplier's file and be available to the DMERCs upon request.[84]

Each CMN has four sections: A, B, C, and D. Section A may be completed by the DMEPOS supplier. Section B may not be completed by the DMEPOS supplier.[85] Section B may only be completed by the treating physician, a non-physician clinician involved in the care of the patient or a physician employee who is knowledgeable about the patient's treatment. If section B was completed by a physician employee, the section must be reviewed by the treating physician or other person authorized to order such equipment for the patient to ensure accuracy. Section C must be completed by the DMEPOS supplier prior to the CMN being furnished to the treating physician or other authorized person for signature.[86] Section D is the attestation statement and may only be signed by the treating physician or other person authorized to order equipment for the patient.[87] The written policies and procedures on completing CMNs should reflect these standards.

DMEPOS suppliers should take all reasonable steps to ensure that each section of the CMN is completed in accordance with the above guidelines. The DMEPOS suppliers' written policies and procedures should require, at a minimum, that they:

- Do not forward blank CMNs to the treating physician or other authorized person for signature;
- Do not complete section B (Medical Necessity) of the CMN;
- Do not include diagnostic information on a cover letter (to the treating physician or other authorized person) attached to the CMN;[88]
- Do not alter or add any information on the CMN after receiving the completed and signed CMN from the physician or other authorized person;[89]
- Do not sign the CMN for the treating physician or other authorized person;
- Do not urge physicians or other authorized person to order equipment or supplies that exceed what is reasonable and necessary for the patient;
- Do not deliver an item that needs pre-authorization prior to receiving the physician order and CMN;[90]
- Do not submit a claim for items or services until the CMN is properly and correctly completed by the treating physician or other authorized person;
- Do maintain the original CMNs in their files;
- Do consult with the treating physician or other authorized person who signed the CMN when there is a question on the order;
- Do properly complete sections A and C of the CMN and forward the remainder of the CMN to the treating physician or other authorized person for his/her review, information, and signature; and
- Only bill for services that the treating physician or other authorized person attests in section D are ordered, covered, reasonable, and necessary for the patient.

d. *Billing.* DMEPOS suppliers should include in their written policies and procedures that they will only submit to Medicare or other Federal, State or private payor health care plans claims for equipment and supplies that are properly completed, accurate, and correctly identify the equipment or supplies ordered by the treating physician or other authorized person and furnished to the patient. Also, before submitting a claim, the DMEPOS supplier should ensure the item or service being claimed was provided, covered, reasonable and necessary.

The written policies and procedures should also clarify that a DMEPOS supplier cannot submit bills or receive payment for drugs used in conjunction with DMEPOS, unless the DMEPOS supplier is licensed to dispense the drug.[91]

e. *Selection of HCPCs Codes.* DMEPOS suppliers' written policies and procedures should state that only the HCPCs code that most accurately describes the item or service ordered and provided should be billed. The OIG views intentional ''upcoding'' (i.e., the selection of a code to maximize reimbursement when such a code is not the most appropriate descriptor of the service) as raising, among other things, false claims issues under the Federal False Claims Act.[92] To ensure code accuracy, the OIG recommends the DMEPOS supplier include a requirement in its policies and procedures that the codes be reviewed (random sample or certain codes) by individuals with technical expertise in coding before claims containing such codes are submitted to the affected payor. If a DMEPOS supplier has questions regarding the appropriate

[81] See 42 CFR 410.38.

[82] As defined in 42 U.S.C. 1395m(j)(2)(B). See also OIG Special Fraud Alert regarding Physician Liability for Certifications in the Provision of Medical Equipment and Supplies and Home Health Services, 64 FR 1813 (January 12, 1999). Special Fraud Alerts are also available on the Internet.

[83] Items or services requiring CMNs are as follows: Home oxygen therapy (HCFA form 484); Hospital beds (HCFA form 841); Support surfaces (HCFA form 842); Motorized wheelchairs (HCFA form 843) (Section C continuation, HCFA form 854); Manual wheelchairs (HCFA form 844) (Section C continuation, HCFA form 854); Continuous positive airway pressure (CPAP) devices (HCFA form 845); Lymphedema pumps (pneumatic compression devices) (HCFA form 846); Osteogenesis stimulators (HCFA form 847); Transcutaneous electrical nerve stimulators (TENS) (HCFA form 848); Seat lift mechanisms (HCFA form 849); Power operated vehicles (HCFA form 850); Infusion pumps (HCFA form 851); Parenteral nutrition (HCFA form 852); and Enteral nutrition (HCFA form 853).

[84] See *Medicare Carrier Manual*, section 3312.

[85] A supplier who knowingly and willfully completes section B of the form is, at a minimum, subject to a civil money penalty up to $1,000 for each form or document completed in such manner. See 42 U.S.C. 1395m(j)(2). That supplier may also face civil or criminal liability.

[86] A supplier who knowingly and willfully fails to include, in section C, the fee schedule amount and the supplier's charge for the equipment or supplies being furnished may be subject to a civil money penalty up to $1,000 for each form or document so distributed. See 42 U.S.C. 1395m(j)(2).

[87] Physicians or other authorized persons should only sign CMNs in which sections A–C are completed and correct. Signature and date stamps are not acceptable. See *Medicare Carriers Manual*, section 3312.

[88] See discussion in section A.II.3.m.

[89] There have been many investigations centering on DMEPOS suppliers who alter information in order to affect their reimbursement (e.g., altering diagnosis code, altering HCPCs code of service provided).

[90] See 42 U.S.C. 1395m(a)(11)(B). See also 42 CFR 410.38.

[91] See Medicare program memoranda B–98–6 and B–98–18.

[92] See 31 U.S.C. 3729, which provides for the imposition of penalties of $5,000 to $10,000 per false claim, plus up to three times the amount of damages suffered by the Federal Government because of the false claim.

code to be used, it should contact the Statistical Analysis Durable Medical Equipment Carrier's (SADMERC) HCPCS coding help line.[93]

f. *Valid Supplier Numbers*. The DMEPOS supplier should ensure that appropriate personnel are knowledgeable in (1) completing the HCFA 855S supplier application;[94] and (2) complying with the Federal requirements of 42 CFR 424.57(e) for updating supplier number applications.

The written policies and procedures should state that the DMEPOS supplier should not bill any other Federal, State or private payor health care plan without obtaining the necessary billing numbers and that the billing numbers will be used correctly.[95]

Prior to applying for a valid supplier number, DMEPOS suppliers providing services to Medicare beneficiaries must meet the supplier standards.[96] DMEPOS suppliers should take all affirmative steps to ensure that no claims for Medicare reimbursement are submitted prior to the DMEPOS supplier being issued a valid supplier number by the National Supplier Clearinghouse. A DMEPOS supplier should not have more than one supplier number unless it is appropriate to identify subsidiary or regional entities under the supplier's ownership or control.[97]

g. *Mail Order Suppliers*. We recommend that any DMEPOS supplier who engages in the mail order supply business clearly articulate its protocol for this segment of its business in the company's written policies and procedures.

