Corporate Compliance & Internal Audits

(Supplemental Handouts)

Leading Age - Ohio
September 2011

Presented by:
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PPACA Medicare Compliance Program Requirements

- Providers will soon be required to establish compliance programs as a condition of participation in the Medicare program

- Who will be required to have a compliance program?

    - Skilled nursing facilities
    - Hospice programs
    - Home health agencies
    - Hospitals
    - Critical access hospitals
    - Comprehensive outpatient rehabilitation facilities

- What is the deadline for establishing a compliance program?

    - No deadline is established by PPACA – it is up to the Secretary of HHS to develop a timeline for implementation

    - Implementation dates may vary by industry or category

- Will there be additional guidance issued regarding the compliance programs?

    - Yes, the Secretary and the OIG will be establishing "core elements" for a compliance program for providers within a particular category
    - The timeline for establishing the "core elements" will also be determined by the Secretary
    - The OIG previously issued compliance guidance for certain providers (http://oig.hhs.gov/fraud/complianceguidance.asp), and it has compiled compliance resources on its website (http://oig.hhs.gov/fraud/complianceresources.asp)

PPACA Medicaid Compliance Program Requirements

- State plans for medical assistance must require "providers and suppliers" under the state plan or under a waiver of the plan to establish compliance programs in accordance with the Medicare compliance program requirements

- Who will be required to have a compliance program?
    - "Providers and suppliers" is not defined

- What is the deadline for establishing a compliance program?
    - No deadline is specified

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- Because the state plan requirements track the Medicare requirements, presumably, the implementation date will match that specified by the Secretary of HHS for Medicare providers

PPACA Nursing Facility Compliance & Ethics Program Requirements

- PPACA's Nursing Home Transparency & Improvement initiatives include compliance & ethics program requirements specific to nursing facilities

- What are the requirements?
  - Entities operating SNFs and NFs are required to establish a compliance & ethics program that is "effective in preventing and detecting criminal, civil, and administrative violations… and in promoting quality of care…"
  - Must address at least the following components:
    - Compliance standards/procedures to be followed by employees/agents to reduce the prospect of criminal, civil, and administrative violations
    - Specific, high-level individuals with sufficient resources and authority to assure compliance are assigned oversight responsibility
    - Uses due care *not* to delegate substantial discretionary authority to individuals whom the organization knows, or should know, have a propensity to engage in violations
    - Take steps to communicate standards/procedures to all employees/agents, such as by requiring participation in training programs or distributing publications
    - Takes reasonable steps to achieve compliance with its standards, *e.g.,* utilizing monitoring and auditing systems, having in place and publicizing a reporting system for employees/agents to report violations without fear of reprisal
    - Standards have been consistently enforced through disciplinary mechanisms, including discipline of individuals responsible for failure to detect an offense
    - After an offense has been detected, the organization takes all reasonable steps to respond appropriately and prevent further similar offenses, including modifications to its program
    - Periodically reassesses the program to identify necessary changes

- What is the deadline for establishing a compliance & ethics program?
  - March 23, 2013 (36 months after the date of enactment)

- Will there be additional guidance issued regarding the compliance programs?
  - Yes, the Secretary of HHS and the OIG will be issuing regulations regarding an

effective compliance & ethics program
  - The regulations are to be issued by March 23, 2012 (within 2 years of enactment)

- Also note that the requirements will take into account the size of the operating entity
  - Organizations that operate 5 or more facilities may be required to have more formal programs, including written policies defining standards/procedures

Nursing Facility Compliance Guidance – Supplemental (2008)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice of Meeting of the Advisory Committee on Organ Transplantation

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of Meeting of the Advisory Committee on Organ Transplantation.

SUMMARY: Pursuant to Public Law 92–463, the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the fourteenth meeting of the Advisory Committee on Organ Transplantation (ACOT), Department of Health and Human Services (HHS). The meeting will be held from approximately 8:30 a.m. to 5 p.m. on November 13, 2008, and from 8:30 a.m. to 3 p.m. on November 14, 2008, at the Hilton Washington DC/Rockville Executive Meeting Center, 1750 Rockville Pike, Rockville, MD 20852. The meeting will be open to the public; however, seating is limited and pre-registration is encouraged (see below).

SUPPLEMENTARY INFORMATION: Under the authority of 42 U.S.C. 217a, Section 222 of the Public Health Service Act, as amended, and 42 CFR 121.12 (2000), ACOT was established to assist the Secretary in enhancing organ donation, ensuring that the system of organ transplantation is grounded in the best available medical science, and assuring the public that the system is as effective and equitable as possible, and, thereby, increasing public confidence in the integrity and effectiveness of the transplantation system. ACOT is composed of up to 25 members, including the Chair. Members are serving as Special Government Employees and have diverse backgrounds in fields such as organ donation, health care public policy, transplantation medicine and surgery, critical care medicine and other medical specialties involved in the identification and referral of donors, non-physician transplant professions, nursing, epidemiology, immunology, law and bioethics, behavioral sciences, economics and statistics, as well as representatives of transplant candidates, transplant recipients, organ donors, and family members.

ACOT will hear presentations on the Report on New York State Transplant Council's Committee on Quality Improvement in Living Kidney Donation; Organ Procurement Organization Quality Assessment/Performance; Status of OPTN Living Donor Follow Up; Risks for Disease Transmission; Factors Affecting Future Donor Potential; Reimbursement and the Changing Nature of the Donor Pool; Projected Growth in End-Stage Renal Disease and Implications for Future Demand for Kidney Transplants; Economic Impact of Transplantation; and Briefing on OPTN White Paper on Charges for Pancreata Recovered for Islet Transplantation. The three ACOT work groups also will update the full Committee on their deliberations on living donor advocacy and post-donation complications, sources of funding for additional data collection, and reducing pediatric deaths on the waitlist.

The draft meeting agenda will be available on October 31 on the Department's donation Web site at *http://www.organdonor.gov/acot.html*.

A registration form will be available on or about October 15. Registration can be completed electronically at *http://www.team-psa.com/dot/acot2008/*. Registration also can be completed through the Department's donation Web site at *http://www.organdonor.gov/acot.html*. The completed registration form should be submitted by facsimile to Professional and Scientific Associates (PSA), the logistical support contractor for the meeting, at fax number (703) 234–1701. Individuals without access to the Internet who wish to register may call Sowjanya Kotakonda with PSA at (703) 234–1737. Individuals who plan to attend the meeting and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the ACOT Executive Secretary, Remy Aronoff, in advance of the meeting. Mr. Aronoff may be reached by telephone at 301–443–3300, e-mail: *remy.aronoff@hrsa.hhs.gov* or in writing at the address provided below. Management and support services for ACOT functions are provided by the Division of Transplantation, Healthcare Systems Bureau, Health Resources and Services Administration, 5600 Fishers Lane, Parklawn Building, Room 12C–06, Rockville, Maryland 20857; telephone number 301–443–7577.

After the presentations and ACOT discussions, members of the public will have an opportunity to provide comments. Because of the Committee's full agenda and the timeframe in which to cover the agenda topics, public comment will be limited. All public comments will be included in the record of the ACOT meeting.

Dated: September 23, 2008.

Elizabeth M. Duke,

Administrator.

[FR Doc. E8–22821 Filed 9–29–08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

OIG Supplemental Compliance Program Guidance for Nursing Facilities

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

ACTION: Notice.

SUMMARY: This **Federal Register** notice sets forth the supplemental compliance program guidance (CPG) for nursing facilities developed by the Office of Inspector General (OIG). OIG is supplementing its prior CPG for nursing facilities issued in 2000. The supplemental CPG contains new compliance recommendations and an expanded discussion of risk areas. The supplemental CPG takes into account Medicare and Medicaid nursing facility payment systems and regulations, evolving industry practices, current enforcement priorities (including the Government's heightened focus on quality of care), and lessons learned in the area of nursing facility compliance. The supplemental CPG provides voluntary guidelines to assist nursing facilities in identifying significant risk areas and in evaluating and, as necessary, refining ongoing compliance efforts.

FOR FURTHER INFORMATION CONTACT: Amanda Walker, Associate Counsel, Office of Counsel to the Inspector General, (202) 619–0335; or Catherine Hess, Senior Counsel, Office of Counsel to the Inspector General, (202) 619–1306.

Background

Beginning in 1998, OIG embarked on a major initiative to engage the private health care community in preventing the submission of erroneous claims and in combating fraud and abuse in the Federal health care programs through voluntary compliance efforts. As part of that initiative, OIG has developed a series of CPGs directed at the following segments of the health care industry: Hospitals; clinical laboratories; home health agencies; third-party billing companies; the durable medical equipment, prosthetics, orthotics, and supply industry; hospices; Medicare Advantage (formerly known as

Medicare+Choice) organizations; nursing facilities; ambulance suppliers; physicians; and pharmaceutical manufacturers.[1] It is our intent that CPGs encourage the development and use of internal controls to monitor adherence to applicable statutes, regulations, and program requirements. The suggestions made in the CPGs are not mandatory, and nursing facilities should not view the CPGs as exhaustive discussions of beneficial compliance practices or relevant risk areas.

OIG originally published a CPG for the nursing facility industry on March 16, 2000.[2] Since that time, there have been significant changes in the way nursing facilities deliver, and receive reimbursement for, health care services, as well as significant changes in the Federal enforcement environment and increased concerns about quality of care in nursing facilities, which continues to be a high priority of OIG. In response to these developments, and in an effort to receive initial input on this guidance from interested parties, OIG published a notice in the **Federal Register** on January 24, 2008, seeking stakeholder comments.[3] After consideration of the public comments and the issues raised, OIG published a draft supplemental CPG for Nursing Facilities in the **Federal Register** on April 16, 2008, to ensure that that all parties had a reasonable and meaningful opportunity to provide input into the final product.[4]

We received seven comments on the draft document, all from trade associations. We also held stakeholder meetings with the commenters who chose to meet with us. OIG considered the written comments and input from the meetings during the development of the final supplemental CPG. Commenters uniformly supported OIG's efforts to update the 2000 Nursing Facility CPG. Some of the commenters suggested that OIG clarify the draft supplemental CPG to reflect more fully the role consultant pharmacists can play, in conjunction with other members of residents' care teams, in achieving appropriate medication management in nursing facilities. Other commenters suggested modifications to other aspects of the draft supplemental CPG, including physician roles and contractual issues. The final supplemental CPG incorporates clarifications responsive to these comments. Several commenters suggested legislative or policy changes outside the scope of the supplemental CPG, and those comments are not addressed by the final supplemental CPG.

In the draft supplemental CPG, we specifically solicited suggestions regarding specific measures of compliance program effectiveness tailored to nursing facilities. We did not receive suggestions proposing such measures, and therefore did not include an effectiveness measures section in the final supplemental CPG.

OIG Supplemental Compliance Program Guidance for Nursing Facilities

This document is organized in the following manner:

I. Introduction

Continuing its efforts to promote voluntary compliance programs for the health care industry, the Office of Inspector General (OIG) of the Department of Health and Human Services (Department) publishes this Supplemental Compliance Program Guidance (CPG) for Nursing Facilities.[5] This document supplements, rather than replaces, OIG's 2000 Nursing Facility CPG, which addressed the fundamentals of establishing an effective compliance program for this industry.[6]

Neither this supplemental CPG, nor the original 2000 Nursing Facility CPG, is a model compliance program. Rather, the two documents collectively offer a set of guidelines that nursing facilities should consider when developing and implementing a new compliance program or evaluating an existing one. We are mindful that many nursing facilities have already devoted substantial time and resources to compliance efforts. For those nursing facilities with existing compliance programs, this document may serve as a roadmap for updating or refining their compliance plans. For facilities with emerging compliance programs, this supplemental CPG, read in conjunction with the 2000 Nursing Facility CPG, should facilitate discussions among facility leadership regarding the inclusion of specific compliance components and risk areas.

In drafting this supplemental CPG, we considered, among other things, public comments; relevant OIG and Centers for Medicare & Medicaid Services (CMS) statutory and regulatory authorities (including CMS's regulations governing long-term care facilities at 42 CFR part 483; CMS transmittals, program memoranda, and other guidance; and the Federal fraud and abuse statutes, together with the anti-kickback safe

[1] Copies of the CPGs are available on our Web site at *http://www.oig.hhs.gov/fraud/complianceguidance.html.*

[2] *See* 65 FR 14289 (March 16, 2000), ''Publication of the OIG Compliance Program Guidance for Nursing Facilities'' (2000 Nursing Facility CPG), available on our Web site at *http://oig.hhs.gov/authorities/docs/cpgnf.pdf.*

[3] *See* 73 FR 4248 (January 24, 2008), ''Solicitation of Information and Recommendations for Revising the Compliance Program Guidance for Nursing Facilities,'' available on our Web site at *http://oig.hhs.gov/authorities/docs/08/CPG_Nursing_Facility_Solicitation.pdf.*

[4] *See* 73 FR 20680 (April 16, 2008), ''Draft OIG Supplemental Compliance Program Guidance for Nursing Facilities,'' available on our Web site at *http://oig.hhs.gov/fraud/docs/complianceguidance/NurseCPGIIFR.pdf.*

[5] For purposes of convenience in this guidance, the term ''nursing facility'' or ''facility'' includes a skilled nursing facility (SNF) and a nursing facility (NF) that meet the requirements of sections 1819 and 1919 of the Social Security Act (Act) (42 U.S.C. 1395i–3, 1396r), respectively, as well as entities that own or operate such facilities. Where appropriate, we distinguish SNFs from NFs. While long-term care providers other than SNFs or NFs, such as assisted living facilities, should find this CPG useful, we recognize that they may be subject to different laws, rules, and regulations and, accordingly, may have different or additional risk areas and may need to adopt different compliance strategies. We encourage all long-term care providers to establish and maintain effective compliance programs.

[6] *See* 2000 Nursing Facility CPG, *supra* note 2.

harbor regulations and preambles); other OIG guidance (such as OIG advisory opinions, special fraud alerts, bulletins, and other public documents); experience gained from investigations conducted by OIG's Office of Investigations, the Department of Justice (DOJ), and the State Medicaid Fraud Control Units; and relevant reports issued by OIG's Office of Audit Services and Office of Evaluation and Inspections. We also consulted with CMS, DOJ, and nursing facility resident advocates.

This supplemental CPG responds to developments in the nursing facility industry, including significant changes in the way nursing facilities deliver, and receive reimbursement for, health care services, evolving business practices, and changes in the Federal enforcement environment. Moreover, this supplemental CPG reflects OIG's continued focus on quality of care in nursing facilities. Together with our law enforcement partners, we have used, with increasing frequency, Federal civil fraud remedies to address cases involving poor quality of care, including troubling failure of care on a systemic level in some organizations. To promote compliance and prevent fraud and abuse, OIG is supplementing the 2000 Nursing Facility CPG with specific risk areas related to quality of care, claims submissions, the Federal anti-kickback statute, and other emerging areas.

A. Benefits of a Compliance Program

Nursing facilities are vital to the health and welfare of millions of Americans. OIG recognizes that most facilities and the people who work in them strive daily to provide high quality, compassionate, cost-effective care to residents. A successful compliance program addresses the public and private sectors' common goals of reducing fraud and abuse, enhancing health care providers' operations, improving the quality of health care services, and reducing their overall cost. Meeting these goals benefits the nursing facility industry, the Government, and residents alike. Compliance programs help nursing facilities fulfill their legal duty to provide quality care; to refrain from submitting false or inaccurate claims or cost information to the Federal health care programs; and to avoid engaging in other illegal practices.