Mail order supplies should only be delivered in accordance with the treating physician's or other authorized person's order. Regularly shipping supplies without such orders may lead to providing supplies substantially in excess of the patient's needs.[98] We also recommend that the supplier utilize a tracking system so it will be able to determine whether or not the patient received the supplies and will be able to track the location of an item or supply at any given time. In addition, the mail order DMEPOS supplier should maintain an accurate inventory list and should not bill for or commit to sending items that are not part of its inventory.

h. Assignment. If a DMEPOS supplier accepts Medicare assignment, its written policies and procedures should state that it will not charge Medicare beneficiaries more than the amounts allowed under the Medicare fee schedule, including coinsurance and deductibles. If the beneficiary pays the DMEPOS supplier prior to the DMEPOS supplier submitting the claim, the DMEPOS supplier should ensure it is not charging the beneficiary more than the coinsurance on the allowed amount under the fee schedule. In the event that the DMEPOS supplier collects excess payments from a Medicare beneficiary, it should have mechanisms in place to promptly refund the overpayment to the beneficiary. DMEPOS suppliers should be knowledgeable about the Medicare rules and instructions for accepting assignment and receiving direct payment from beneficiaries for items or services.

If a DMEPOS supplier chooses not to accept Medicare assignment, it is still responsible for submitting the claim to Medicare on behalf of the beneficiary.[99]

If the DMEPOS supplier chooses to utilize a billing agent, the DMEPOS supplier should ensure it is complying with all of the relevant statutes and requirements governing such an arrangement.[100] The OIG strongly recommends that the supplier coordinate closely with the billing company to establish compliance responsibilities. Once the responsibilities have been clearly delineated, they should be formalized in the written contract between the DMEPOS supplier and the billing agent. The OIG recommends that the contract enumerate those functions that are shared responsibilities and those that are the sole responsibility of either the billing agent or the DMEPOS supplier.

i. Liability Issues. A DMEPOS supplier or Medicare beneficiary is not liable for payment on assigned claims where the beneficiary did not know, and could not reasonably have been expected to know, that the payment for such services would not be made.[101] However, when the DMEPOS supplier knew, or could have been expected to know, the items or services would be denied, the liability for the charges for the denied items or services rest with the DMEPOS supplier.[102]

When a DMEPOS supplier knows or has reason to believe that the equipment or supplies ordered by the treating physician or other authorized person will be denied, the DMEPOS supplier should inform the patient prior to furnishing the item or service and ask the patient to sign a written notice.[103] If the DMEPOS supplier has not received a signed written notice from the beneficiary and the claim is denied, the DMEPOS supplier should not bill the beneficiary. The written notice must be in writing, must clearly identify the particular item or service, must state that the payment for the particular service likely will be denied, and must give the reason(s) for the belief that payment is likely to be denied. It is the beneficiary's decision whether or not to sign the written notice. If the beneficiary does sign the notice, the supplier should: (1) include the appropriate modifier on the claim form; (2) maintain the written notice in its files; and (3) be able to produce the written notice to the DMERC, upon request.

Routine notices to beneficiaries that do no more than state that denial of payment is possible or that they never know whether payment will be denied are not considered acceptable evidence of written notice. Notices should not be given to beneficiaries unless there is some genuine doubt regarding the likelihood of payment as evidenced by the reasons stated on the written notice. Giving notice for all claims, items or services is not an acceptable practice.

The DMEPOS supplier should include liability issues (e.g., circumstances where the DMEPOS supplier knows or could be expected to know of a denial, use of advance beneficiary notice, etc.) in their written policies and procedures.

j. Routine Waiver of Deductibles and Coinsurance. Routine waivers of deductibles and coinsurance may result in false claims, violations of the anti-kickback statute and overutilization of items or services.[104] DMEPOS suppliers are permitted to waive the Medicare coinsurance amounts for cases of

[93] The phone number for the SADMERC's HCPCS coding help line is: (803) 736–6809. The hours of operation are Monday through Friday from 9:00 am to 4:00 pm, EST. The SADMERC will aid the DMEPOS supplier in choosing the most accurate code for the item or service ordered and supplied. However, DMEPOS suppliers should be aware that assigning a HCPCs code to an item or service does not necessarily guarantee reimbursement.

[94] By signing the certification statement of the enrollment application, the applicant agrees that he/she has read, understood, meets and will continue to meet the supplier standards and will be disenrolled from the program if any standards are not met or violated.

[95] E.g., if a DMEPOS supplier has more than one location, the supplier number of the location that filled the physician's order will be used on the claim form.

[96] See 42 CFR 424.57.

[97] See 42 U.S.C. 1395m(j)(1)(D).

[98] Providing a substantially excessive amount of supplies may, for example, constitute grounds for a supplier's exclusion under 42 U.S.C. 1320a–7(b)(6)(B).

[99] See 42 U.S.C. 1395w–4(g)(4).

[100] See 42 U.S.C. 1395u(b)(6); 42 CFR 424.73; *Medicare Carrier Manual*, section 3060. See also OIG Ad. Op. 98–1 (1998) and OIG Ad. Op. 98–4 (1998).

[101] See 42 U.S.C. 1395pp.

[102] Id.

[103] See *Medicare Carriers Manual*, section 7300.5.

[104] See 59 FR 31157 (December 19, 1994) or the OIG web site at http://www.dhhs.gov/progorg/oig for the OIG Special Fraud Alert on Medicare Deductibles and Copayments.

indigency.[105] However, we recommend the supplier develop and maintain written criteria documenting its policy for determining indigency, and consistently apply these criteria to all cases. This indigency exception must not be used routinely and a good faith effort must be made to collect deductibles and coinsurance.

DMEPOS suppliers' written policies and procedures should state that they will not routinely waive deductibles and coinsurance for Medicare beneficiaries. Such policies and procedures should include, but not be limited to, statements that DMEPOS supplier personnel are prohibited from: advertising an intent to waive deductibles or coinsurance; advertising an intent to discount services for Medicare beneficiaries; giving unsolicited advice to patients that they need not pay; charging Medicare beneficiaries more than other patients for similar services and items; or collecting deductibles and coinsurance only when a patient has a certain insurance. Routine waivers of deductibles and coinsurance may result in civil monetary penalties, False Claims Act liability, and/or a violation of the anti-kickback statute.[106]

K. Capped Rentals. DMEPOS suppliers' written policies and procedures should address Government and private payor requirements when providing rental equipment to beneficiaries (e.g., the purchase option [107] and servicing and maintenance [108]). DMEPOS suppliers must offer a purchase option to beneficiaries during the 10th continuous rental month.[109] The DMEPOS supplier should clearly, accurately, and non-deceptively discuss the pros and cons of the different options with the beneficiary. If the beneficiary does not accept the purchase option, the DMEPOS supplier must continue to provide the item without charge to the beneficiary or Medicare after the 15th continuous month of receiving rental payments from Medicare, providing the item or service continues to be medically necessary.

However, the DMEPOS supplier may submit additional claims for the maintenance and servicing fees associated with the rental item.[110] The DMEPOS supplier should ensure it is performing basic safety and operational function checks after use by each patient, and is performing routine and preventative maintenance on equipment. The DMEPOS supplier must ensure it has qualified staff or contractors to service, set up, and instruct the patient on the proper use of the equipment. The DMEPOS supplier should ensure it maintains current service manuals for all equipment they supply. In addition, the policies and procedures should also establish an internal control system which allowed the DMEPOS suppler to track the location of each piece of equipment at any given time.

The policies and procedures should also address the guidelines for determining continuous use and criteria for a new rental period.[111] If a beneficiary dies during a rental period, the DMEPOS supplier may receive the entire monthly rental payment.[112] However, if the DMEPOS supplier continues to bill for the item because it did not receive notice of the beneficiary's death until the following month, any payments received for rental items the month after the beneficiary dies are considered an overpayment and must promptly be refunded. The DMEPOS supplier should create internal mechanisms to ensure the correct rental month appears on the claim and the correct modifier is used.

In addition, the DMEPOS supplier should ensure it is not submitting claims for rental equipment when the beneficiary is residing in an institution. The OIG is aware that some DMEPOS suppliers deliver equipment to beneficiaries residing in institutions just prior to the beneficiary being discharged. However, if the beneficiary is residing in an institution when the DMEPOS supplier delivers the equipment, the HCFA claim form should indicate the date of delivery as being the date the beneficiary is discharged from the institution. The DMEPOS supplier may not submit the claim prior to the beneficiary's date of discharge.

l. ZX Modifier. The ZX modifier is used to indicate that the DMEPOS supplier is maintaining medical necessity documentation in its files. Such documentation only needs to be submitted to the DMERC upon request.

DMEPOS suppliers should create internal mechanisms to ensure the proper use of the ZX modifier. Improper use of the modifier may result in the submission of false claims. The written policies and procedures should address the DMEPOS supplier's protocol for using the ZX modifier.[113]

m. Cover Letters. The DMEPOS supplier should address the use of cover letters in its written policies and procedures, if applicable.[114]

In many instances, the DMEPOS supplier will send a cover letter along with the CMN to the physician. The information contained in the cover letter should address issues relating to HCFA or DMERC regulation/policy changes, brief descriptions of the item(s) being provided and changes in the patient's regimen. The cover letter must not (i) lead physicians to order medically unnecessary items or supplies or (ii) include diagnostic information. In addition, the DMEPOS supplier should not distribute completed ''sample'' CMNs to physicians. DMEPOS suppliers should maintain on file a copy of the cover letter sent to physicians. The DMERCs may request to review the information provided in cover letters to ensure the DMEPOS supplier is in compliance with the law.

n. Communication. The OIG suggests DMEPOS suppliers create mechanisms that increase the communication between treating physicians or other authorized persons who refer business to the DMEPOS supplier, the patients, and the DMEPOS supplier. Such mechanisms should be included in the DMEPOS supplier's written policies and procedures and may include the DMEPOS supplier periodically calling the patient to ensure the equipment is still being used and operating properly or an arrangement between the DMEPOS supplier and the physician whereby the physician immediately informs the DMEPOS supplier when equipment is no longer medically necessary. The DMEPOS supplier should create mechanisms to ensure communications between different departments (e.g., sales and billing) in order to prevent the filing of incorrect claims.

o. Oxygen and Oxygen Equipment. The OIG recommends the written policies and procedures for DMEPOS suppliers furnishing oxygen state that the DMEPOS supplier will ensure that initial claims for oxygen therapy include the written results of an arterial blood gas study or oximetry test (on the CMN) that has been ordered and evaluated by the patient's treating physician. Further, the written policies

[105] See section 5520 of the *Medicare Carriers Manual.*

[106] See 42 U.S.C. 1320a–7a(a)(5); 31 U.S.C. 3729–3733; 42 U.S.C. 1320a–7b.

[107] See 42 CFR 414.229(d).

[108] See 42 CFR 414.229(e).

[109] DMEPOS suppliers must offer beneficiaries the option of purchasing power-driven wheelchairs at the time the DMEOS supplier first furnishes the item. See 42 CFR 414.229(d)(1).

[110] See 42 CFR 414.229(e).

[111] See 42 CFR 414.230.

[112] See *Medicare Carriers Manual,* section 4105.3.

[113] See relevant DMERC supplier manual(s) for guidelines on proper use.

[114] Id.

and procedures should provide for the DMEPOS supplier to maintain such test results and any other independent physiological laboratory (IPL) documents supporting the patient's medical necessity for the oxygen. The DMEPOS supplier should have the IPLs from which they receive tests results submit all raw test results to the ordering physician for the physician's benefit, and not just a summary of the results. The written policies and procedures should provide that a DMEPOS supplier is not qualified to conduct the blood gas study or to prescribe the oxygen therapy.[115] When submitting an oxygen or oxygen equipment claim for reimbursement, the DMEPOS supplier must ensure it is complying with the payment rules.[116]

4. Anti-Kickback and Self-Referral Concerns. The DMEPOS supplier should have policies and procedures in place with respect to compliance with Federal and State laws, including the anti-kickback statute, as well as the Stark physician self-referral law.[117] Such policies should provide that:

- All of the DMEPOS supplier's contracts and arrangements with actual or potential referral sources (e.g., physicians) are reviewed by counsel and comply with all applicable statutes and regulations, including the anti-kickback statute and the Stark physician self-referral law provisions; [118]
- The DMEPOS supplier not submit or cause to be submitted to the Federal health care programs claims for patients who were referred to the DMEPOS supplier in accordance with contracts or financial arrangements that were designed to induce such referrals in violation of the anti-kickback statute or similar Federal or State statute or regulation or that otherwise violates the Stark physician self-referral law; and
- The DMEPOS supplier does not offer or provide gifts, free services, or other incentives or things of value to patients, relatives of patients, physicians, home health agencies, nursing homes, hospitals, contractors, assisted living facilities, or other potential referral sources for the purpose of inducing referrals in violation of the anti-kickback statute or similar Federal or State statute or regulation.[119]