A nursing facility may gain important additional benefits by voluntarily implementing a compliance program, including:

- Demonstrating the nursing facility's commitment to honest and responsible corporate conduct;
- Increasing the likelihood of preventing unlawful and unethical behavior or identifying and correcting such behavior at an early stage;
- Encouraging employees and others to report potential problems, which permits appropriate internal inquiry and corrective action and reduces the risk of False Claims Act lawsuits, and administrative sanctions (*e.g.*, penalties, assessments, and exclusion), as well as State actions;
- Minimizing financial loss to the Government and taxpayers, as well as corresponding financial loss to the nursing facility;
- Enhancing resident satisfaction and safety through the delivery of improved quality of care; and
- Improving the nursing facility's reputation for integrity and quality, increasing its market competitiveness and reputation in the community.

OIG recognizes that implementation of a compliance program may not entirely eliminate improper or unethical conduct from nursing facility operations. However, an effective compliance program demonstrates a nursing facility's good faith effort to comply with applicable statutes, regulations, and other Federal health care program requirements, and may significantly reduce the risk of unlawful conduct and corresponding sanctions.

B. Application of Compliance Program Guidance

Given the diversity of the nursing facility industry, there is no single ''best'' nursing facility compliance program. OIG recognizes the complexities of the nursing facility industry and the differences among facilities. Some nursing facilities are small and may have limited resources to devote to compliance measures; others are affiliated with well-established, large, multi-facility organizations with a widely dispersed work force and significant resources to devote to compliance.

Accordingly, OIG does not intend this supplemental CPG to be a ''one-size-fits-all'' guidance. OIG strongly encourages nursing facilities to identify and focus their compliance efforts on those areas of potential concern or risk that are most relevant to their organizations. A nursing facility should tailor its compliance measures to address identified risk areas and to fit the unique environment of the facility (including its structure, operations, resources, the needs of its resident population, and prior enforcement experience). In short, OIG recommends that each nursing facility adapt the objectives and principles underlying this guidance to its own particular circumstances.

In section II below, for contextual purposes, we provide a brief overview of the reimbursement system. In section III, entitled ''Fraud and Abuse Risk Areas,'' we present several fraud and abuse risk areas that are particularly relevant to the nursing facility industry. Each nursing facility should carefully examine these risk areas and identify those that potentially affect it. Next, in section IV, ''Other Compliance Considerations,'' we offer recommendations for establishing an ethical culture and for assessing and improving an existing compliance program. Finally, in section V, ''Self-Reporting,'' we set forth the actions nursing facilities should take if they discover credible evidence of misconduct.

II. Reimbursement Overview

We begin with a brief overview of Medicare and Medicaid reimbursement for nursing facilities as context for the subsequent risk areas section. This overview is intended to be a summary only. It does not establish or interpret any program rules or regulations. Nursing facilities are advised to consult the relevant program's payment, coverage, and participation rules, regulations, and guidance, which change over time. Any questions regarding payment, coverage, or participation in the Medicare or Medicaid programs should be directed to the relevant contractor, carrier, CMS office, or State Medicaid agency.

A. Medicare

Medicare reimbursement to SNFs and NFs depends on several factors, including the character of the facility, the beneficiary's circumstances, and the type of items and services provided. Generally speaking, SNFs are Medicare-certified facilities that provide extended skilled nursing or rehabilitative care under Medicare Part A. They are typically reimbursed under Part A for the costs of most items and services, including room, board, and ancillary items and services. In some circumstances (discussed further below), SNFs may receive payment under Medicare Part B. Facilities that are not SNFs are not reimbursed under Part A. They may be reimbursed for some items and services under Part B.

Medicare pays SNFs under a prospective payment system (PPS) for beneficiaries covered by the Part A extended care benefit.[7] Covered

[7] Section 1888(e) of the Act (42 U.S.C. 1395yy(e)) (noting the PPS rate applied to services provided on

beneficiaries are those who require skilled nursing or rehabilitation services and receive the services from a Medicare-certified SNF after a qualifying hospital stay of at least 3 days.[8] The PPS rate is a fixed, per diem rate.[9] The maximum benefit is 100 days per ''spell of illness.'' [10]

CMS adjusts the PPS per diem rate per resident to ensure that the level of payment made for a particular resident reflects the resource intensity that would typically be associated with that resident's clinical condition.[11] This methodology, referred to as the Resource Utilization Group (RUG) classification system, currently in version RUG-III, uses beneficiary assessment data extrapolated from the Minimum Data Set (MDS) to assign beneficiaries to one of the RUG-III groups.[12] The MDS is composed of data variables for each resident, including diagnoses, treatments, and an evaluation of the resident's functional status, which are collected via a Resident Assessment Instrument (RAI).[13] Such assessments are conducted at established intervals throughout a resident's stay. The resident's RUG assignment and payment rate are then adjusted accordingly for each interval.[14]

The PPS payments cover virtually all of the SNF's costs for furnishing services to Medicare beneficiaries covered under Part A. Under the ''consolidated billing'' rules, SNFs bill Medicare for most of the services provided to Medicare beneficiaries in SNF stays covered under Part A, including items and services that outside practitioners and suppliers provide under arrangement with the SNF.[15] The SNF is responsible for paying the outside practitioners and suppliers for these services.[16] Services covered by this consolidated billing requirement include, by way of example, physical therapy, occupational therapy, and speech therapy services; certain non-self-administered drugs and supplies furnished ''incident to'' a physician's services (*e.g.*, ointments, bandages, and oxygen); braces and orthotics; and the technical component of most diagnostic tests.[17] These items and services must be billed to Medicare by the SNF.[18]

The consolidated billing requirement does not apply to a small number of excluded services, such as physician professional fees and certain ambulance services.[19] These excluded services are separately billable to Part B by the individual or entity furnishing the service. For example, professional services furnished personally by a physician to a Part A SNF resident are excluded from consolidated billing and are billed by the physician to the Part B carrier.[20]

Some Medicare beneficiaries reside in a Medicare-certified SNF, but are not eligible for Part A extended care benefits (*e.g.*, a beneficiary who did not have a qualifying hospital stay of at least 3 days or a beneficiary who has exhausted his or her Part A benefit). These beneficiaries—sometimes described as being in ''non-covered Part A stays''—may still be eligible for Part B coverage of certain individual services. Consolidated billing would not apply to such individual services, with the exception of therapy services.[21] Physical therapy, occupational therapy, and speech language pathology services furnished to SNF residents are always subject to consolidated billing.[22] Claims for therapy services furnished during a non-covered Part A stay must be submitted to Medicare by the SNF itself.[23] Thus, according to CMS guidance, the SNF is reimbursed under the Medicare fee schedule for the therapy services, and is responsible for reimbursing the therapy provider.[24]

When a beneficiary resides in a nursing facility (or part thereof) that is not certified as an SNF by Medicare, the beneficiary is not considered an SNF resident for Medicare billing purposes.[25] Accordingly, ancillary services, including therapy services, are not subject to consolidated billing.[26] Either the supplier of the ancillary service or the facility may bill the Medicare carrier for the Part B items and services directly.[27] In these circumstances, it is the joint responsibility of the facility and the supplier to ensure that only one of them bills Medicare.

Part B coverage for durable medical equipment (DME) presents special circumstances because the benefit extends only to items furnished for use in a patient's home.[28] DME furnished for use in an SNF or in certain other facilities providing skilled care is not covered by Part B. Instead, such DME is covered by the Part A PPS payment or applicable inpatient payment.[29] In some cases, NFs that are not SNFs can be considered a ''home'' for purposes of DME coverage under Part B.[30]

B. Medicaid

Medicaid provides another means for nursing facility residents to pay for skilled nursing care, as well as room and board in a nursing facility certified by the Government to provide services to Medicaid beneficiaries. Medicaid is a State and Federal program that covers certain groups of low-income and medically needy people. Medicaid also helps residents dually eligible for Medicare and Medicaid pay their Medicare premiums and cost-sharing amounts. Because Medicaid eligibility criteria, coverage limitations, and reimbursement rates are established at the State level, there is significant variation across the nation. Many States, however, pay nursing facilities a flat daily rate that covers room, board, and routine care for Medicaid beneficiaries.

III. Fraud and Abuse Risk Areas

This section should assist nursing facilities in their efforts to identify operational areas that present potential liability risks under several key Federal fraud and abuse statutes and regulations. This section focuses on areas that are currently of concern to the enforcement community. It is not intended to address all potential risk areas for nursing facilities. Identifying a particular practice or activity in this section is not intended to imply that the practice or activity is necessarily illegal

or after July 1, 1998). *See also* CMS, ''Consolidated Billing,'' available on CMS's Web site at *http://www.cms.hhs.gov/SNFPPS/05_ConsolidatedBilling.asp.*

[8] Sections 1812(a)(2) and 1861(i) of the Act (42 U.S.C. 1395d(a)(2), 1395x(i)).

[9] Section 1888(e) of the Act (42 U.S.C. 1395yy(e)).

[10] Section 1812(a)(2)(A) of the Act (42 U.S.C. 1395d(a)(2)(A)).

[11] Section 1888(e)(4)(G)(i) of the Act (42 U.S.C. 1395yy(e)(4)(G)(i)).

[12] *Id.*

[13] Sections 1819(b)(3) and 1919(b)(3) of the Act (42 U.S.C. 1395i–3(b)(3), 1396r(b)(3)), and their implementing regulation, 42 CFR 483.20, require nursing facilities participating in the Medicare or Medicaid programs to use a standardized RAI to assess each nursing facility resident's strengths and needs.

[14] *See id.*

[15] Sections 1842(b)(6)(E) and 1862(a)(18) of the Act (42 U.S.C. 1395u, 1395aa); Section 1888(e) of the Act (42 U.S.C. 1395yy(e)) (noting the PPS rate applied to services provided on or after July 1, 1998). *See also* Consolidated Billing, *supra* note 7.

[16] *See id.*

[17] Section 1888(e) of the Act (42 U.S.C. 1395yy); Consolidated Billing, *supra* note *7.*

[18] *Id.*

[19] *Id.*

[20] *Id.*

[21] Section 1888(e)(2)(A) of the Act (42 U.S.C. 1395yy(e)(2)(A)); CMS, ''Skilled Nursing Facilities (SNF) Consolidated Billing (CB) as It Relates to Therapy Services,'' MLN Matters Number: SE0518 (MLN Matters SE0518), available on CMS's Web site at *http://www.cms.hhs.gov/MLNMattersArticles/downloads/SE0518.pdf.*

[22] *Id.*

[23] MLN Matters SE0518, *supra* note 21.

[24] Id.

[25] *Id.*

[26] *Id.*

[27] *Id.*

[28] Section 1861(n) of the Act (42 U.S.C. 1395x(n)).

[29] Section 1861(h)(5) of the Act (42 U.S.C. 1395x(h)(5)).

[30] Section 1861(n) of the Act (42 U.S.C. 1395x(n)).

in all circumstances or that it may not have a valid or lawful purpose. This section addresses the following areas of significant concern for nursing facilities: Quality of care, submission of accurate claims, Federal anti-kickback statute, other risk areas, and Health Insurance Portability and Accountability Act of 1996 (HIPAA) privacy and security rules.

This guidance does not create any new law or legal obligations, and the discussions in this guidance are not intended to present detailed or comprehensive summaries of lawful or unlawful activity. This guidance is not intended as a substitute for consultation with CMS, a facility's fiscal intermediary or Program Safeguard Contractor, a State Medicaid agency, or other relevant State agencies with respect to the application and interpretation of payment, coverage, licensure, or other provisions that are subject to change. Rather, this guidance should be used as a starting point for a nursing facility's legal review of its particular practices and for development or refinement of policies and procedures to reduce or eliminate potential risk.

A. Quality of Care

By 2030, the number of older Americans is estimated to rise to 71 million,[31] making the aging of the U.S. population ''one of the major public health challenges we face in the 21st century.'' [32] In addressing this challenge, a national focus on the quality of health care is emerging.

In cases that involve failure of care on a systemic and widespread basis, the nursing facility may be liable for submitting false claims for reimbursement to the Government under the Federal False Claims Act, the Civil Monetary Penalties Law (CMPL), or other authorities that address false and fraudulent claims or statements made to the Government.[33] Thus, compliance with applicable quality of care standards and regulations is essential for the lawful behavior and success of nursing facilities.

Nursing facilities that fail to make quality a priority, and consequently fail to deliver quality health care, risk becoming the target of governmental investigations. Highlighted below are common risk areas associated with the delivery of quality health care to nursing facility residents that frequently arise in enforcement cases. These include sufficient staffing, comprehensive care plans, medication management, appropriate use of psychotropic medications, and resident safety. This list is not exhaustive. Moreover, nursing facilities should recognize that these issues are often inter-related. Nursing facilities that attempt to address one issue will often find that they must address other areas as well. The risk areas identified in sections III.B. (Submission of Accurate Claims), III.C. (Anti-Kickback), and III.D. (Other Risk Areas) below are also intertwined with quality of care risk areas and should be considered as well.

As a starting point, nursing facilities should familiarize themselves with 42 CFR part 483 (part 483), which sets forth the principal requirements for nursing facility participation in the Medicare and Medicaid programs. It is essential that key members of the organization understand these requirements and support their facility's commitment to compliance with these regulations. Targeted training for care providers, managers, administrative staff, officers, and directors on the requirements of part 483 will help nursing facilities ensure that they are fulfilling their obligation to provide quality health care.[34]

1. Sufficient Staffing

OIG is aware of facilities that have systematically failed to provide staff in sufficient numbers and with appropriate clinical expertise to serve their residents. Although most facilities strive to provide sufficient staff, nursing facilities must be mindful that Federal law requires sufficient staffing necessary to attain or maintain the highest practicable physical, mental, and psychosocial well-being of residents.[35] Thus, staffing numbers and staff competency are critical.

The relationship between staff ratios, staff competency, and quality of care is complex.[36] No single staffing model will suit every facility. A staffing model that works in a nursing facility today may not meet the facility's needs in the future. Nursing facilities, therefore, are strongly encouraged to assess their staffing patterns regularly to evaluate whether they have sufficient staff members who are competent to care for the unique acuity levels of their residents.

Important considerations for assessing staffing models include, among others, resident case-mix, staff skill levels, staff-to-resident ratios, staff turnover,[37] staffing schedules, disciplinary records, payroll records, timesheets, and adverse

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[31] Centers for Disease Control and Prevention (CDC), ''The State of Aging and Health in America 2007,'' available on CDC's Web site at *http://www.cdc.gov/aging/pdf/saha_2007.pdf*.

[32] *Id.* (quoting Julie Louise Gerberding, M.D., MPH, Director, CDC, U.S. Department of Health and Human Services).

[33] ''Listening Session: Abuse of Our Elders: How We Can Stop It: Hearing Before the Senate Special Committee on Aging,'' 110th Congress (2007) (testimony of Gregory Demske, Assistant Inspector General for Legal Affairs, Office of Inspector General, U.S. Department of Health and Human Services), available at *http://aging.senate.gov/events/hr178gd.pdf*; *see also* 18 U.S.C. 287 (concerning false, fictitious, or fraudulent claims); 18 U.S.C. 1001 (concerning statements or entries generally); 18 U.S.C. 1035 (concerning false statements relating to health care matters); 18 U.S.C. 1347 (concerning health care fraud); 18 U.S.C. 1516 (concerning obstruction of a Federal audit); the Federal False Claims Act (31 U.S.C. 3729–3733); section 1128A of the Act (42 U.S.C. 1320a–7a) (concerning civil monetary penalties); section 1128B(c) of the Act (42 U.S.C. 1320a–7b(c)) (concerning false statements or representations with respect to condition or operation of institutions). In addition to the Federal criminal, civil, and administrative liability for false claims and kickback violations outlined in this CPG, nursing facilities also face exposure under State laws, including criminal, civil, and administrative sanctions.

[34] The requirement to deliver quality health care is a continuing obligation for nursing facilities. As regulations change, so too should the training. Therefore, this recommendation envisions more than an initial employee ''orientation'' training on the nursing facility's obligations to provide quality health care. CMS has multiple resources available to assist nursing facilities in developing training programs. See CMS, ''Sharing Innovations in Quality, Resources for Long Term Care,'' available on CMS's Web site at *http://siq.air.org/default.aspx*; CMS, ''Skilled Nursing Facilities/Long-Term Care Open Door Forum,'' available on CMS's Web site at *http://www.cms.hhs.gov/OpenDoorForums/25_ODF_SNFLTC.asp*; CMS, ''State Operations Manual,'' Pub. No. 100–07, available on CMS's Web site at *http://www.cms.hhs.gov/Manuals/IOM/list.asp*; *see also* Medicare Quality Improvement Community, ''MedQIP—Medicare Quality Improvement Community,'' available on CMS's Web site at *http://www.medqic.org*. Nursing facilities may also find it useful to review the CMS Quality Improvement Organizations Statement of Work, available at *http://www.cms.hhs.gov/QualityImprovementOrgs/04_9thsow.asp*. In addition, facilities may wish to stay abreast of emerging best practices, which are often promoted by industry associations.

[35] Sections 1819(b)(4)(A) and 1919(b)(4)(A) of the Act (42 U.S.C. 1395i–3(b)(4)(A), 1396r(b)(4)(A)); 42 CFR 483.30.

[36] For example, State nursing facility staffing standards, which exist for the majority of States, vary in types of regulated staff, the ratios of staff, and the facilities to which the regulations apply. *See* Jane Tilly, *et al.*, ''State Experiences with Minimum Nursing Staff Ratios for Nursing Facilities: Findings from Case Studies of Eight States'' (November 2003) (joint paper by The Urban Institute and the Department), available at *http://aspe.hhs.gov/daltcp/reports/8statees.htm*.

[37] Nursing facilities operate in an environment of high staff turnover where it is difficult to attract, train, and retain an adequate workforce. Turnover among nurse aides, who provide most of the hands-on care in nursing facilities, means that residents are constantly receiving care from new staff who often lack experience and knowledge of individual residents. Furthermore, research correlates staff shortages and insufficient training with substandard care. *See* OIG, OEI Report OEI–01–04–00070, ''Emerging Practices in Nursing Homes,'' March 2005, available on our Web site at *http://oig.hhs.gov/oei/reports/oei-01-04-00070.pdf* (reviewing emerging practices that nursing facility administrators believe reduce their staff turnover).

event reports (e.g., falls or adverse drug events), as well as interviews with staff, residents, and residents' family or legal guardians. Facilities should ensure that the methods used to assess staffing accurately measure actual ''on-the-floor'' staff rather than theoretical ''on-paper'' staff. For example, payroll records that reflect actual hours and days worked may be more useful than prospectively generated staff schedules.

2. Comprehensive Resident Care Plans

Development of comprehensive resident care plans is essential to reducing risk. Prior OIG reports revealed that a significant percentage of resident care plans did not reflect residents' actual care needs.[38] Through its enforcement and compliance monitoring activities, OIG continues to see insufficient care plans and their impact on residents as a risk area for nursing facilities.

Medicare and Medicaid regulations require nursing facilities to develop a comprehensive care plan for each resident that addresses the medical, nursing, and mental and psychosocial needs for each resident and includes reasonable objectives and timetables.[39] Nursing facilities should ensure that care planning includes all disciplines involved in the resident's care.[40] Perfunctory meetings or plans developed without the full clinical team may create less than comprehensive resident-centered care plans. Inadequately prepared plans make it less likely that residents will receive coordinated, multidisciplinary care. Insufficient plans jeopardize residents' well-being and risk the provision of inadequate care, medically unnecessary care services, or medically inappropriate services.

To reduce these risks, nursing facilities should design measures to ensure an interdisciplinary and comprehensive approach to developing care plans. Basic steps, such as appropriately scheduling meetings to accommodate the full interdisciplinary team, completing all clinical assessments before the meeting is convened,[41] opening lines of communication between direct care providers and interdisciplinary team members, involving the resident and the residents' family members or legal guardian,[42] and documenting the length and content of each meeting, may assist facilities with meeting this requirement.

Another risk area related to care plans includes the involvement of attending physicians in resident care. Although specific regulations govern the role and responsibilities of attending physicians,[43] the nursing facility also has a critical role—ensuring that a physician supervises each resident's care.[44] Facilities must also include the attending physician in the development of the resident's care plan.[45] Thus, an effective compliance program would ensure physician involvement in these processes.[46] For example, many facilities schedule meetings to discuss a particular resident's care plan. Facilities may wish to develop policies and procedures to facilitate participation by attending physicians, who often are not physically present at the nursing facility on a daily basis. Facilities may improve communication with physicians by providing advance notice of care planning meetings. Nursing facilities should evaluate, in conjunction with the attending physician, how best to ensure physician participation—whether via consultation and post-meeting debriefing, or telephone or personal attendance at meetings—with a focus on serving the best interests of the resident and complying with applicable regulations.

3. Medication Management

The Act requires nursing facilities to provide ''pharmaceutical services (including procedures that assure accurate acquiring, receiving, dispensing, and administering of all drugs and biologicals) to meet the needs of each resident.'' [47] Nursing facilities should be mindful of potential quality of care problems when adopting and implementing policies and procedures to provide these services. A failure to manage pharmaceutical services properly can seriously jeopardize resident safety and even result in resident deaths.

Nursing facilities can promote compliance by having in place proper medication management processes that advance patient safety, minimize adverse drug interactions, and ensure that irregularities in a resident's drug regimen are promptly discovered and addressed. Nursing facilities should implement policies and procedures for maintaining accurate drug records and tracking medications. Nursing facilities should provide appropriate training on a regular basis to familiarize all staff involved in the pharmaceutical care of residents with proper medication management. To this end, the facility's consultant pharmacist is an important resource. Consultant pharmacists, who specialize in the medication needs specific to older adults or institutionalized individuals, can help facilities ''identify, evaluate, and address medication issues that may affect resident care, medical care, and quality of life.'' [48]

CMS regulations require that nursing facilities employ or obtain the services of a licensed pharmacist to ''provide[] consultation on all aspects of the provision of pharmacy services in the facility * * *.'' [49] The pharmacist must review the drug regimen of each resident at least once a month and

[38] See, *e.g.*, OIG, OEI Report OEI–02–99–00040, ''Nursing Home Resident Assessment Quality of Care,'' January 2001, available on our Web site at *http://oig.hhs.gov/oei/reports/oei-02–99–00040.pdf.*

[39] 42 CFR 483.20(k). An effective compliance program would also monitor discharge and transfer of residents for compliance with Federal and State regulations. *See, e.g.*, 42 CFR 483.12 (detailing transfer and discharge obligations). Because many of the legitimate reasons for transfer or discharge relate to the medical or psychosocial needs of the resident, the care plan team may be in a position to provide recommendations on discharge or transfer of a resident.

[40] 42 CFR 483.20(k)(2)(ii) (requiring an interdisciplinary team, including the physician, a registered nurse with responsibility for the resident, and other disciplines involved in the resident's care).

[41] Nursing facilities with residents with mental illness or mental retardation should ensure that they have the Preadmission Screening and Resident Review (PASRR) screens for their residents. *See* 42 CFR 483.20(m). In addition, for residents who do not require specialized services, facilities should ensure that they are providing the ''services of lesser intensity'' as set forth in CMS regulations. *See* 42 CFR 483.120(c). Care plan meetings can provide nursing facilities with an ideal opportunity to ensure that these obligations are met.

[42] Where possible, residents and their family members or legal guardians should be included in the development of care and treatment plans. Unless the resident has been declared incompetent or otherwise found to be incapacitated under State law, the resident has a right to participate in his or her care planning and treatment. 42 CFR 483.10(d)(3).

[43] *See, e.g.*, 42 CFR 483.40(b), (c), (e).

[44] 42 CFR 483.40(a).

[45] 42 CFR 483.20(k)(2)(ii).

[46] *See* 42 CFR 483.40(a) (obligating a facility to ensure a physician supervises resident care); 42 CFR 483.40(b) (requiring physicians to review the resident's ''total program of care'').

[47] Sections 1819(b)(4)(A)(iii) and 1919(b)(4)(A)(iii) of the Act (42 U.S.C. 1395i–3(b)(4)(A)(iii) and 1396r(b)(4)(A)(iii)). In addition, under 42 CFR 483.60, SNFs and NFs must ''provide routine and emergency drugs and biologicals to [their] residents, or obtain them under an agreement described in [section] 483.75(h) * * *'' Nursing facilities must meet this obligation even if a pharmacy charges a Medicare Part D copayment to a dual eligible beneficiary who cannot afford to pay the copayment. See CMS, ''Part D Questions re: Co-pays for Institutionalized Individuals April 19, 2006,'' Question 2. and Response, in ''Medicare Part D Claims Filing Window Extended to 180 Days,'' Medicare Rx Update: May 9, 2006, available on CMS's Web site at *http://www.cms.hhs.gov/Pharmacy/downloads/update050906.pdf.*

[48] CMS, ''State Operations Manual,'' Pub. No. 100–07, Appendix PP, section 483.60, available on CMS's Web site at *http://cms.hhs.gov/manuals/Downloads/som107ap_pp_guidelines_ltcf.pdf.*

[49] 42 CFR 483.60(b)(1).

report any irregularities discovered in a resident's drug regimen to the attending physician and the director of nursing.[50] These pharmacists are also required to: (1) ''[e]stablish[] a system of records of receipt and disposition of all controlled drugs * * *;'' and (2) ''[d]etermine[] that drug records are in order and that an account of all controlled drugs is maintained and periodically reconciled.'' [51] As indicated in CMS guidance, ''[t]he facility may provide for this service through any of several methods (in accordance with [S]tate requirements) such as direct employment or contractual agreement with a pharmacist.'' [52] Some of the consultant pharmacists obtained by nursing facilities are employed by long-term care pharmacies that furnish drugs and supplies to nursing facilities.[53] Whatever the arrangement or method used, the nursing facility and consultant pharmacist should work together to achieve proper medication management in the facility.

4. Appropriate Use of Psychotropic Medications

Based on our enforcement and compliance monitoring activities, OIG has identified inappropriate use of psychotropic medications for residents as a risk area in at least two ways—the prohibition against inappropriate use of chemical restraints and the requirement to avoid unnecessary drug usage.

Facilities have affirmative obligations to ensure appropriate use of psychotropic medications. Specifically, nursing facilities must ensure that psychopharmacological practices comport with Federal regulations and generally accepted professional standards.[54] The facility is responsible for the quality of drug therapy provided in the facility. Federal law prohibits facilities from using any medication as a means of chemical restraint for ''purposes of discipline or convenience, and not required to treat the resident's medical symptoms.'' [55] In addition, resident drug regimens must be free from unnecessary drugs.[56] For residents who specifically require antipsychotic medications, CMS regulations also require, unless contraindicated, that residents receive gradual dose reductions and behavioral interventions aimed at reducing medication use.[57]

In light of these requirements, nursing facilities should ensure that there is an adequate indication for the use of the medication and should carefully monitor, document, and review the use of each resident's psychotropic drugs. Working together, the attending physicians, medical director, consultant pharmacist, and other resident care providers play a critical role in achieving these objectives. Compliance measures could include educating care providers regarding appropriate monitoring and documentation practices and auditing drug regimen reviews [58] and resident care plans to determine if they incorporate an assessment of the resident's ''medical, nursing, and mental and psychosocial needs,'' [59] including the need for psychotropic medications for a specific medical condition.[60] The attending physicians, the medical director, the consultant pharmacist, and other care providers should collaborate to analyze the outcomes of care using the results of the drug regimen reviews, progress notes, and monitoring of the resident's behaviors.

5. Resident Safety

Nursing facility residents have a legal right to be free from abuse and neglect.[61] Facilities should take steps to ensure that they are protecting their residents from these risks.[62] Of particular concern is harm caused by staff and fellow residents.[63]

(a) Promoting Resident Safety

Federal regulations mandate that nursing facilities develop and implement policies and procedures to prohibit mistreatment, neglect, and abuse of residents.[64] Facilities must also thoroughly investigate and report incidents to law enforcement, as required by State laws.[65] Although experts continue to debate the most effective systems for enhancing the reporting, investigation, and prosecution of nursing facility resident abuse, an effective compliance program recognizes the value of a demonstrated internal commitment to eliminating resident abuse.[66] An effective compliance program will include policies, procedures, and practices to prevent, investigate, and respond to instances of potential resident abuse, neglect, or mistreatment, including injuries resulting from staff-on-resident abuse and neglect, resident-on-resident abuse, and abuse from unknown causes.

Confidential reporting is a key component of an effective resident safety program. Such a mechanism enables staff, contractors, residents, family members, visitors, and others to report threats, abuse, mistreatment, and other safety concerns confidentially to senior staff empowered to take immediate action. Posters, brochures, and online resources that encourage readers to report suspected safety problems to senior facility staff are commonly used. Another commonly

[50] 42 CFR 483.60(c).

[51] 42 CFR 483.60(b)(2), (3).

[52] CMS, ''State Operations Manual,'' Pub. No. 100–07, Appendix PP, section 483.60, available on CMS's Web site at *http://cms.hhs.gov/manuals/Downloads/som107ap_pp_guidelines_ltcf.pdf*. In cases where the nursing facilities employ or contract directly with pharmacists to provide consultant pharmacist services, the nursing facility should ensure that the pharmacist's compensation is not structured in any manner that reflects the volume or value of drugs prescribed for, or administered to, patients.

[53] Nursing facilities that receive consultant pharmacist services under contract with a long-term care pharmacy should be mindful that the provision or receipt of free services or services at non-fair-market value rates between actual or potential referral sources present a heightened risk of fraud and abuse. For further discussion of the anti-kickback statute and service arrangements, see sections III.C.1. and III.C.2.

[54] *See, e.g.*, 42 CFR 483.20(k)(3) (requiring services that are ''provided or arranged by the facility'' to comport with professional standards of quality); 42 CFR 483.25 (requiring facilities to provide necessary care and services, including the resident's right to be free of unnecessary drugs); 42 CFR 483.75(b) (requiring facilities to provide services in compliance ''with all applicable Federal, State, and local laws, regulations, and codes, and with accepted professional standards and principles * * *'').

[55] 42 CFR 483.13(a).

[56] 42 CFR 483.25(l)(1). An unnecessary drug includes any medication, including psychotropic medications, that is excessive in dose, used excessively in duration, used without adequate monitoring, used without adequate indications for its use, used in the presence of adverse consequences, or any combination thereof. *Id.*

[57] 42 CFR 483.25(l)(2).

[58] 42 CFR 483.60(c).

[59] 42 CFR 483.20(k).

[60] 42 CFR 483.25(l)(2).