Further, the written policies and procedures should specifically reference and take into account the OIG's safe harbor regulations, which describe those payment practices that are immune from criminal and administrative prosecution under the anti-kickback statute.[120]

5. Marketing. DMEPOS supplier compliance programs should require honest, straightforward, fully informative and non-deceptive marketing, where marketing is permitted. It is in the best interest of patients, DMEPOS suppliers, physicians and health care programs that physicians or other persons authorized to order DMEPOS fully understand the services offered by the DMEPOS supplier, the items or services that will be provided when ordered and the financial consequences for Medicare as well as other payors for items or services ordered. If the DMEPOS supplier services a large number of non-English speaking patients, it should ensure its marketing materials are available in that other language. The DMEPOS supplier's written policies and procedures should ensure that its marketing information is clear, correct, and fully informative. Salespeople must not offer physicians, patients or other potential referral sources incentives, in cash or in kind, for their business.[121] Similarly, they must not engage in any marketing activity that either explicitly or implicitly implies that Medicare beneficiaries are not obligated to pay their coinsurance or can receive ''free'' services.[122] In addition, DMEPOS suppliers must not promote items or services to patients or physicians that are not reasonable or necessary for the treatment of the individual patient. The OIG suggests the DMEPOS supplier's written policies and procedures create internal mechanisms to avoid these situations.

With respect to marketing and sales, the OIG has a longstanding concern that percentage compensation arrangements for sales and marketing personnel may increase the risk of such persons violating the anti-kickback statute.[123] The OIG recommends the DMEPOS supplier monitor its sales representatives on a regular basis (e.g., rotate sales staff or send sales manager on some sales calls).

DMEPOS suppliers are prohibited from making unsolicited telephone contacts to Medicare beneficiaries.[124] In addition, a DMEPOS supplier cannot accomplish through an agent that which it cannot do itself. Since a DMEPOS supplier has no control over the means by which a non-employee sales or other representative might contact a Medicare beneficiary regarding the furnishing of such items, DMEPOS suppliers may not accept any referral from a sales or other representative who is not an employee of the DMEPOS supplier, regardless of the means allegedly used to contact the beneficiary. We suggest the DMEPOS supplier's written policies and procedures reflect this prohibition.

DMEPOS suppliers are prohibited from using symbols, emblems, or names in reference to Social Security or Medicare in a manner that such person knows or should know would convey the false impression that such item is approved, endorsed, or authorized by the Social Security Administration, the Health Care Financing Administration, or the Department of Health and Human Services or that such person has some connection with, or authorization from, any of these agencies.[125]

6. Retention of Records. DMEPOS supplier compliance programs should provide for the implementation of a records system. DMEPOS suppliers should ensure that records are maintained for the length of time required by Federal and State law and private payors, or by the supplier's record retention policies, whichever is longer. This system should establish policies and procedures regarding the creation, distribution, retention, storage, retrieval, and destruction of documents.[126] The three types of documents developed under this system should include: (1) all records and documentation (e.g., billing and claims documentation) required either by Federal or State law and the program requirements of Federal, State and private health plans; (2) records listing the persons responsible for implementing each part of the

[115] See *Coverage Issues Manual*, section 60–4.

[116] See 42 CFR 414.226.

[117] Towards this end, the DMEPOS supplier 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 DMEPOS supplier's policies reflect the guidance provided by the OIG. See 42 U.S.C. 1395nn(a) for the Stark physician referral laws. See also 42 U.S.C. 1320a–7b for prohibited activities under the anti-kickback statute.

[118] If the DMEPOS supplier questions an arrangement it may enter into, it should consider asking the OIG for an advisory opinion regarding the anti-kickback statute or HCFA for an advisory opinion regarding Stark. See 62 FR 7350 (February 19, 1997) and 63 FR 38311 (July 16, 1998) for instructions on how to submit an Advisory Opinion to the OIG. These instructions are also located on the Internet at: http://www.dhhs.gov/progorg/oig. See 63 FR 1645 (January 9, 1998) on how to submit an advisory opinion to HCFA.

[119] See 42 U.S.C. 1320a–7(a)(5), which provides for civil money penalties for improper inducements to beneficiaries. See also 42 U.S.C. 1320a–7b(b).

[120] See 42 CFR 1001.952.

[121] See anti-kickback statute discussion in section II.A.4.

[122] See discussion in section II.A.3.j.

[123] See, e.g., 42 U.S.C. 1320a–7b(b); OIG Ad. Op. 98–10 (1998); section II.A.4.

[124] See 42 U.S.C. 1395m(a)(17), Pub. L. 103–432, section 132(a).

[125] See 42 U.S.C. 1320b–10.

[126] This records system should be tailored to fit the individual needs and financial resources of the DMEPOS supplier.

compliance program; and (3) all records necessary to protect the integrity of the DMEPOS supplier's compliance process and confirm the effectiveness of the program. The documentation necessary to satisfy the third requirement includes, but is not limited to: evidence of adequate employee training; reports from the DMEPOS supplier's hotline; results of any investigation conducted as a consequence of a hotline call; modifications to the compliance program; self-disclosure; all written notifications to providers;[127] and the results of the DMEPOS supplier's auditing and monitoring efforts.[128]

7. 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. Employees should be periodically trained in new compliance policies and procedures. In addition, all managers and supervisors involved in the claims development and submission processes should:

- Discuss with all supervised employees and relevant contractors the compliance policies and legal requirements applicable 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 DMEPOS supplier 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, the compliance officer or DMEPOS supplier management should include 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.

B. Designation of a Compliance Officer and a Compliance Committee

1. Compliance Officer. Every DMEPOS supplier should designate a compliance officer to serve as the focal point for compliance activities. The compliance officer should be a person of high integrity. This responsibility may be the individual's sole duty or added to other management responsibilities, depending upon the size and resources of the DMEPOS supplier and the complexity of the task. When a compliance officer has other duties, the other duties should not be in conflict with the compliance goals.[129]

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 DMEPOS supplier with direct access to the DMEPOS supplier's owner(s), president or CEO, governing body, all other senior management, and legal counsel.[130] The compliance officer should be highly enough placed in the company so that he or she can exercise independent judgment without fear of reprisal, and so that employees will know that bringing a problem to that person's attention is not a wasted exercise. The compliance officer should have sufficient funding and staff to fully perform his or her responsibilities. 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;[131]
- Reporting on a regular basis to the DMEPOS supplier's owner(s), governing body, CEO, president, and compliance committee (if applicable) on the progress of implementation, and assisting these components in establishing methods to improve the DMEPOS supplier's efficiency and quality of services, and to reduce the DMEPOS supplier's vulnerability to fraud, abuse and waste;
- Periodically revising the program in light of changes in the organization's needs, and in the statutes, rules, regulations, and requirements of Federal, State and private payor health care 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 appropriate employees and management are knowledgeable of, and comply with, pertinent Federal, State and private payor health care program requirements;
- Ensuring independent contractors and agents who provide services (e.g., billing companies, delivery services and sources of referrals) to the DMEPOS supplier are aware of the requirements of the DMEPOS supplier's compliance program with respect to coverage, billing, and marketing, among other things;
- Coordinating personnel issues with the DMEPOS supplier's Human Resources/Personnel office (or its equivalent) to ensure that the National Practitioner Data Bank,[132] Cumulative Sanction Report,[133] and the General Services Administration's List of Parties Excluded from Federal Procurement and Nonprocurement Programs [134] have been checked with respect to all employees, referring physicians or other authorized persons, and independent contractors (as appropriate);[135]
- Assisting the DMEPOS supplier's financial management in coordinating internal compliance review and monitoring activities, including annual or periodic reviews of departments;
- Independently investigating and acting on matters related to compliance,

[127] This should include notifications regarding inappropriate claims and overpayments.

[128] 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.

[129] E.g., companies should not choose a sales manager who may be pressured to achieve high sales, which might result in a conflict with compliance goals.

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

[131] For DMEPOS supplier chains, the OIG encourages coordination with each DMEPOS supplier location through the use of a headquarter's compliance officer, communicating with parallel positions in each facility or regional office, as appropriate.

[132] The National Practitioner Data Bank, maintained by the Public Health Service, 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.

[133] 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 individuals and entities who have been excluded from participation in the Medicare and Medicaid programs.

[134] The List of Parties from Federal Procurement and Nonprocurement programs is a GSA-produced report available on the Internet at: http://www.arnet.gov/epls.

[135] Depending upon State requirements or DMEPOS supplier policy, the Compliance Officer may also conduct a criminal background check of employees.

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 DMEPOS supplier policies and practices, taking appropriate disciplinary action, etc.) with all DMEPOS supplier departments, independent contractors, and health care professionals;

- 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.[136]

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 (where appropriate), billing records, and DMEPOS supplier records concerning the marketing efforts of the DMEPOS supplier and the DMEPOS supplier's arrangements with other parties, including employees, home health agencies, skilled nursing facilities, and ordering physicians or other authorized persons. 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 or other statutory or regulatory requirements.

In addition, the compliance officer should be copied on the results of all internal audit reports and work closely with key managers to identify aberrant trends in the coding and billing areas. The compliance officer should ascertain patterns that require a change in policy and forward these issues to the compliance committee to remedy the problem. The compliance officer should have full authority to stop the processing of claims that he or she believes are problematic until such time as the issue in question has been resolved.

2. Compliance Committee. The OIG recommends, where feasible,[137] that a compliance committee be established to advise the compliance officer and assist in the implementation of the compliance program.[138] When assembling a team of people to serve as the DMEPOS supplier's compliance committee, the DMEPOS supplier should include individuals with a variety of skills.[139] The OIG strongly recommends that the compliance officer manage the compliance committee. Once a DMEPOS supplier chooses the people that will accept the responsibilities vested in members of the compliance committee, the DMEPOS supplier must train these individuals on the policies and procedures of the compliance program, as well as how to discharge their duties.

The committee's responsibilities should include:

- Analyzing the organization's regulatory environment, the legal requirements with which it must comply,[140] and specific risk areas;
- Assessing existing policies and procedures that address these risk areas for possible incorporation into the compliance program;
- Working with appropriate DMEPOS supplier departments to develop standards of conduct and policies and procedures that promote allegiance to the DMEPOS supplier's compliance program;
- 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;[141]
- 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 DMEPOS supplier, and implementing corrective and preventive action.

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

C. Conducting Effective Training and Education

1. Initial Training in Compliance. The proper education and training of corporate officers, managers, employees and the continual retraining of current personnel at all levels, are significant elements of an effective compliance program. In order to ensure the appropriate information is being disseminated to the correct individuals, the training should be separated into sessions. All employees should attend the general session on compliance, employees whose job primarily focuses on submission of claims for reimbursement should receive additional training on this subject, and employees who are involved in sales and marketing should receive additional training on this subject.

a. General Sessions. As part of their compliance programs, DMEPOS suppliers should require all affected personnel to attend training on an annual basis, including appropriate training in Federal and State statutes, regulations and guidelines, the policies of private payors, and training in corporate ethics. The general training sessions should emphasize the DMEPOS

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

[137] The OIG recognizes that smaller DMEPOS suppliers may not be able to establish a compliance committee. In those situations, the compliance officer should fulfill the responsibility of the compliance committee.

[138] The compliance committee benefits from having the perspectives of individuals with varying responsibilities in the organization, such as operations, billing, coding, marketing, and human resources, 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 the DMEPOS supplier's policies and procedures as recommended by the committee. A compliance committee for a DMEPOS supplier that is part of another organization (e.g., home health agency) might benefit from the participation of officials from other departments in the organization, such as the accounting and billing departments.

[139] A DMEPOS supplier 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 DMEPOS supplier. The DMEPOS supplier's compliance committee members should also have significant professional experience working with billing, documentation, and auditing principles.

[140] This includes, but is not limited to, the civil False Claims Act, 31 U.S.C. 3729–3733; the criminal false claims statutes, 18 U.S.C. 287, 1001; the fraud and abuse provisions of the Balanced Budget Act of 1997, Pub. L. 105–33; the Health Insurance Portability and Accountability Act of 1996, Pub. L. 104–191; and compliance with the Medicare supplier standards, 42 CFR 424.57.

[141] With respect to national DMEPOS supplier chains, this may include fostering coordination and communication between those employees responsible for compliance at headquarters and those responsible for compliance at the individual supplier branches.

supplier's commitment to compliance with these legal requirements and policies.

These training programs should include sessions highlighting the DMEPOS supplier's compliance program, summarizing fraud and abuse laws and regulations, Federal, State and private payor health care program requirements, claim submission procedures and marketing practices that reflect current legal and program standards. The DMEPOS supplier must take steps to communicate effectively its standards and procedures to all affected employees, physicians, independent contractors and other significant agents, e.g., by requiring participation in training programs and disseminating publications that explain specific requirements in a practical manner.[142] Managers of specific departments can assist in identifying areas that require training and in carrying out such training.[143] Training instructors may come from outside or inside the organization. New employees should be targeted for training early in their employment.[144]

As part of the initial training, the standards of conduct should be distributed to all employees.[145] At the end of this training session, every employee, as well as physicians, independent contractors, and other significant agents, should be required to sign and date a statement that reflects their knowledge of and commitment to the standards of conduct. This attestation should be retained in the employee's personnel file. For physicians, independent contractors, and other significant agents, the attestation should become part of the contract and remain in the file that contains such documentation.