[61] Sections 1819 and 1919 of the Act (42 U.S.C. 1351i–3 and 1396r); 42 CFR 483.10; *see also* 42 CFR 483.15 and 483.25.

[62] *See id.*

[63] For an overview of research relating to resident abuse and neglect, see Catherine Hawes, Ph.D., ''Elder Abuse in Residential Long-Term Care Settings: What is Known and What Information is Needed?,'' *in* Elder Mistreatment: Abuse, Neglect, and Exploitation in an Aging America (National Research Council, 2003); U.S. Government Accountability Office (GAO), GAO Report GAO–02–312, ''Nursing Homes: More Can Be Done to Protect Residents from Abuse,'' March 2002, available on GAO's Web site at *http://www.gao.gov/new.items/d02312.pdf*; Administration on Aging, Elder Abuse Web site, available at *http://www.aoa.gov/eldfam/elder_rights/elder_abuse/elder_abuse.aspx*.

[64] 42 CFR 483.13(c); *see also* 42 CFR 483.13(a).

[65] *Id.*

[66] Under State mandatory reporting statutes, persons such as health care professionals, human service professionals, clergy, law enforcement, and financial professionals may have a legal obligation to make a formal report to law enforcement officials or a central reporting agency if they suspect that a nursing facility resident is being abused or neglected. To ensure compliance with these statutes, nursing facilities should consider training relating to compliance with their relevant States' laws. Nursing facilities can also assist by providing ready access to law enforcement contact information.

used compliance component for reporting violations is a dedicated hotline that allows staff, contractors, residents, family members, visitors, and others with concerns to report suspicions. Regardless of the reporting vehicle, ideally coverage for reporting and addressing resident safety issues would be on a constant basis (*i.e.*, 24 hours per day/7 days per week). Moreover, nursing facilities should make clear to caregivers, facility staff, and residents that the facility is committed to protecting those who make reports from retaliation.

Facilities may also want to consider a program to engage everyone who comes in contact with nursing facility residents—whether health care professionals, administrative and custodial staff, family and friends, visiting therapists, or community members—in the mission of protecting residents. Such a program could include specialized training for everyone who interacts on a regular basis with residents on recognizing warning signs of neglect or abuse and on effective methods to communicate with potentially fearful residents in a way likely to induce candid self-reporting of neglect or abuse.[67]

(b) Resident Interactions

The nursing facility industry, resident advocacy groups, and law enforcement are becoming increasingly concerned about resident abuse committed by fellow residents. Abuse can occur as a result of the failure to properly screen and assess, or the failure of staff to monitor, residents at risk for aggressive behavior. Such failures can jeopardize both the resident with aggressive behaviors and the victimized resident.

Heightened awareness and monitoring for abuse are crucial to eradicating resident-on-resident abuse. Nursing facilities can advance their mission to provide a safe environment for residents through targeted education relating to resident-on-resident abuse (particularly for staff with responsibilities for admission evaluations). Thorough resident assessments, comprehensive care plans, periodic resident assessments, and proper staffing assignments would also assist nursing facilities in their mission to provide a safe environment for residents.

(c) Staff Screening

Nursing facilities cannot employ individuals ''[f]ound guilty of abusing, neglecting, or mistreating residents,'' or individuals with ''a finding entered into [a] State nurse aide registry concerning abuse, neglect, mistreatment of residents or misappropriation of their property.'' [68] Effective recruitment, screening, and training of care providers are essential to ensure a viable workforce. Although no pre-employment background screening can provide nursing facilities with absolute assurance that a job applicant will not commit a crime in the future, nursing facilities must make reasonable efforts to ensure that they have a workforce that will maintain the safety of their residents.

Commonly, nursing facilities screen potential employees against criminal record databases. OIG is aware that there is a ''great diversity in the way States systematically identify, report, and investigate suspected abuse.'' [69] Nonetheless, a comprehensive examination of a prospective employee's criminal record in all States in which the person has worked or resided may provide a greater degree of protection for residents.[70]

Verification of education, licensing, certifications, and training for care providers can also assist nursing facilities in their efforts to ensure they provide patients with qualified and skilled caregivers. Many States have requirements that nursing facilities conduct these checks for all professional care providers, such as therapists, medical directors, and nurses. Federal regulations require a nursing facility to check its State nurse aide registry to ensure that potential hires for nurse aide positions have met competency evaluation requirements or are otherwise exempted from registration requirements.[71] In addition, the facility must also check every State nurse aide registry it ''believes will include information'' on the individual.[72] To ensure compliance with this requirement, facilities should have mechanisms in place to identify which State registries they must examine.

B. Submission of Accurate Claims

Nursing facilities must submit accurate claims to Federal health care programs. Examples of false or fraudulent claims include claims for items not provided or not provided as claimed, claims for services that are not medically necessary, and claims when there has been a failure of care. Submitting a false claim, or causing a false claim to be submitted, to a Federal health care program may subject the individual, the entity, or both to criminal prosecution, civil liability (including treble damages and penalties) under the False Claims Act, and exclusion from participation in Federal health care programs.

Common and longstanding risks associated with claim preparation and submission include duplicate billing, insufficient documentation, and false or fraudulent cost reports. While nursing facilities should continue to be vigilant with respect to these important risk areas, we believe these risk areas are relatively well understood in the industry, and therefore they are not specifically addressed in this section.

As reimbursement systems have evolved, OIG has uncovered other types of fraudulent transactions related to the provision of health care services to residents of nursing facilities reimbursed by Medicare and Medicaid. In this section, we will discuss some of these risk areas. This list is not exhaustive. It is intended to assist facilities in evaluating their own risk areas. In addition, section III.A. above outlines other regulatory requirements that, if not met, may subject nursing facilities to potential liability for submission of false or fraudulent claims.

1. Proper Reporting of Resident Case-Mix by SNFs

We are aware of instances in which SNFs have improperly upcoded resident RUG assignments.[73] Classifying a resident into the correct RUG, through resident assessments, requires accurate and comprehensive reporting about the resident's conditions and needs. Inaccurate reporting of data could result in the misrepresentation of the resident's status, the submission of false claims, and potential enforcement actions. Therefore, we have identified

[67] Facilities could explore partnering with the ombudsmen and other consumer advocates in sponsoring or participating in special training programs designed to prevent abuse. *See* ''Elder Justice: Protecting Seniors from Abuse and Neglect: Hearing Before the Senate Committee on Finance,'' 107th Congress (2002) (testimony of Catherine Hawes, Ph.D., titled ''Elder Abuse in Residential Long-Term Care Facilities: What is Known About the Prevalence, Causes, and Prevention''), available at *http://finance.senate.gov/hearings/testimony/061802chtest.pdf.*

[68] 42 CFR 483.13(c)(1)(ii).

[69] OIG, Audit Report A–12–12–97–0003, ''Safeguarding Long-Term Care Residents,'' September 1998, available on our Web site at *http://oig.hhs.gov/oas/reports/aoa/d9700003.pdf.*

[70] Because there is no one central repository for criminal records, there is a significant limitation to searching the criminal record databases only for the State in which the facility is located. A better practice may be to search databases for all States in which the applicant resided or was employed.

[71] 42 CFR 483.75(e)(5).

[72] 42 CFR 483.75(e)(6).

[73] A 2006 OIG report found that 22 percent of claims were upcoded, representing $542 million in potential overpayments for FY 2002. OIG, OEI Report OEI–02–02–00830, ''A Review of Nursing Facility Resource Utilization Groups,'' February 2006, available on our Web site at *http://oig.hhs.gov/oei/reports/oei-02-02-00830.pdf.*

the assessment, reporting, and evaluation of resident case-mix data as a significant risk area for SNFs.[74]

Because of the critical role resident case-mix data play in resident care planning and reimbursement, training on the collection and use of case-mix data is important. An effective compliance program will include training of responsible staff to ensure that persons collecting the data and those charged with analyzing and responding to the data are knowledgeable about the purpose and utility of the data. Facilities must also ensure that data reported to the Federal Government are accurate. Both internal and external periodic validation of data may prove useful. Moreover, as authorities continue to scrutinize quality-reporting data,[75] nursing facilities are well-advised to review such data regularly to ensure their accuracy and to identify and address potential quality of care issues.[76]

2. Therapy Services

The provision of physical, occupational, and speech therapy services continues to be a risk area for nursing facilities. Potential problems include: (i) Improper utilization of therapy services to inflate the severity of RUG classifications and obtain additional reimbursement; (ii) overutilization of therapy services billed on a fee-for-service basis to Part B under consolidated billing; and (iii) stinting on therapy services provided to patients covered by the Part A PPS payment.[77] These practices may result in the submission of false claims.[78]

In addition, unnecessary therapy services may place frail but otherwise functioning residents at risk for physical injury, such as muscle fatigue and broken bones, and may obscure a resident's true condition, leading to inadequate care plans and inaccurate RUG classifications.[79] Too few therapy services may expose residents to risk of physical injury or decline in condition, resulting in potential failure of care problems.

OIG strongly advises nursing facilities to develop policies, procedures, and measures to ensure that residents are receiving medically appropriate therapy services.[80] Some practices that may be beneficial include: Requirements that therapy contractors provide complete and contemporaneous documentation of each resident's services; regular and periodic reconciliation of the physician's orders and the services actually provided; interviews with the residents and family members to be sure services are delivered; and assessments of the continued medical necessity for services during resident care planning meetings at which the attending physician attends.

3. Screening for Excluded Individuals and Entities

No Federal health care program payment may be made for items or services furnished by an excluded individual or entity.[81] This payment ban applies to all methods of Federal health care program reimbursement. Civil monetary penalties (CMP) may be imposed against any person who arranges or contracts (by employment or otherwise) with an individual or entity for the provision of items or services for which payment may be made under a Federal health care program,[82] if the person knows or should know that the employee or contractor is excluded from participation in a Federal health care program.[83]

To prevent hiring or contracting with an excluded person, OIG strongly advises nursing facilities to screen all prospective owners, officers, directors, employees, contractors,[84] and agents prior to engaging their services against OIG's List of Excluded Individuals/Entities (LEIE) on OIG's Web site,[85] as well as the U.S. General Services Administration's Excluded Parties List System.[86] In addition, facilities should consider implementing a process that requires job applicants to disclose, during the pre-employment process (or, for vendors, during the request for proposal process), whether they are excluded. Facilities should strongly consider periodically screening their current owners, officers, directors, employees, contractors, and agents to ensure that they have not been excluded since the initial screening.

Facilities should also take steps to ensure that they have policies and procedures that require removal of any owner, officer, director, employee, contractor, or agent from responsibility for, or involvement with, a facility's business operations related to the Federal health care programs if the facility has actual notice that such a person is excluded. Facilities may also wish to consider appropriate training for human resources personnel on the effects of exclusion. Exclusion continues to apply to an individual even if he or she changes from one health care profession to another while excluded. That exclusion remains in effect until OIG has reinstated the individual, which is not automatic.[87] A useful tool for the training is OIG's Special Advisory Bulletin, titled ''The Effect of Exclusion From Participation in Federal Health Care Programs.'' [88]

4. Restorative and Personal Care Services

Facilities must ensure that residents receive appropriate restorative and

[74] To the extent a State Medicaid program relies upon RUG classification, or a variation of this system, to calculate its reimbursement rate, nursing facilities, as defined in section 1919 of the Act (42 U.S.C. 1396r), should be aware of this risk area as well.

[75] *See, e.g.*, CMS, ''2007 Action Plan for (Further Improvement of) Nursing Home Quality,'' September 2006, available on CMS's Web site at *http://www.cms.hhs.gov/SurveyCertificationGenInfo/downloads/2007ActionPlan.pdf.*

[76] In addition to assisting facilities with ensuring that claims data are accurate, monitoring MDS data may assist facilities in recognizing common warning signs of a systemic care problem (*e.g.*, increase in or excessive pressure ulcers or falls).

[77] There may be additional risk areas for outside therapy suppliers.

[78] Additional risks related to the anti-kickback statute are discussed below in section III.C.

[79] *See* 42 CFR 483.20(b) and (k).

[80] *See* OIG, OEI Report OEI–09–99–00563, ''Physical, Occupational, and Speech Therapy for Medicare Nursing Home Patients: Medical Necessity and Quality of Care Based on Treatment Diagnosis,'' August 2001, available on our Web site at *http://oig.hhs.gov/oei/reports/oei-09–99–00563.pdf.*

[81] 42 CFR 1001.1901. Exclusions imposed prior to August 5, 1997, cover Medicare and all State health care programs (including Medicaid), but not other Federal health care programs. *See* The Balanced Budget Act of 1997 (Pub. L. 105–33) (amending section 1128 of the Act (42 U.S.C. 1320a–7) to expand the scope of exclusions imposed by OIG).

[82] Such items or services could include administrative, clerical, and other activities that do not directly involve patient care. *See* section 1128A(a)(6) of the Act (42 U.S.C. 1320a–7a(a)(6)).

[83] *Id.*

[84] A nursing facility that relies upon third-party agencies to provide temporary or contract staffing should consider including provisions in its contracts that require the vendors to screen staff against OIG's List of Excluded Individuals/Entities before determining that they are eligible to work at the nursing facility. Although a nursing facility would not avoid liability for violating Medicare's prohibition on payment for services rendered by the excluded staff person merely by including such a provision, requiring the vendors to screen staff may help a nursing facility avoid engaging the services of excluded persons, and could be taken into account in the event of a Government enforcement action.

[85] Available on our Web site at *http://oig.hhs.gov/fraud/exclusions/listofexcluded.html.*

[86] Available at *http://www.epls.gov/.*

[87] Reinstatement of excluded entities and individuals is not automatic. Those wishing to again participate in the Medicare, Medicaid, and all Federal health care programs must apply for reinstatement and receive authorized notice from OIG that reinstatement has been granted. Obtaining a provider number from a Medicare contractor, a State agency, or a Federal health care program does not reinstate eligibility to participate in those programs. There are no provisions for retroactive reinstatement. *See* 42 CFR 1001.1901.

[88] OIG, ''The Effect of Exclusion From Participation in Federal Health Care Programs,'' September 1999, available on our Web site at *http://oig.hhs.gov/fraud/docs/alertsandbulletins/effected.htm.*

personal care services to allow residents to attain and maintain their highest practicable level of functioning.[89] These services include, among others, care to avoid pressure ulcers, active and passive range of motion, ambulation, fall prevention, incontinence management, bathing, dressing, and grooming activities.[90]

OIG is aware of facilities that have billed Federal health care programs for restorative and personal care services despite the fact that the services were not provided or were so wholly deficient that they amounted to no care at all. Federal health care programs do not reimburse for restorative and personal care services under these circumstances. Nursing facilities that fail to provide necessary restorative and personal care services risk billing for services not rendered as claimed, and therefore may be subject to liability under fraud and abuse statutes and regulations.

To avoid this risk, nursing facilities are strongly encouraged to have comprehensive procedures in place to ensure that services are of an appropriate quality and level and that services are in fact delivered to nursing facility residents. To accomplish this, facilities may wish to engage in resident and staff interviews; medical record reviews; [91] consultations with attending physicians, the medical director, and consultant pharmacists; and personal observations of care delivery. Moreover, complete and contemporaneous documentation of services is critical to ensuring that services are rendered.

C. The Federal Anti-Kickback Statute

The Federal anti-kickback statute, section 1128B(b) of the Act,[92] places constraints on business arrangements related directly or indirectly to items or services reimbursable by Federal health care programs, including, but not limited to, Medicare and Medicaid. The anti-kickback statute prohibits the health care industry from engaging in some practices that are common in other business sectors, such as offering or receiving gifts to reward past or potential new referrals.