Further, to assist in ensuring that employees continuously meet the expected high standards of conduct, any employee handbook delineating or expanding upon these standards should be regularly updated as applicable statutes, regulations and Federal health care program requirements are modified.[146] DMEPOS suppliers should provide an additional attestation in the modified standards that stipulates the employee's knowledge of and commitment to the modifications.

b. Claim Development and Billing Training. In addition to specific training in the risk areas identified in section II.A.2, above, primary training to appropriate corporate officers, managers and other claim development and billing staff should include such topics as:

- Specific Government and private payor reimbursement principles;[147]
- Providing DMEPOS items or services without proper authorization;
- Proper documentation of services rendered, including the correct application of official ICD–9 and HCPCs coding rules and guidelines;
- Improper alterations to documentation (e.g., patient records, CMNs);
- Compliance with the Federal, State and privator payor supplier standards;
- Signing a form for a physician without the physician's authorization; and
- Duty to report misconduct.
- Clarifying and emphasizing these areas of concern through training and educational programs are particularly relevant to a DMEPOS supplier's billing and coding personnel, in that the pressure to meet business goals may render employees vulnerable to engaging in prohibited practices.

c. *Sales and Marketing Training.* In addition to specific training in the risk areas identified in section II.A.2, above, primary training to sales and marketing personnel should include such topics as:

- General prohibition on paying or receiving renumeration to induce referrals;
- Routine waiver of deductibles and/or coinsurance;
- Disguising referral fees as salaries;
- Offering free items or services to induce referrals;
- High pressure marketing of non-covered or unnecessary services;
- Improper patient solicitation; and
- Duty to report misconduct.

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

2. Format of the Training Program. The OIG suggests that all relevant levels of personnel be made part of various educational and training programs of the DMEPOS supplier.[148] Employees should be required to have a minimum number of educational hours per year, as appropriate, as part of their employment responsibilities.[149] For example, as discussed above, employees involved in billing functions should be required to attend periodic training in applicable reimbursement coverage and documentation of records.[150]

A variety of teaching methods, such as interactive training and training in several different languages, particularly where a DMEPOS supplier has a culturally diverse staff, should be implemented so that all affected employees are knowledgeable about the DMEPOS supplier's standards of conduct and procedures for alerting senior management to problems and concerns.[151] 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 coding, billing, sales, and marketing processes. All training materials should be designed to take into account the skills, knowledge and experience of the individual trainees. Given the complexity and interdependent relationships of many departments, it is

[142] Publications such as 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.

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

[144] Certain positions, such as those involving developing and submitting claims, as well as sales and marketing, create a greater organizational legal exposure, and therefore require specialized training. DMEPOS suppliers should fill such positions with individuals who have the appropriate educational background, training, experience, and credentials.

[145] Where the DMEPOS supplier has a culturally diverse employee base, the standards of conduct should be translated into other languages and written at appropriate reading levels.

[146] 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 employees' training. The DMEPOS supplier should determine what additional training to provide categories of employees based upon their job responsibilities.

[147] Government, in this context, includes the appropriate Medicare DMERC(s).

[148] In addition, where feasible, the OIG recommends that a DMEPOS supplier afford outside contractors and its physician clients that opportunity to participate in the DMEPOS supplier's compliance training and educational programs, or develop their own programs that complement the DMEPOS supplier's standards of conduct, compliance requirements and other rules and practices.

[149] Currently, the OIG is monitoring a significant number of corporate integrity agreements that require many of these training elements. The OIG usually requires a minimum of one to three hours annually for basic training in compliance areas. Additional training is required for specialty fields such as billing, coding, sales and marketing.

[150] Appropriate coding and billing depends upon the quality and completeness of documentation. Therefore, the OIG believes that the DMEPOS supplier must foster an environment where interactive communication is encouraged.

[151] Post training tests can be used to assess the success of training provided and employee comprehension of the DMEPOS supplier's policies and procedures.

important for the compliance officer to supervise and coordinate the training program.

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 DMEPOS supplier should retain adequate records of its training of employees, including attendance logs and material distributed at training sessions.

3. Continuing Education on Compliance Issues. It is essential that compliance issues remain at the forefront of the DMEPOS supplier's priorities. The OIG recommends that DMEPOS supplier compliance programs address the need for periodic professional education courses for DMEPOS supplier personnel. In particular, the DMEPOS supplier should ensure that coding personnel receive annual professional training on the updated codes for the current year and have knowledge of the SADMERC's HCPCs coding helpline. [152]

In order to maintain a sense of seriousness about compliance in a DMEPOS supplier's operations, the DMEPOS supplier must continue to disseminate the compliance message. One effective mechanism for maintaining a consistent presence of the compliance message is to publish a monthly newsletter to address compliance concerns. This would allow the DMEPOS supplier to address specific examples of problems the company encountered during its ongoing audits and risk analyses, while reinforcing the DMEPOS supplier's firm commitment to the general principles of compliance and ethical conduct. The newsletter could also include the risk areas published by the OIG in its Special Fraud Alerts. Finally, the DMEPOS supplier could use the newsletter as a mechanism to address areas of ambiguity in the coding and billing process and/or its sales and marketing practices. The DMEPOS supplier should maintain its newsletters in a central location to document the guidance offered, and provide new employees with access to guidance previously provided.

[152] See note 93.

D. Developing Effective Lines of Communication

1. Access to the Compliance Officer. An open line of communication between the compliance officer and DMEPOS supplier 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. [153] The compliance committee should also develop several independent reporting paths for an employee to report fraud, waste or abuse so that such reports cannot be diverted by supervisors or other personnel.

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

2. Hotlines and Other Forms of Communication. The OIG encourages the use of hotlines, [154] e-mails, written memoranda, newsletters, suggestion boxes and other forms of information exchange to maintain these open lines of communication. [155] If the DMEPOS supplier 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. [156] Employees should be permitted to report matters on an anonymous basis. [157] Matters reported through the hotline or other communication sources that suggest substantial violations of compliance policies, Federal, State or private payor 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. [158] Such information should be included in reports to the owner(s), governing body, the CEO, president, and compliance committee. [159] Further, while the DMEPOS supplier 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.

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 DMEPOS supplier's standards

[153] 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.

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

[155] In addition to methods of communication used by current employees, an effective employee exit interview program could be designed to solicit information from departing employees regarding potential misconduct and suspected violations of DMEPOS supplier policies and procedures.

[156] DMEPOS suppliers 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.