The anti-kickback statute is a criminal prohibition against remuneration (in any form, whether direct or indirect) made purposefully to induce or reward the referral or generation of Federal health care program business. The anti-kickback statute prohibits offering or paying anything of value for patient referrals. It also prohibits offering or paying of anything of value in return for purchasing, leasing, ordering, or arranging for or recommending the purchase, lease, or order of any item or service reimbursable in whole or in part by a Federal health care program. The statute also covers the solicitation or acceptance of remuneration for referrals for, or the generation of, business payable by a Federal health care program. Liability under the anti-kickback statute is determined separately for each party involved. In addition to criminal penalties, violators may be subject to CMPs and exclusion from the Federal health care programs. Nursing facilities should also be aware that compliance with the anti-kickback statute is a condition of payment under Medicare and other Federal health care programs.[93] As such, liability may arise under the False Claims Act if the anti-kickback statute violation results in the submission of a claim for payment under a Federal health care program.

Nursing facilities make and receive referrals of Federal health care program business. Nursing facilities need to ensure that these referrals comply with the anti-kickback statute. Nursing facilities may obtain referrals of Federal health care program beneficiaries from a variety of health care sources, including, for example, physicians and other health care professionals, hospitals and hospital discharge planners, hospices, home health agencies, and other nursing facilities. Physicians, pharmacists, and other health care professionals may generate referrals for items and services reimbursed to the nursing facilities by Federal health care programs. In addition, when furnishing services to residents, nursing facilities often direct or influence referrals to others for items and services reimbursable by Federal health care programs. For example, nursing facilities may refer patients to, or order items or services from, hospices; DME companies; laboratories; diagnostic testing facilities; long-term care pharmacies; hospitals; physicians; other nursing facilities; and physical, occupational, and speech therapists. All of these circumstances call for vigilance under the anti-kickback statute.

Although liability under the anti-kickback statute ultimately turns on a party's intent, it is possible to identify arrangements or practices that may present a significant potential for abuse. For purposes of identifying potential kickback risks under the anti-kickback statute, the following inquiries are useful:

- Does the nursing facility (or its affiliates or representatives) provide anything of value to persons or entities in a position to influence or generate Federal health care program business for the nursing facility (or its affiliates) directly or indirectly?
- Does the nursing facility (or its affiliates or representatives) receive anything of value from persons or entities for which the nursing facility generates Federal health care program business, directly or indirectly?
- Could one purpose of an arrangement be to induce or reward the generation of business payable in whole or in part by a Federal health care program? Importantly, under the anti-kickback statute, neither a legitimate business purpose for an arrangement nor a fair-market value payment will legitimize a payment if there is also an illegal purpose (i.e., inducing Federal health care program business).

Any arrangement for which the answer to any of these inquiries is affirmative implicates the anti-kickback statute and requires careful scrutiny.

Several potentially aggravating considerations are useful in identifying arrangements at greatest risk of prosecution. In particular, in assessing risk, nursing facilities should ask the following questions, among others, about any potentially problematic arrangements or practices they identify:

- Does the arrangement or practice have a potential to interfere with, or skew, clinical decision-making?
- Does the arrangement or practice have a potential to increase costs to Federal health care programs or beneficiaries?
- Does the arrangement or practice have a potential to increase the risk of overutilization or inappropriate utilization?
- Does the arrangement or practice raise patient safety or quality of care concerns?

Nursing facilities should be mindful of these concerns when structuring and reviewing arrangements. An affirmative answer to one or more of these questions is a red flag signaling an arrangement or practice that may be particularly susceptible to fraud and abuse.

Nursing facilities that have identified potentially problematic arrangements or

[89] 42 CFR 483.25 (requiring facilities to provide care and services necessary to ensure a resident's ability to participate in activities of daily living do not diminish unless a clinical condition makes the decline unavoidable).

[90] *Id.*

[91] Indicators to watch for include, but are not limited to, bedsores, falls, unexplained weight loss, and dehydration.

[92] 42 U.S.C. 1320a–7b(b).

[93] *See, e.g.,* CMS, Form 855A, ''Medicare Federal Health Care Provider/Supplier Application,'' Certification Statement at section 15, paragraph A.3., available on CMS's Web site at *http://www.cms.hhs.gov/CMSForms/downloads/CMS855a.pdf.*

practices can take a number of steps to reduce or eliminate the risk of an anti-kickback violation. Most importantly, the anti-kickback statute and the corresponding regulations establish a number of ''safe harbors'' for common business arrangements. The safe harbors protect arrangements from liability under the statute. The following safe harbors are of most relevance to nursing facilities:

- Investment interests safe harbor (42 CFR 1001.952(a)),
- Space rental safe harbor (42 CFR 1001.952(b)),
- Equipment rental safe harbor (42 CFR 1001.952(c)),
- Personal services and management contracts safe harbor (42 CFR 1001.952(d)),
- Discount safe harbor (42 CFR 1001.952(h)),
- Employee safe harbor (42 CFR 1001.952(i)),
- Electronic health records items and services safe harbors (42 CFR 1001.952(y)), and
- Managed care and risk sharing arrangements safe harbors (42 CFR 1001.952(m), (t), and (u)).

To receive protection, an arrangement must fit squarely in a safe harbor. Safe harbor protection requires strict compliance with all applicable conditions set out in the relevant regulation.[94] Compliance with a safe harbor is voluntary. Failure to comply with a safe harbor does not mean an arrangement is illegal per se. Nevertheless, we recommend that nursing facilities structure arrangements to fit in a safe harbor whenever possible.

Nursing facilities should evaluate potentially problematic arrangements with referral sources and referral recipients that do not fit into a safe harbor by reviewing the totality of the facts and circumstances, including the intent of the parties. Depending on the circumstances, some relevant factors include:

- *Nature of the relationship between the parties.* What degree of influence do the parties have, directly or indirectly, on the generation of business for each other?
- *Manner in which participants were selected.* Were parties selected to participate in an arrangement in whole or in part because of their past or anticipated referrals?
- *Manner in which the remuneration is determined.* Does the remuneration take into account, directly or indirectly, the volume or value of business generated? Is the remuneration conditioned in whole or in part on referrals or other business generated between the parties? Is the arrangement itself conditioned, directly or indirectly, on the volume or value of Federal health care program business? Is there any service provided other than referrals?
- *Value of the remuneration.* Is the remuneration fair-market value in an arm's-length transaction for legitimate, reasonable, and necessary services that are actually rendered? Is the nursing facility paying an inflated rate to a potential referral source? Is the nursing facility receiving free or below-market-rate items or services from a provider or supplier? Is compensation tied, directly or indirectly, to Federal health care program reimbursement? Is the determination of fair-market value based upon a reasonable methodology that is uniformly applied and properly documented?
- *Nature of items or services provided.* Are items and services actually needed and rendered, commercially reasonable, and necessary to achieve a legitimate business purpose?
- *Potential Federal program impact.* Does the remuneration have the potential to affect costs to any of the Federal health care programs or their beneficiaries? Could the remuneration lead to overutilization or inappropriate utilization?
- *Potential conflicts of interest.* Would acceptance of the remuneration diminish, or appear to diminish, the objectivity of professional judgment? Are there patient safety or quality-of-care concerns? If the remuneration relates to the dissemination of information, is the information complete, accurate, and not misleading?
- *Manner in which the arrangement is documented.* Is the arrangement properly and fully documented in writing? Are the nursing facilities and outside providers and suppliers documenting the items and services they provide? Is the nursing facility monitoring items and services provided by outside providers and suppliers? Are arrangements actually conducted according to the terms of the written agreements? It is the substance, not the written form, of an arrangement that is determinative.

These inquiries—and appropriate follow-up inquiries—can help nursing facilities identify, address, and avoid problematic arrangements.

Available OIG guidance on the anti-kickback statute includes OIG Special Fraud Alerts and advisory bulletins. OIG also issues advisory opinions to specific parties about their particular business arrangements.[95] A nursing facility concerned about an existing or proposed arrangement may request a binding OIG advisory opinion regarding whether the arrangement violates the Federal anti-kickback statute or other OIG fraud and abuse authorities. Procedures for requesting an advisory opinion are set out at 42 CFR part 1008. The safe harbor regulations (and accompanying **Federal Register** preambles), fraud alerts and bulletins, advisory opinions (and instructions for obtaining them, including a list of frequently asked questions), and other guidance are available on our Web site at *http://oig.hhs.gov.*

The following discussion highlights several known areas of potential risk under the anti-kickback statute. The propriety of any particular arrangement can only be determined after a detailed examination of the attendant facts and circumstances. The identification of a given practice or activity as ''suspect'' or as an area of risk does not mean it is necessarily illegal or unlawful, or that it cannot be properly structured to fit in a safe harbor. It also does not mean that the practice or activity is not beneficial from a clinical, cost, or other perspective. Instead, the areas identified below are practices that have a potential for abuse and that should receive close scrutiny from nursing facilities.

1. Free Goods and Services

OIG has a longstanding concern about the provision of free goods or services to an existing or potential referral source. There is a substantial risk that free goods or services may be used as a vehicle to disguise or confer an unlawful payment for referrals of Federal health care program business. For example, OIG gave the following warning about free computers in the preamble to the 1991 safe harbor regulations:

> A related issue is the practice of giving away free computers. In some cases the computer can only be used as part of a particular service that is being provided, for example, printing out the results of laboratory tests. In this situation, it appears

[94] Parties to an arrangement cannot obtain safe harbor protection by entering into a sham contract that complies with the written agreement requirement of a safe harbor and appears, on paper, to meet all of the other safe harbor requirements, but does not reflect the actual arrangement between the parties. In other words, in assessing compliance with a safe harbor, the question is not whether the terms in a written contract satisfy all of the safe harbor requirements, but whether the actual arrangement satisfies the requirements.

[95] While informative for guidance purposes, an OIG advisory opinion is binding only with respect to the particular party or parties that requested the opinion. The analyses and conclusions set forth in OIG advisory opinions are fact-specific. Accordingly, different facts may lead to different results.

that the computer has no independent value apart from the service being provided and that the purpose of the free computer is not to induce an act that is prohibited by the statute * * *. In contrast, sometimes the computer that is given away is a regular personal computer, which the physician is free to use for a variety of purposes in addition to receiving test results. In that situation the computer has a definite value to the physician, and, depending on the circumstances, may well constitute an illegal inducement.[96]

Similarly, with respect to free services, OIG observed in a Special Fraud Alert that:

> While the mere placement of a laboratory employee in the physician's office would not necessarily serve as an inducement prohibited by the anti-kickback statute, the statute is implicated when the phlebotomist performs additional tasks that are normally the responsibility of the physician's office staff. These tasks can include taking vital signs or other nursing functions, testing for the physician's office laboratory, or performing clerical services. Where the phlebotomist performs clerical or medical functions not directly related to the collection or processing of laboratory specimens, a strong inference arises that he or she is providing a benefit in return for the physician's referrals to the laboratory. In such a case, the physician, the phlebotomist, and the laboratory may have exposure under the anti-kickback statute. This analysis applies equally to the placement of phlebotomists in other health care settings, including nursing homes, clinics and hospitals.[97]

The principles illustrated by each of the above examples also apply in the nursing facility context. The provision of goods or services that have independent value to the recipient or that the recipient would otherwise have to provide at its own expense confers a benefit on the recipient. This benefit may constitute prohibited remuneration under the anti-kickback statute, if one purpose of the remuneration is to generate referrals of Federal health care program business.

Examples of suspect free goods and services arrangements that warrant careful scrutiny include:

- Pharmaceutical consultant services, medication management, or supplies offered by a pharmacy;
- Infection control, chart review, or other services offered by laboratories or other suppliers;
- Equipment, computers, or software applications[98] that have independent value to the nursing facility;
- DME or supplies offered by DME suppliers for patients covered by the SNF Part A benefit;
- A laboratory phlebotomist providing administrative services;
- A hospice nurse providing nursing services for non-hospice patients; and
- A registered nurse provided by a hospital.

Nursing facilities should be mindful that, depending on the circumstances, these and similar arrangements may subject the parties to liability under the anti-kickback statute, if the requisite intent is present.

2. Services Contracts

(a) Non-Physician Services

Often kickbacks are disguised as otherwise legitimate payments or are hidden in business arrangements that appear, on their face, to be appropriate. In addition to the provision of free goods and services, the provision or receipt of goods or services at non-fair-market value rates presents a heightened risk of fraud and abuse. Nursing facilities often arrange for certain services and supplies to be provided to residents by outside suppliers and providers, such as pharmacies; clinical laboratories; DME suppliers; ambulance providers; parenteral and enteral nutrition (PEN) suppliers; diagnostic testing facilities; rehabilitation companies; and physical, occupational, and speech therapists. These relationships need to be scrutinized closely under the anti-kickback statute to ensure that they are not vehicles to disguise kickbacks from the suppliers and providers to the nursing facility to influence the nursing facility to refer Federal health care program business to the suppliers and providers.

To minimize their risk, nursing facilities should periodically review contractor and staff arrangements to ensure that: (i) There is a legitimate need for the services or supplies; (ii) the services or supplies are actually provided and adequately documented; (iii) the compensation is at fair-market value in an arm's-length transaction; and (iv) the arrangement is not related in any manner to the volume or value of Federal health care program business. Nursing facilities are well-advised to have all of the preceding facts documented contemporaneously and prior to payment to the provider of the supplies or services. To eliminate their risk, nursing facilities should structure services arrangements to comply with the personal services and management contracts safe harbor[99] whenever possible.

Nursing facilities should also adopt and implement policies and procedures to minimize the risk of improper pharmaceutical decisions tainted by kickbacks. For example, depending on the circumstances, a consultant pharmacist employed by a long-term care pharmacy may face a potential conflict of interest when making recommendations about a resident's drug regimen if a drug that is not on the pharmacy's formulary is prescribed.[100] Nursing facilities should establish policies that make clear that all prescribing decisions must be based on the best interests of the individual patient.[101] Drug switches may only be made upon authorization of the attending physician, medical director, or other licensed prescriber (except in certain limited circumstances where permitted by State law, e.g., permissible generic substitutions or changes allowed under a collaborative practice agreement between a physician and a pharmacist). Nursing facilities should consider implementing policies and procedures to monitor drug records for patterns that may indicate inappropriate drug switching or steering. All staff and practitioners involved in prescribing, administering, and managing pharmaceuticals should be educated on the legal prohibition against accepting anything of value from a pharmacy or pharmaceutical manufacturer to influence the choice of drug or to switch a resident from one drug to another.

(b) Physician Services

Nursing facilities also arrange for physicians to provide medical director, quality assurance, and other services. Such physician oversight and

[96] 56 FR 35952, 35978 (July 29, 1991), ''Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions,'' available on our Web site at *http://oig.hhs.gov/fraud/docs/safeharborregulations/072991.htm.*

[97] 59 FR 65372, 65377 (December 19, 1994), ''Publication of OIG Special Fraud Alerts,'' available on our Web site at *http://oig.hhs.gov/fraud/docs/alertsandbulletins/121994.html.*

[98] There is a safe harbor for electronic health records software arrangements at 42 CFR 1001.952(y), which can be used by nursing facilities. The safe harbor is available if all of its conditions are satisfied. The safe harbor does not protect free hardware or equipment.

[99] 42 CFR 1001.952(d).

[100] Long-term care pharmacies, many of which employ consultant pharmacists, have purchasing agreements with pharmaceutical manufacturers and contracts with health plans. In addition, long-term care pharmacies typically employ their own formularies for some residents. As a result of these arrangements and contracts, long-term care pharmacies may prefer that nursing facility customers and residents use some drugs over others.

[101] In all cases, prescribing decisions should be based upon the unique needs of the patients being served in that facility, established clinical guidelines, and evidence of cost effectiveness. The determination of clinical efficacy and appropriateness of the particular drugs should precede, and be paramount to, the consideration of costs.

involvement at the nursing facility contributes to the quality of care furnished to the residents. These physicians, however, may also be in a position to generate Federal health care program business for the nursing facility. For instance, these physicians may refer patients for admission. They may order items and services that result in an increased RUG or that are billable separately by the nursing facility. Physician arrangements need to be closely monitored to ensure that they are not vehicles to pay physicians for referrals. As with other services contracts, nursing facilities should periodically review these arrangements to ensure that: (i) There is a legitimate need for the services; (ii) the services are provided; (iii) the compensation is at fair-market value in an arm's-length transaction; and (iv) the arrangement is not related in any manner to the volume or value of Federal health care program business. In addition, prudent nursing facilities will maintain contemporaneous documentation of the arrangement, including, for example, the compensation terms, time logs or other accounts of services rendered, and the basis for determining compensation. Prudent facilities will also take steps to ensure that they have not engaged more medical directors or other physicians than necessary for legitimate business purposes. They will also ensure that compensation is commensurate with the skill level and experience reasonably necessary to perform the contracted services. To eliminate their risk, nursing facilities should structure services arrangements to comply with the personal services and management contracts safe harbor [102] whenever possible.

3. Discounts

(a) Price Reductions

Public policy favors open and legitimate price competition in health care. Thus, the anti-kickback statute contains an exception for discounts offered to customers that submit claims to the Federal health care programs, if the discounts are properly disclosed and accurately reported. However, to qualify for the exception, the discount must be in the form of a reduction in the price of the good or service based on an arm's-length transaction. In other words, the exception covers only reductions in the product's or service's price.

In conducting business, nursing facilities routinely purchase items and services reimbursable by Federal health care programs. Therefore, they should familiarize themselves with the discount safe harbor at 42 CFR 1001.952(h). In particular, nursing facilities should ensure that all discounts—including any rebates—are properly disclosed and accurately reflected on their cost reports (and in any claims as appropriate) filed with a Federal program. In addition, some nursing facilities purchase products through group purchasing organizations (GPO) to which they belong. Any discounts received from vendors who sell their products under a GPO contract should be properly disclosed and accurately reported on the nursing facility's cost reports. Although there is a safe harbor for administrative fees paid by a vendor to a GPO,[103] that safe harbor does not protect discounts provided by a vendor to purchasers of products.

(b) Swapping

Nursing facilities often obtain discounts from suppliers and providers on items and services that the nursing facilities purchase for their own account. In negotiating arrangements with suppliers and providers, a nursing facility should be careful that there is no link or connection, explicit or implicit, between discounts offered or solicited for business that the nursing facility pays for and the nursing facility's referral of business billable by the supplier or provider directly to Medicare or another Federal health care program. For example, nursing facilities should not engage in ''swapping'' arrangements by accepting a low price from a supplier or provider on an item or service covered by the nursing facility's Part A per diem payment in exchange for the nursing facility referring to the supplier or provider other Federal health care program business, such as Part B business excluded from consolidated billing, that the supplier or provider can bill directly to a Federal health care program. Such ''swapping'' arrangements implicate the anti-kickback statute and are not protected by the discount safe harbor. Nursing facility arrangements with clinical laboratories, DME suppliers, and ambulance providers are some examples of arrangements that may be prone to ''swapping'' problems.

As we have previously explained in other guidance,[104] the size of a discount is not determinative of an anti-kickback statute violation. Rather, the appropriate question to ask is whether the discount is tied or linked, directly or indirectly, to referrals of other Federal health care program business. When evaluating whether an improper connection exists between a discount offered to a nursing facility and referrals of Federal health care program business billed by a supplier or provider, suspect arrangements include below-cost arrangements or arrangements at prices lower than the prices offered by the supplier or provider to other customers with similar volumes of business, but without Federal health care program referrals. Other suspect practices include, but are not limited to, discounts that are coupled with exclusive provider agreements and discounts or other pricing schemes made in conjunction with explicit or implicit agreements to refer other facility business. In sum, if any direct or indirect link exists between a price offered by a supplier or provider to a nursing facility for items or services that the nursing facility pays for out-of-pocket and referrals of Federal business for which the supplier or provider can bill a Federal health care program, the anti-kickback statute is implicated.

4. Hospices

Hospice services for terminally ill patients are typically provided in the patients' homes. In some cases, however, a nursing facility is the patient's home. In such cases, nursing facilities often arrange for the provision of hospice services in the nursing facility if the resident meets the hospice eligibility criteria and elects the hospice benefit. These arrangements pose several fraud and abuse risks. For example, to induce referrals, a hospice may offer a nursing facility remuneration in the form of free nursing services for non-hospice patients; additional room and board payments; [105] or inflated payments for providing hospice services to the

[102] 42 CFR 1001.952(d).

[103] 42 CFR 1001.952(j).

[104] *See, e.g.*, OIG's September 22, 1999, letter regarding ''Discount Arrangements Between Clinical Laboratories and SNFs'' (referencing OIG Advisory Opinion No. 99–2 issued February 26, 1999), available on our Web site at *http://oig.hhs.gov/fraud/docs/safeharborregulations/rs.htm*; 56 FR 35952 at the preamble (July 29, 1991), ''Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions,'' available on our Web site at *http://oig.hhs.gov/fraud/docs/safeharborregulations/072991.htm*.

[105] The Medicare reimbursement rate for routine hospice services provided in a nursing facility does not include room and board expenses, so payment for room and board may be the responsibility of the patient. CMS, ''Medicare Benefit Policy Manual,'' Pub. No. 100–02, chapter 9, section 20.3, available on CMS's Web site at *http://www.cms.hhs.gov/Manuals/IOM/list.asp*. For Medicaid patients, the State will pay the hospice at least 95 percent of the State's Medicaid daily nursing facility rate, and the hospice is then responsible for paying the nursing facility for the beneficiary's room and board. Section 1902(a)(13)(B) of the Act (42 U.S.C. 1396a(a)(13)(B)).

hospice's patients.[106] Nursing facilities should be mindful that requesting or accepting remuneration from a hospice may subject the nursing facility and the hospice to liability under the anti-kickback statute if the remuneration might influence the nursing facility's decision to do business with the hospice.[107]

Some of the practices that are suspect under the anti-kickback statute include:

- A hospice offering free goods or goods at below-fair-market value to induce a nursing facility to refer patients to the hospice;
- A hospice paying room and board payments to the nursing facility in excess of what the nursing facility would have received directly from Medicaid had the patient not been enrolled in hospice. Any additional payment must represent the fair-market value of additional services actually provided to that patient that are not included in the Medicaid daily rate;
- A hospice paying amounts to the nursing facility for additional services that Medicaid considers to be included in its room and board payment to the hospice;
- A hospice paying above fair-market value for additional services that Medicaid does not consider to be included in its room and board payment to the nursing facility;
- A hospice referring its patients to a nursing facility to induce the nursing facility to refer its patients to the hospice;
- A hospice providing free (or below-fair-market value) care to nursing facility patients, for whom the nursing facility is receiving Medicare payment under the SNF benefit, with the expectation that after the patient exhausts the SNF benefit, the patient will receive hospice services from that hospice; and
- A hospice providing staff at its expense to the nursing facility.

For additional guidance on arrangements with hospices, nursing facilities should review OIG's Special Fraud Alert on Nursing Home Arrangements with Hospices.[108] Whenever possible, nursing facilities should structure their relationships with hospices to fit in a safe harbor, such as the personal services and management contracts safe harbor.[109]

5. Reserved Bed Payments

Sometimes hospitals enter into reserved bed arrangements with nursing facilities to receive guaranteed or priority placement for their discharged patients.[110] Under some reserved bed arrangements, hospitals provide remuneration to nursing facilities to keep certain beds available and open. These arrangements could be problematic under the anti-kickback statute if one purpose of the remuneration is to induce referrals of Federal health care program business from the nursing facility to the hospital.[111] Payments should not be determined in any manner that reflects the volume or value of existing or potential referrals of Federal health care program business from the nursing facility to the hospital. Examples of some reserved bed payments that may give rise to an inference that the arrangement is connected to referrals include: (1) Payments that result in double-dipping by the nursing facility (*e.g.*, sham payments for beds that are actually occupied or for which the facility is otherwise receiving reimbursement); (2) payments for more beds than the hospital legitimately needs; and (3) excessive payments (*e.g.*, payments that exceed the nursing facility's actual costs of holding a bed or the actual revenues a facility reasonably stands to forfeit by holding a bed given the facility's occupancy rate and patient acuity mix). Reserved bed arrangements should be entered into only when there is a bona fide need to have the arrangement in place. Reserved bed arrangements should serve the limited purpose of securing needed beds, not future referrals.

D. Other Risk Areas

1. Physician Self-Referrals

Nursing facilities should familiarize themselves with the physician self-referral law (section 1877 of the Act),[112] commonly known as the ''Stark'' law. The physician self-referral law prohibits entities that furnish ''designated health services'' (DHS) from submitting—and Medicare from paying—claims for DHS if the referral for the DHS comes from a physician with whom the entity has a prohibited financial relationship. This is true even if the prohibited financial relationship is the result of inadvertence or error. Violations can result in refunding of the prohibited payment and, in cases of knowing violations, CMPs, and exclusion from the Federal health care programs. Knowing violations of the physician self-referral law can also form the basis for liability under the False Claims Act.

Nursing facility services, including SNF services covered by the Part A PPS payment, are not DHS for purposes of the physician self-referral law. However, laboratory services, physical therapy services, and occupational therapy services are among the DHS covered by the statute.[113] Nursing facilities that bill Part B for laboratory services, physical therapy services, occupational therapy services, or other DHS pursuant to the consolidated billing rules are considered entities that furnish DHS.[114] Accordingly, nursing facilities should review all financial relationships with physicians who refer or order such services to ensure compliance with the physician self-referral law.

When analyzing potential physician self-referral situations, the following three-part inquiry is useful:

- Is there a referral (including, but not limited to, ordering a service for a resident) from a physician for a designated health service? If not, there

[106] Under the regulations at 42 CFR 418.80, hospices must generally furnish substantially all of the core hospice service themselves. Hospices are permitted to furnish non-core services under arrangements with other providers or suppliers, including nursing facilities. 42 CFR 418.56; CMS, ''State Operations Manual,'' Pub. No. 100–07, chapter 2, section 2082C, available on CMS's Web site at *http://www.cms.hhs.gov/Manuals/IOM/list.asp*.

[107] Under certain circumstances, a nursing facility that knowingly refers to hospice patients who do not qualify for the hospice benefit may be liable for the submission of false claims. The Medicare hospice eligibility criteria are found at 42 CFR 418.20.

[108] OIG Special Fraud Alert on Fraud and Abuse in Nursing Home Arrangements With Hospices, March 1998, available on our Web site at *http://oig.hhs.gov/fraud/docs/alertsandbulletins/hospice.pdf*.

[109] 42 CFR 1001.952(d).

[110] The Provider Reimbursement Manual provides as follows:

Providers are permitted to enter into reserved bed agreements, as long as the terms of that agreement do not violate the provisions of the statute and regulations which govern provider agreements, which (1) prohibit a provider from charging the beneficiary or other party for covered services; (2) prohibit a provider from discriminating against Medicare beneficiaries, as a class, in admission policies; or (3) prohibit certain types of payments in connection with referring patients for covered services. A provider may jeopardize its provider agreement or incur other penalties if it enters into a reserved bed agreement that violates these requirements.

CMS, ''Provider Reimbursement Manual,'' Pub. No. 15–1, pt. 1, ch. 21, section 2105.3(D), available on CMS's Web site at *http://www.cms.hhs.gov/Manuals/PBM*.

[111] Nursing facilities should be mindful that conditioning the offer of reserved beds specifically on referrals of Federal health care program beneficiaries by the hospital to the nursing facility would raise concerns under the anti-kickback statute, even if no payments were made.

[112] 42 U.S.C. 1395nn.

[113] The complete list of DHS is found at section 1877(h)(6) of the Act (42 U.S.C. 1395nn(h)(6)) and 42 CFR 411.351.

[114] *See* 66 FR 856, 923 (January 4, 2001), ''Medicare and Medicaid Programs; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships; Final Rule,'' available on CMS's Web site at *http://www.cms.hhs.gov/PhysicianSelfReferral/Downloads/66FR856.pdf*.

is no physician self-referral issue. If yes, then the next inquiry is:

• Does the physician (or an immediate family member) have a direct or indirect financial relationship with the nursing facility? A financial relationship can be created by ownership, investment, or compensation; it need not relate to the furnishing of DHS. If there is no financial relationship, there is no physician self-referral issue. If there is a financial relationship, the next inquiry is:

• Does the financial relationship fit in an exception? If not, the statute is violated.

Detailed regulations regarding the italicized terms are set forth at 42 CFR 411.351 through 411.361 (substantial additional explanatory material appears in preambles to the final regulations: 66 FR 856 (January 4, 2001), 69 FR 16054 (March 26, 2004), 72 FR 51012 (September 5, 2007), and 73 FR 48434 (August 19, 2008)).[115]

Nursing facilities should pay particular attention to their relationships with attending physicians who treat residents and with physicians who are nursing facility owners, investors, medical directors, or consultants. The statutory and regulatory exceptions are key to compliance with the physician self-referral law. Exceptions exist for many common types of arrangements.[116] To fit in an exception, an arrangement must squarely meet all of the conditions set forth in the exception. Importantly, it is the actual relationship between the parties, and not merely the paperwork, that must fit in an exception. Unlike the anti-kickback safe harbors, which are voluntary, fitting in an exception is mandatory under the physician self-referral law. Compliance with a physician self-referral law exception does not immunize an arrangement under the anti-kickback statute. Therefore, arrangements that implicate the physician self-referral law should also be analyzed under the anti-kickback statute.

In addition to reviewing particular arrangements, nursing facilities can implement several systemic measures to guard against violations. First, many of the potentially applicable exceptions require written, signed agreements between the parties. Nursing facilities should enter into appropriate written agreements with physicians. In addition, nursing facilities should review their contracting processes to ensure that they obtain and maintain signed agreements covering all time periods for which an arrangement is in place. Second, many exceptions require fair-market value compensation for items and services actually needed and rendered. Thus, nursing facilities should have appropriate processes for making and documenting reasonable, consistent, and objective determinations of fair-market value and for ensuring that needed items and services are furnished or rendered. Nursing facilities should also implement systems to track non-monetary compensation provided annually to referring physicians (such as free parking or gifts) and ensure that such compensation does not exceed limits set forth in the physician self-referral regulations.

Further information about the physician self-referral law and applicable regulations can be found on CMS's Web site at *http://www.cms.hhs.gov/PhysicianSelfReferral/*. Information regarding CMS's physician self-referral advisory opinion process can be found at *http://www.cms.hhs.gov/PhysicianSelfReferral/07_advisory_opinions.asp#TopOfPage*.