[157] The OIG recognizes that guaranteeing anonymity may be infeasible for small DMEPOS suppliers. In such instances, we recommend DMEPOS employees need not fear retribution when reporting a portential violation.

[158] To efficiently and accurately fulfill such an obligation, the DMEPOS supplier 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, any corrective action implemented, any disciplinary measures imposed, and any overpayments returned.

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

of conduct, policies and procedures, Federal and State statutes, rules, and regulations or Federal, State or private payor health care program requirements. It should also address disciplinary actions for those who have engaged in wrongdoing, which has the potential to impair the DMEPOS supplier'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 DMEPOS supplier's standards, 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 managers, while others may have to be resolved by the owner(s), president or CEO. 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 DMEPOS supplier 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 corporate officers, managers, and other DMEPOS supplier 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 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 DMEPOS supplier. The OIG believes that corporate officers, managers, supervisors, and 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, statutes, rules, regulations 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, DMEPOS suppliers should conduct a reasonable and prudent background investigation, including a reference check,[160] as part of every such employment application. The application should specifically require the applicant to disclose any criminal conviction, as defined by 42 U.S.C. 1320a–7(i), or exclusion action. In accordance with the compliance program, DMEPOS supplier policies should prohibit the employment of individuals who have been recently convicted of a criminal offense related to health care or who are listed as debarred, excluded, or otherwise ineligible for participation in Federal health care programs (as defined in 42 U.S.C. 1320a–7b(f)).[161] In addition, pending the resolution of any criminal charges or proposed debarment or exclusion, the OIG recommends that such individuals should be removed from direct responsibility for, or involvement with, the DMEPOS supplier's business operations related to any Federal health care program. In addition, we recommend the DMEPOS supplier remove such individual from any position(s) for which the individual's salary or the items or services rendered, ordered, or prescribed by the individual are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds.[162] Similarly, with regard to current employees or independent contractors, if resolution of the matter results in conviction, debarment, or exclusion, then the DMEPOS supplier should remove the individual from direct responsibility for or involvement with all Federal health care programs.

[160] See notes 132–135. Since the employees of DMEPOS suppliers have access to potentially vulnerable people and their property, DMEPOS suppliers should also strictly scrutinize whether it should employ individuals who have been convicted of crimes of neglect, violence or financial misconduct.

[161] Likewise, DMEPOS supplier compliance programs should establish standards prohibiting the execution of contracts with companies that have been recently convicted of a criminal offense related to health care or that are listed by a federal agency as debarred, excluded, or otherwise ineligible for participation in Federal health care programs. See notes 133 and 134.

[162] 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.

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 the DMEPOS supplier's corporate officers.[163] Compliance reports created by this ongoing monitoring, including reports of suspected noncompliance, should be maintained by the compliance officer and shared with the DMEPOS supplier's corporate officers and the compliance committee. The extent and frequency of the audit function may vary depending on factors such as the size of the DMEPOS supplier, the resources available to the DMEPOS supplier, the DMEPOS supplier's prior history of noncompliance, and the risk factors that are prevalent in a particular DMEPOS supplier.

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, rules, regulations, and Federal, State and private payor health care program requirements. The audits should focus on the different DMEPOS supplier's departments, including external relationships with third-party contractors, specifically those with substantive exposure to Government enforcement actions. At a minimum, these audits should be designed to address the DMEPOS supplier's compliance with laws governing kickback arrangements, the physician self-referral prohibition, pricing, contracts, claim development and submission, reimbursement, sales and marketing. In addition, the audits and reviews should examine the DMEPOS supplier's compliance with the Federal, State and private payor supplier standards and the specific rules and policies that have been the focus of particular attention on the part of the Medicare DMERCs, and law enforcement, as evidenced by educational and other communications from OIG Special Fraud Alerts, advisory opinions, OIG audits and evaluations,

[163] Even when a DMEPOS supplier is owned by a larger corporate entity, the regular auditing and monitoring of the compliance activities of an individual DMEPOS supplier 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.

and law enforcement's initiatives.[164] In addition, the DMEPOS supplier should focus on any areas of specific concern identified within that DMEPOS supplier and those that may have been identified by any entity, whether Federal, State, private or internal.

Monitoring techniques may include sampling protocols that permit the compliance officer to identify and review variations from an established baseline.[165] 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 DMEPOS supplier 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 DMEPOS supplier should take prompt steps to correct the problem.[166] Any overpayments discovered as a result of such deviations should be returned promptly to the affected payor, with the following information: (1) That the refund is being made pursuant to a voluntary compliance program; (2) a description of the complete causes and circumstances surrounding the overpayment; (3) the methodology by which the overpayment was determined; (4) the amount of the overpayment; and (5) any claim-specific information, reviewed as part of the self-audit, used to determine the overpayment (e.g., beneficiary health insurance claims number, claim number, date of service, and payment date).

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.[167] 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 DMEPOS supplier's operations. Such reviews could support a determination that appropriate records have been created and maintained to document the implementation of an effective program.[168] However, when monitoring discloses that deviations were not detected in a timely manner due to program deficiencies, appropriate modifications must be implemented. Such evaluations, when developed with the support of management, can help ensure compliance with the DMEPOS supplier's policies and procedures.

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

- Testing 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);
- On-site visits to all facilities and locations;
- Ongoing risk analysis and vulnerability assessments of the DMEPOS supplier's operations;
- Assessment of existing relationships with physicians, and other potential referral sources;
- Unannounced audits, mock surveys, and investigations;
- Examination of DMEPOS supplier 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, sales and marketing, claim development and submission, and other related activities;
- Questionnaires developed to solicit impressions of the DMEPOS supplier's employees;
- Interviews with physicians or other authorized persons who order services provided by the DMEPOS supplier;
- Interviews with independent contractors who provide services to the DMEPOS supplier;
- Reviews of medical necessity documentation (e.g., physicians orders, CMNs), and other documents that support claims for reimbursement;
- Validation of qualifications of physicians or other authorized persons who order services provided by the DMEPOS supplier;
- Evaluation of written materials and documentation outlining the DMEPOS supplier's policies and procedures; and
- Utilization/trend analyses that uncover deviations, positive or negative, for specific HCPCs codes or types of items over a given period.

The reviewers should:

- Possess the qualifications and experience necessary to adequately identify potential issues with the subject matter to be reviewed;
- Be objective and independent of line management;[169]
- 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 owner(s), president, CEO, governing body, and members of the compliance committee on a regular basis, but not less than annually; and
- Specifically identify areas where corrective actions are needed.

We recommend these audit reports be prepared and submitted to the compliance officer and senior management to ensure they are aware of the results. We suggest the reports specifically identify areas where corrective actions are needed. With these reports, DMEPOS supplier 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 actions have been implemented successfully.

The DMEPOS supplier should document its efforts to comply with applicable Federal and State statutes, rules, and regulations, and Federal, State and private payor health care program requirements. For example, where a DMEPOS supplier, in its efforts to comply with a particular statute, regulation or program requirement, requests advice from a Government agency (including a Medicare DMERC) charged with administering a Federal health care program, the DMEPOS supplier should document and retain a record of the request and any written or

[164] See also section II.A.2.

[165] The OIG recommends that when a compliance program is established in a DMEPOS supplier, the compliance officer, with the assistance of department managers, should take a ''snapshot'' of 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 DMEPOS supplier's progress in reducing or eliminating potential areas of vulnerability.

[166] 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.

[167] One way to assess the knowledge, awareness, and perceptions of the DMEPOS supplier's employees is through the use of a validated survey instrument (e.g., employee questionnaires, interviews, or focus groups).

[168] Such records should include, but not be limited to, logs of hotline calls, logs of training attendees, training agenda and materials, and summaries of corrective action and improvements with respect to DMEPOS supplier policies as a result of compliance activities.

[169] The OIG recognizes that DMEPOS suppliers that are small in size and have limited resources may not be able to use internal reviewers who are not part of line management or hire outside reviewers.

oral response, including the identity and position of the individual providing the response. DMEPOS suppliers should take the same steps when requesting advice from private payors. This step is extremely important if the DMEPOS supplier 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 DMEPOS supplier and third parties will help the organization document its attempts at compliance. In addition, the DMEPOS supplier 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 DMEPOS supplier's compliance program, failures to comply with applicable Federal or State statutes, rules, regulations or Federal, State or private payor health care program requirements, and other types of misconduct threaten a DMEPOS supplier's status as a reliable, honest and trustworthy health care provider. Detected but uncorrected misconduct can seriously endanger the mission, reputation, and legal status of the DMEPOS supplier. 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, rules or program instructions or the requirements of the compliance program has occurred, and if so, take decisive steps to correct the problem.[170] As appropriate, such steps may include an immediate referral to criminal and/or civil law enforcement authorities, a corrective action plan,[171] a report to the Government,[172] and the return of any overpayments, if applicable.

Where potential fraud or False Claims Act liability is not involved, the OIG recommends that the DMEPOS supplier promptly return overpayments to the affected payor as they are discovered. However, even if the overpayment detection and return process is working and is being monitored by the DMEPOS supplier, 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, such as submitted claims and CMNs. Some DMEPOS suppliers should consider engaging outside 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 any corrective action implemented. Although any action taken as the result of an investigation will necessarily vary depending upon the DMEPOS supplier and the situation, DMEPOS suppliers should strive for some consistency by utilizing sound practices and disciplinary protocols.[173] 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 DMEPOS supplier 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 DMEPOS supplier determines disciplinary action is warranted, it should be prompt and imposed in accordance with the DMEPOS supplier's written standards of disciplinary action.

2. Reporting. If the compliance officer, compliance committee or other 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 DMEPOS supplier should promptly report the existence of misconduct to the appropriate Federal and State authorities[174] within a reasonable period, but not more than sixty (60) days[175] after determining that there is credible evidence of a violation.[176] Prompt reporting will demonstrate the DMEPOS supplier'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

[170] Instances of non-compliance 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.

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

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

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

[174] Appropriate Federal and State authorities include the Office of Inspector General, Department of Health and Human Services; the Criminal and Civil Divisions of the Department of Justice; the U.S. Attorney in the relevant district(s); and the other investigative arms for the agencies administering the affected Federal or State health care programs, such as: the State Medicaid Fraud Control Unit; the Defense Criminal Investigative Service; the Department of Veterans Affairs; the Office of Inspector General, U.S. Department of Labor (which has primary criminal jurisdiction over FECA, Black Lung and Longshore programs); and the Office of Inspector General, U.S. Office of Personnel Management (which has primary jurisdiction over the Federal Employee Health Benefits Program).

[175] 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 DMEPOS supplier first obtained the information. See 31 U.S.C. 3729(a).

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

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.[177]

When reporting misconduct to the Government, a DMEPOS supplier should provide all evidence relevant to the alleged violation of applicable Federal or State law(s) and potential cost impact. The compliance officer, if applicable, with 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 authorities [178] should be notified immediately.

3. Corrective Actions. As previously stated, the DMEPOS supplier 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, the overpayment should be promptly refunded to the affected payor. The refund should also include the information as outlined in section II.F. Failure to disclose overpayments within a reasonable period of time could be interpreted as an intentional attempt to conceal the overpayment from the Government, thereby establishing an independent basis for a criminal violation with respect to the DMEPOS supplier, as well as any individuals who may have been involved. For this reason, DMEPOS supplier compliance programs should emphasize that overpayments obtained from Medicare or other Federal health care programs should be promptly disclosed and returned to the payor that made the erroneous payment.

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

[178] See note 174.

III. Conclusion

Through this document, the OIG has attempted to provide a foundation to the process necessary to develop an effective and cost-efficient DMEPOS supplier compliance program. As previously stated, however, each program must be tailored to fit the needs and resources of an individual DMEPOS supplier, depending upon its size; number of locations; type of equipment provided; or corporate structure. The Federal and State health care statutes, rules, and regulations and Federal, State and private payor health care program requirements, should be integrated into every DMEPOS supplier'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, legislation has been passed that creates additional Medicare program participation requirements, such as requiring DMEPOS suppliers to purchase surety bonds and expanding the Medicare supplier standards.[179] As stated throughout this guidance, compliance is a dynamic process that helps to ensure DMEPOS suppliers and other health care providers are better able to fulfill their commitment to ethical behavior, as well as meet the changes and challenges being imposed upon them by Congress and private insurers. Ultimately, it is OIG's hope that a voluntarily created compliance program will enable DMEPOS suppliers to meet their goals, improve the quality of service to patients, and substantially reduce fraud, waste, and abuse, as well as the cost of health care, to Federal, State and private health insurers.

Dated: January 22, 1999.

Michael Mangano,

Principal Deputy Inspector General.

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[179] See 63 FR 2926 (January 20, 1998).

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 Initial Review Group, Subcommittee F—Manpower & Training.

Date: March 7–10, 1999.

Time: 6:30 p.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn Central, 1501 Rhode Island Avenue, NW, Washington, DC 20005.

Contact Person: Mary Bell, Scientific Review Administrator, Division of Extramural Activities, National Cancer Institute, National Institutes of Health, PHS, DHHS, 6130 Executive Boulevard, Rockville, MD 20892, (301) 496–7978.

(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: January 22, 1999.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 99–1962 Filed 1–27–99; 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 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, Oncogene