2. Anti-Supplementation

As a condition of its Medicare provider agreement and under applicable Medicaid regulations and a criminal provision precluding supplementation of Medicaid payment rates, a nursing facility must accept the applicable Medicare or Medicaid payment (including any beneficiary coinsurance or copayments authorized under those programs), respectively, for covered items and services as the complete payment.[117] For covered items and services, a nursing facility may not charge a Medicare or Medicaid beneficiary, or another person in lieu of the beneficiary, any amount in addition to what is otherwise required to be paid under Medicare or Medicaid (*i.e.*, a cost-sharing amount). For example, an SNF may not condition acceptance of a beneficiary from a hospital upon receiving payment from the hospital or the beneficiary's family in an amount greater than the SNF would receive under the PPS. For Medicare and Medicaid beneficiaries, a nursing facility may not accept supplemental payments, including, but not limited to, cash and free or discounted items and services, from a hospital or other source merely because the nursing facility considers the Medicare or Medicaid payment to be inadequate (although a nursing facility may accept donations unrelated to the care of specific patients). The supplemental payment would be a prohibited charge imposed by the nursing facility on another party for services that are already covered by Medicare or Medicaid.[118]

3. Medicare Part D

Medicare Part D extends voluntary prescription drug coverage to all Medicare beneficiaries,[119] including individuals who reside in nursing facilities. Like all Medicare beneficiaries, nursing facility residents who decide to enroll in Part D have the right to choose their Part D plans.[120] Part D plans offer a variety of drug formularies and have arrangements with a variety of pharmacies to dispense drugs to the plan's enrollees. Nursing facilities also enter into arrangements with pharmacies to dispense drugs. Typically, these are exclusive or semi-exclusive arrangements designed to ease administrative burdens and coordinate accurate administration of drugs to residents. When a resident is selecting a particular Part D plan, it may be that the Part D plan that best satisfies a beneficiary's needs does not have an arrangement with the nursing facility's pharmacy. CMS has stated that it expects nursing facilities ''to work with their current pharmacies to assure that they recognize the Part D plans chosen by that facility's Medicare beneficiaries, or, in the alternative, to add additional pharmacies to achieve that objective.'' [121] CMS also suggests that a nursing facility ''could contract exclusively with another pharmacy that contracts more broadly with Part D plans.'' [122]

CMS has explained that ''[n]ursing homes may, and are encouraged to, provide information and education to residents on all available Part D plans.'' [123] When educating residents,

[115] Available on CMS's Web site at *http://www.cms.hhs.gov/PhysicianSelfReferral/*.

[116] Section 1877(b)–(e) of the Act (42 U.S.C. 1395nn(b)–(e)). *See also* 42 CFR 411.351–.357.

[117] Section 1866(a) of the Act (42 U.S.C. 1395cc(a)); 42 CFR 489.20; section 1128B(d) of the Act (42 U.S.C. 1320a–7b(d)); 42 CFR 447.15; 42 CFR 483.12(d)(3).

[118] *See id.; see also* CMS, ''Skilled Nursing Facility Manual,'' Pub. No. 12, chapter 3, sections 317 and 318, available on CMS's Web site at *http://www.cms.hhs.gov/Manuals/PBM/list.asp.*

[119] Section 1860D–1 of the Act (42 U.S.C. 1395w–101).

[120] *Id.*

[121] *See* CMS Survey and Certification Group's May 11, 2006, letter to State Survey Agency Directors, available on CMS's Web site at *http://www.cms.hhs.gov/SurveyCertificationGenInfo/downloads/SCLetter06–16.pdf*. This letter communicates CMS's current guidance on these Part D issues. As the Part D program evolves, nursing facilities should keep current with any guidance issued by CMS and conform their policies and procedures accordingly.

[122] *Id.*

[123] *Id.*

nursing facilities should ensure that the information provided is complete and objective. It may be helpful for nursing facilities to walk residents through the important details of the plans available to the residents, including items such as premium and cost-sharing structures, and to discuss the extent to which each plan does, or does not, provide coverage of the resident's medications. Nursing facilities must be particularly careful, however, not to act in ways that would frustrate a beneficiary's freedom of choice in choosing a Part D plan. As stated by CMS, ''[u]nder no circumstances should a nursing home require, request, coach or steer any resident to select or change a plan for any reason,'' nor should it ''knowingly and/or willingly allow the pharmacy servicing the nursing home'' to do the same.[124] Providing residents with complete and objective information about all of the plans available to the residents helps reduce the risk that efforts to educate residents will lead to steering.

Nursing facilities and their employees and contractors should not accept any payments from any plan or pharmacy to influence a beneficiary to select a particular plan. Beneficiary freedom of choice in choosing a Part D Plan is ensured by section 1860D–1 of the Act.[125] Nursing facilities may not limit this choice in the Part D program.

E. HIPAA Privacy and Security Rules

As of April 14, 2003, all nursing facilities that conduct electronic transactions governed by HIPAA are required to comply with the Privacy Rule adopted under HIPAA.[126] Generally, the HIPAA Privacy Rule addresses the use and disclosure of individuals' personally identifiable health information (called ''protected health information'' or ''PHI'') by covered nursing facilities and other covered entities. The Privacy Rule also covers individuals' rights to understand and control how their health information is used. The Privacy Rule also requires nursing facilities to disclose PHI to the individual who is the subject of the PHI or to the Secretary of the Department of Health and Human Services under certain circumstances. The Privacy Rule and helpful information about how it applies can be found on the Web site of the Department's Office for Civil Rights (OCR).[127] Questions about the Privacy Rule should be submitted to OCR.[128]

The Privacy Rule gives covered nursing facilities and other covered entities some flexibility to create their own privacy procedures. Each nursing facility should make sure that it is compliant with all applicable provisions of the Privacy Rule, including standards for the use and disclosure of PHI with and without patient authorization and the provisions pertaining to permitted and required disclosures.

The HIPAA Security Rule specifies a series of administrative, technical, and physical security safeguards for covered entities to ensure the confidentiality of electronic PHI.[129] Nursing facilities that are covered entities were required to be compliant with the Security Rule by April 20, 2005. The Security Rule requirements are flexible and scalable, which allows each covered entity to tailor its approach to compliance based on its own unique circumstances. Covered entities may consider their organization and capabilities, as well as costs, in designing their security plans and procedures. Questions about the HIPAA Security Rule should be submitted to CMS.[130]

IV. Other Compliance Considerations

A. An Ethical Culture

As laid out in the 2000 Nursing Facility CPG, it is important for a nursing facility to have an organizational culture that promotes compliance. OIG commends nursing facilities that have adopted a code of conduct that details the fundamental principles, values, and framework for action within the organization, and that articulates the organization's commitment to compliance. OIG encourages those facilities that have not yet adopted codes of conduct to do so.

In addition to codes of conduct, an organization can adopt other measures to express its commitment to compliance. First, and foremost, a nursing facility's leadership should foster an organizational culture that values, and even rewards, the prevention, detection, and resolution of quality of care and compliance problems. Good compliance practices may include the development of a mechanism, such as a ''dashboard,'' [131] designed to communicate effectively appropriate compliance and performance-related information to a nursing facility's board of directors and senior officers. The dashboard or other communication tool should include quality of care information. Further information and resources about quality of care dashboards are available on our Web site.[132]

When communication tools such as dashboards are properly implemented and include quality of care information, the directors and senior officers can, among other things: (1) Demonstrate a commitment to quality of care and foster an organization-wide culture that values quality of care; (2) improve the facility's quality of care through increased awareness of and involvement in the oversight of quality of care issues; and (3) track and trend quality of care data (*e.g.*, State agency survey results, outcome care and delivery data, and staff retention and turnover data) to identify potential quality of care problems, identify areas in which the organization is providing high quality of care, and measure progress on quality of care initiatives. Each dashboard should be tailored to meet the specific needs and sophistication of the implementing nursing facility, its board members, and senior officers. OIG views the use of dashboards, and similar tools, as a helpful compliance practice that can lead to improved quality of care and assist the board members and senior officers in fulfilling, respectively, their oversight and management responsibilities.

In summary, the nursing facility should endeavor to develop a culture that values compliance from the top down and fosters compliance from the bottom up. Such an organizational culture is the foundation of an effective compliance program.

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[124] *Id.*

[125] 42 U.S.C. 1395w–101.

[126] 45 CFR parts 160 and 164, subparts A and E; available at *http://www.hhs.gov/ocr/hipaa/finalreg.html.* In addition to the HIPAA Privacy and Security Rules, facilities should also take steps to adhere to the privacy and confidentiality requirements for residents' personal and clinical records, 42 CFR 483.10(e), and any applicable State privacy laws.

[127] OCR, ''HHS—Office of Civil Rights—HIPAA,'' available at *http://www.hhs.gov/ocr/hipaa/.*

[128] Nursing facilities can contact OCR by following the instructions on its Web site, available at *http://www.hhs.gov/ocr/contact.html*, or by calling the HIPAA toll-free number, (866) 627–7748.

[129] 45 CFR parts 160 and 164, subparts A and C, available on CMS's Web site at *http://www.cms.gov/SecurityStandard/02_Regulations.asp.*

[130] Nursing facilities can contact CMS by following the instructions on its Web site, *http://www.cms.hhs.gov/HIPAAGenInfo/.*

[131] Much like the dashboard of a car, a ''dashboard'' is an instrument that provides the recipient with a user-friendly (*i.e.*, presented in an appropriate context) snapshot of the key pieces of information needed by the recipient to oversee and manage effectively the operation of an organization and forestall potential problems, while avoiding information overload.

[132] *See, e.g.*, OIG, ''Driving for Quality in Long-Term Care: A Board of Director's Dashboard—Government-Industry Roundtable,'' available on our Web site at *http://oig.hhs.gov/fraud/docs/complianceguidance/Roundtable013007.pdf.*

B. Regular Review of Compliance Program Effectiveness

Nursing facilities should regularly review the implementation and execution of their compliance program systems and structures. This review should be conducted periodically, typically on annual basis. The assessment should include an evaluation of the overall success of the program, as well as each of the basic elements of a compliance program individually, which include:

- Designation of a compliance officer and compliance committee;
- Development of compliance policies and procedures, including standards of conduct;
- Developing open lines of communication;
- Appropriate training and teaching;
- Internal monitoring and auditing;
- Response to detected deficiencies; and
- Enforcement of disciplinary standards.

Nursing facilities seeking guidance for establishing and evaluating their compliance operations should review OIG's 2000 Nursing Facility CPG, which explains in detail the fundamental elements of a compliance program.[133] Nursing facilities may also wish to consult quality of care corporate integrity agreements (CIA) entered into between OIG and parties settling specific matters.[134] Other issues a nursing facility may want to evaluate are whether there has been an allocation of adequate resources to compliance initiatives; whether there is a reasonable timetable for implementation of the compliance measures; whether the compliance officer and compliance committee have been vested with sufficient autonomy, authority, and accountability to implement and enforce appropriate compliance measures; and whether compensation structures create undue pressure to pursue profit over compliance.

V. Self-Reporting

If the compliance officer, compliance committee, or a member of senior management discovers credible evidence of misconduct from any source and, after a reasonable inquiry, believes that the misconduct may violate criminal, civil, or administrative law, the nursing facility should promptly report the existence of the misconduct to the appropriate Federal and State authorities.[135] The reporting should occur within a reasonable period, but not longer than 60 days,[136] after determining that there is credible evidence of a violation.[137] Prompt voluntary reporting will demonstrate the nursing facility's good faith and willingness to work with governmental authorities to correct and remedy the problem. In addition, prompt reporting of misconduct will be considered a mitigating factor by OIG in determining administrative sanctions (*e.g.*, penalties, assessments, and exclusion) if the reporting nursing facility becomes the subject of an OIG investigation.[138]

To encourage providers to make voluntary disclosures to OIG, OIG published the Provider Self-Disclosure Protocol.[139] When reporting to the Government, a nursing facility should provide all relevant information regarding the alleged violation of applicable Federal or State law(s) and the potential financial or other impact of the alleged violation. The compliance officer, under advice of counsel and with guidance from governmental authorities, may be requested to continue to investigate the reported violation. Once the investigation is completed, and especially if the investigation ultimately reveals that criminal, civil, or administrative violations have occurred, the compliance officer should notify the appropriate governmental authority of the outcome of the investigation. This notification should include a description of the impact of the alleged violation on the applicable Federal health care programs or their beneficiaries.

VI. Conclusion

In today's environment of increased scrutiny of corporate conduct and increasingly large expenditures for health care, it is imperative for nursing facilities to establish and maintain effective compliance programs. These programs should foster a culture of compliance and a commitment to delivery of quality health care that begins at the highest levels and extends throughout the organization. This supplemental CPG is intended as a resource for nursing facilities to help them operate effective compliance programs that decrease errors, fraud, and abuse and increase quality of care and compliance with Federal health care program requirements for the benefit of the nursing facilities and their residents.

Dated: September 24, 2008.

Daniel R. Levinson,

Inspector General.

[FR Doc. E8–22796 Filed 9–29–08; 8:45 am]

BILLING CODE 4152–01–P

[133] 2000 Nursing Facility CPG, *supra* note 2, at 14289.

[134] OIG, ''HHS—OIG—Fraud Prevention & Detection—Corporate Integrity Agreements,'' available on our Web site at *http://oig.hhs.gov/fraud/cias.html.*

[135] Appropriate Federal and State authorities include OIG, CMS, the Criminal and Civil Divisions of the Department of Justice, the U.S. Attorney in relevant districts, the Food and Drug Administration, the Department's Office for Civil Rights, the Federal Trade Commission, the Drug Enforcement Administration, the Federal Bureau of Investigation, 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 Health Resources and Services Administration, and the Office of Personnel Management (which administers the Federal Employee Health Benefits Program).

[136] To qualify for the ''not less than double damages'' provision of the False Claims Act, the provider must provide the report to the Government within 30 days after the date when the provider first obtained the information. 31 U.S.C. 3729(a).

[137] Some violations may be so serious that they warrant immediate notification to governmental authorities prior to, or simultaneous with, commencing an internal investigation. By way of example, OIG believes a provider should immediately report misconduct that: (i) Is a clear violation of administrative, civil, or criminal laws; (ii) poses an imminent danger to a patient's safety; (iii) has a significant adverse effect on the quality of care provided to Federal health care program beneficiaries; or (iv) indicates evidence of a systemic failure to comply with applicable laws or an existing corporate integrity agreement, regardless of the financial impact on Federal health care programs.

[138] OIG has published criteria setting forth those factors that OIG takes into consideration in determining whether it is appropriate to exclude an individual or entity from program participation pursuant to section 1128(b)(7) of the Act (42 U.S.C. 1320a–7(b)(7)) for violations of various fraud and abuse laws. *See* 62 FR 67392 (December 24, 1997), ''Criteria for Implementing Permissive Exclusion Authority Under Section 1128(b)(7) of the Social Security Act.''

[139] For details regarding the Provider Self-Disclosure Protocol, including timeframes and required information, see 63 FR 58399 (October 30, 1998), ''Publication of the OIG's Provider Self-Disclosure Protocol,'' available on our Web site at *http://oig.hhs.gov/authorities/docs/selfdisclosure.pdf. See also* OIG's April 15, 2008, Open Letter to Health Care Providers, available on our Web site at *http://oig.hhs.gov/fraud/docs/openletters/OpenLetter4–15–08.pdf;* OIG's April 24, 2006, Open Letter to Health Care Providers, available on our Web site at *http://oig.hhs.gov/fraud/docs/openletters/Open%20Letter%20to%20Providers%202006.pdf.*

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S.

Nursing Facility Compliance Guidance – Original (2000)

Rolf | Healthcare Counsel
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6. Problems or adverse events connected with a shortage of pharmacists, *e.g.,* medication errors;

7. The impact a drug benefit for the Medicare population might have on prescription volume and the demand for pharmacists;

8. Uses of automation or technology to assist pharmacists, such as the use of electronic transmission of prescriptions, methods of streamlining dispensing processes, and technologies that may be under development to improve efficiency of pharmacists in their duties;

9. The impact of Internet and mail order pharmacies on the demand for pharmacists; and

10. Existing information on the current pharmacist education process; in particular, applications to pharmacy programs, the impact that the shift to the doctor of pharmacy as the first professional degree may have on pharmacy supply, trends in graduates taking residencies, and students' job preferences.

Dated: March 9, 2000.

Claude Earl Fox,

Administrator.

[FR Doc. 00–6427 Filed 3–15–00; 8:45 am]

BILLING CODE 4160–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Publication of the OIG Compliance Program Guidance for Nursing Facilities

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

ACTION: Notice.

SUMMARY: This **Federal Register** notice sets forth the recently issued Compliance Program Guidance for Nursing Facilities developed by the Office of Inspector General (OIG). The OIG has previously developed and published compliance program guidance focused on several other areas and aspects of the health care industry. We believe that the development and issuance of this compliance program guidance for nursing facilities will continue to serve as a positive step toward promoting a higher level of ethical and lawful conduct throughout the entire health care industry.

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

SUPPLEMENTARY INFORMATION:

Background

The creation of compliance program guidances is a major initiative of the OIG in its effort to engage the private health care community in combating fraud and abuse. In the last several years, the OIG has developed and issued compliance program guidances directed at the following segments of the health care industry: the hospital industry; home health agencies; clinical laboratories; third-party medical billing companies; the durable medical equipment, prosthetics, orthotics and supply industry; hospices; and Medicare+Choice organizations offering coordinated care plans. The development of these types of compliance program guidances is based on our belief that a health care provider can use internal controls to more efficiently monitor adherence to applicable statutes, regulations and program requirements.

Copies of these compliance program guidances can be found on the OIG web site at http://www.hhs.gov/oig.

Developing Compliance Program Guidance for Nursing Facilities

On December 18, 1998, the OIG published a solicitation notice seeking information and recommendations for developing formal guidance for nursing facilities (63 FR 70137). In response to that solicitation notice, the OIG received 16 comments from various outside sources. We carefully considered those comments, as well as previous OIG publications, such as other compliance program guidances and Special Fraud Alerts, in developing a compliance program guidance for nursing facilities. In addition, we have taken into account past and recent fraud investigations conducted by the OIG's Office of Investigations and the Department of Justice, and have consulted with the Health Care Financing Administration. In an effort to ensure that all parties had a reasonable opportunity to provide input into a final product, the draft guidance for nursing facilities was published in the **Federal Register** on October 29, 1999 (64 FR 58419) for further comments and recommendations.

Elements for an Effective Compliance Program

This compliance guidance for nursing facilities contains seven elements that the OIG has determined to be 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 previous guidances issued by the OIG. As with previously-issued guidances, this compliance program guidance represents the OIG's suggestions on how nursing facilities can best establish internal controls and prevent fraudulent activities. The contents of this guidance should not be viewed as mandatory or as an exclusive discussion of the advisable elements of a compliance program; the document is intended to present voluntary guidance to the industry and not represent binding standards for nursing facilities.

Office of Inspector General's Compliance Program Guidance for Nursing Facilities

I. Introduction

The Office of Inspector General (OIG) of the Department of Health and Human Services (DHHS) continues in its efforts to promote voluntarily implemented compliance programs for the health care industry.[1] This compliance guidance is intended to assist nursing facilities [2] develop and implement internal controls and procedures that promote adherence to applicable statutes and regulations of the Federal health care programs [3] and private insurance

[1] The OIG1 has issued compliance program guidances for the following seven industry sectors: hospitals, clinical laboratories, home health agencies, durable medical equipment suppliers, third-party medical billing companies, hospices, and Medicare+Choice organizations offering coordinated care plans. Over the next year, the OIG plans to issue compliance guidances for ambulance companies and individual and small group physician practices.

[2] For the purpose of this guidance, the term ''nursing facility'' includes a skilled nursing facility (SNF) and a nursing facility (NF) that meet the requirements of sections 1819 and 1919 of the Social Security Act (Act), respectively, 42 U.S.C. 1395i–3 and 42 U.S.C. 1396r. Where appropriate, we distinguish between SNFs and other nursing facilities.

[3] The term ''Federal health care programs'' 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 Health Benefits Act, 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

Continued

program requirements. Compliance programs strengthen Government efforts to prevent and reduce fraud and abuse, as well as further the mission of all nursing facilities to provide quality care to their residents.

Through this document, the OIG provides its views on the fundamental elements of nursing facility compliance programs, as well as the principles that each nursing facility should consider when developing and implementing an effective compliance program. While this document presents basic procedural and structural guidance for designing a compliance program, it is not in and of itself a compliance program. Rather, it is a set of guidelines that nursing facilities should consider when developing and implementing a compliance program. For those nursing facilities that have an existing program or are already in the process of implementing a compliance program, these guidelines may serve as a benchmark against which to measure their ongoing efforts.

Implementing an effective compliance program in a nursing facility may require a significant commitment of time and resources by all parts of the organization. However, superficial efforts or programs that are hastily constructed and implemented without a long term commitment to a culture of compliance likely will be ineffective and may expose the nursing facility to greater liability than if it had no program at all.[4] Although an effective compliance program may require a reallocation of existing resources, the long term benefits of establishing a compliance program significantly outweigh the initial costs. In short, compliance measures are an investment that advance the goals of the nursing facility, the solvency of the Federal health care programs, and the quality of care provided to the nursing home resident.

In a continuing effort to collaborate closely with health care providers and the private sector, the OIG placed a notice in the **Federal Register** soliciting comments and recommendations on what should be included in this compliance program guidance.[5] In addition to considering these comments in drafting this guidance, we reviewed previous OIG publications, including OIG Special Fraud Alerts and OIG Medicare Advisory Bulletins, as well as reports issued by OIG's Office of Audit Services (OAS) and Office of Evaluation and Inspections (OEI) affecting the nursing home industry.[6] In addition, we relied on the experience gained from fraud investigations of nursing home operators conducted by OIG's Office of Investigations, the Department of Justice, and the Medicaid Fraud Control Units.

A. Benefits of a Compliance Program

The OIG believes a comprehensive compliance program provides a mechanism that brings the public and private sectors together to reach mutual goals of reducing fraud and abuse, enhancing operational functions, improving the quality of health care services, and decreasing the cost of health care. Attaining these goals provides positive results to the nursing facility, 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 nursing facility may gain numerous other benefits by voluntarily implementing a compliance program. The benefits may include:

- the formulation of effective internal controls to ensure compliance with statutes, regulations and rules;
- a concrete demonstration to employees and the community at large of the nursing facility's commitment to responsible corporate conduct;
- the ability to obtain an accurate assessment of employee and contractor behavior;
- an increased likelihood of identifying and preventing unlawful and unethical behavior;
- the ability to quickly react to employees' operational compliance concerns and effectively target resources to address those concerns;
- an improvement in the quality, efficiency, and consistency of providing services;
- a mechanism to encourage employees to report potential problems and allow for appropriate internal inquiry and corrective action;
- a centralized source for distributing information on health care statutes, regulations and other program directives;[7]
- a mechanism to improve internal communications;
- procedures that allow prompt and thorough investigation of alleged misconduct; and
- through early detection and reporting, minimizing loss to the Government from false claims, and thereby reducing the nursing facility's exposure to civil damages and penalties, criminal sanctions, and administrative remedies.[8]

The OIG recognizes that the implementation of a compliance program may not entirely eliminate fraud and abuse from the operations of a nursing facility. However, a sincere effort by the nursing facility to comply with applicable statutes and regulations as well as Government and private payer health care program requirements, through the establishment of a compliance program, significantly reduces the risk of unlawful or improper conduct.

B. Application of Compliance Program Guidance

Given the diversity within the long term care industry, there is no single ''best'' nursing facility compliance program. The OIG recognizes the complexities of this industry and is sensitive to the differences among large national chains, regional multi-facility operators, and small independent homes. However, the elements of this guidance can be used by all nursing facilities to establish a compliance program, regardless of size (in terms of employees and gross revenues), number of locations, or corporate structure.

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or child health services). *See* 42 U.S.C. 1320a–7b(f). In this document, the term ''Federal health care program requirements'' refers to the statutes, regulations and other written directives governing Medicare, Medicaid, and all other Federal health care programs.

[4] 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 Int'l Inc. Derivative Litig.,* 698 A.2d 959, 970 (Ct. Chanc. Del. 1996).

[5] *See* 63 FR 70137 (December 12, 1998), Notice for Solicitation of Information and Recommendations for Developing OIG Compliance Program Guidance for the Nursing Home Industry.

[6] The OIG periodically issues advisory opinions responding to specific inquires concerning the application of the OIG's authorities and Special Fraud Alerts, setting forth activities that raise legal and enforcement issues. These documents, as well as reports from OAS and OEI can be obtained on the Internet at: http://www.hhs.gov/oig. We also recommend that nursing home providers regularly review the Health Care Financing Administration (HCFA) website on the Internet at: http://www.hcfa.gov, for up-to-date regulations, manuals, and program memoranda related to the Medicare and Medicaid programs.

[7] Counsel to the nursing facility should be consulted as appropriate regarding interpretation and legal analysis of laws related to the Federal health care programs and laws related to fraud, abuse and other legal requirements.

[8] For example, the OIG 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 nursing facility to demonstrate the operational effectiveness of the 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). In addition, criminal sanctions may be mitigated by an effective compliance program that was in place at the time of the criminal offense. *See* note 11.

Similarly, a corporation that provides long term care as part of an integrated health care delivery system may incorporate these elements into its structure.[9]

We recognize that some nursing facilities may not be able to adopt certain elements to the same degree as others with more extensive resources. At the end of several sections of this document, the OIG has offered suggestions to assist these smaller nursing facility providers in implementing the principles expressed in this guidance. Regardless of size, structure or available resources, the OIG recommends that every nursing facility should strive to accomplish the objectives and principles underlying all of the compliance polices and procedures in this guidance.

By no means should the contents of this guidance be viewed as an exclusive or complete discussion of the advisable elements of a compliance program. On the contrary, the OIG strongly encourages nursing facilities to develop and implement compliance elements that uniquely address the areas of potential problems, common concerns, or high risk areas that apply to their own facilities. Furthermore, this guidance may be modified and expanded as more information and knowledge is obtained by the OIG, and as changes occur in the statutes, regulations and rules of the Federal health care programs and private health plans. New compliance practices also may be incorporated into this guidance if the OIG discovers enhancements that promote effective compliance.

II. Compliance Program Elements

A. The Seven Basic Compliance Elements

The OIG believes that every effective compliance program must begin with a formal commitment [10] by the nursing facility's governing body to address *all* of the applicable elements listed below, which are based on the seven steps of the Federal Sentencing Guidelines.[11] The OIG recognizes that full implementation of all elements may not be immediately feasible for all nursing facilities. However, as a first step, a good faith and meaningful commitment on the part of nursing facility management will substantially contribute to the program's successful implementation. As the compliance program is effectuated, that commitment should cascade down through management to every employee and contractor of the nursing facility.

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

(1) The development and distribution of written standards of conduct, as well as written policies, procedures and protocols that promote the nursing facility's commitment to compliance (*e.g.,* including adherence to the compliance program as an element in evaluating managers and employees) and address specific areas of potential fraud and abuse, such as claims development and submission processes, quality of care issues, and financial arrangements with physicians and outside contractors;

(2) The designation of a compliance officer and other appropriate bodies (*e.g.,* a corporate compliance committee) charged with the responsibility for developing, operating and monitoring the compliance program, and who reports directly to the owner(s), governing body and/or CEO; [12]

(3) The development and implementation of regular, effective education and training programs for all affected employees; [13]

(4) The creation and maintenance of an effective line of communication between the compliance officer and all employees, including 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 whistle blowers from retaliation;

(5) The use of audits and/or other risk evaluation techniques to monitor compliance, identify problem areas, and assist in the reduction of identified problems; [14]

(6) The development of policies and procedures addressing the non-employment or retention of excluded individuals or entities and the enforcement of appropriate disciplinary action against employees or contractors who have violated corporate or compliance policies and procedures, applicable statutes, regulations, or Federal, State, or private payor health care program requirements; and

(7) The development of policies and procedures with respect to the investigation of identified systemic problems, which include direction regarding the prompt and proper response to detected offenses, such as the initiation of appropriate corrective action, repayments, and preventive measures.

B. Written Policies and Procedures

Every compliance program should develop and distribute written compliance standards, procedures, and practices that guide the nursing facility and the conduct of its employees throughout day-to-day operations. These policies and procedures should be developed under the direction and supervision of the compliance officer, the compliance committee, and operational managers. At a minimum, they should be provided to all employees who are affected by these policies, as well as physicians, suppliers, nursing facility agents, and contractors, as applicable to those entities.[15] In addition to general corporate policies and procedures, an effective compliance program should include specific policies and procedures for the different clinical, financial, and administrative functions of a nursing facility.

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[9] For example, this would include providers that own hospitals, skilled nursing facilities, long term care facilities and hospices.

[10] A formal commitment may include a resolution by the board of directors, owner(s), or president, where applicable. Evidence of that commitment should include the allocation of adequate resources, a timetable, and the identification of an individual to serve as a compliance officer or coordinator to ensure that each of the recommended and adopted elements is addressed. Once a commitment has been established, a compliance officer should immediately be chosen to oversee the implementation and ongoing operation of the compliance program.

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

[12] The roles of the compliance officer and the corporate compliance committee in implementing an effective compliance program are discussed throughout this guidance. However, the OIG recognizes that differences in the sizes and structures of nursing facilities may result in differences in the ways in which compliance programs function.

[13] Training and educational programs for nursing facilities should be detailed, comprehensive and at the same time targeted to address the needs of specific employees based on their responsibilities within the facility. Existing in-service training programs can be expanded to address general compliance issues, as well as the risk areas identified in that part of nursing home operations.

[14] For example, periodically spot-checking the work of coding and billing personnel should be part of a compliance program. In addition, procedures to regularly monitor the care provided to nursing facility residents and to ensure that deficiencies identified by surveyors are corrected should be incorporated into the compliance program's evaluation and monitoring functions.

[15] 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).

1. Code of Conduct

While a clear statement of policies and procedures is at the core of a compliance program, the OIG recommends that nursing facilities start the process with the development of a corporate statement of principles that will guide the operations of the provider. One common expression of this statement of principles is the code of conduct.[16] The code 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 an organization. The code of conduct for a nursing facility should articulate the organization's expectations of employees, as well as summarize the basic legal principles under which the organization must operate. Unlike the more detailed policies and procedures, the code of conduct should be brief, easily readable and cover general principles applicable to all employees.

The code of conduct should be distributed to, and comprehensible by, all affected employees.[17] Depending on the facility's work force, this may mean that the code should be translated into other languages when necessary and written at appropriate reading levels. Further, any employee handbook delineating the standards of conduct should be regularly updated to reflect developments in applicable Government and private health care program requirements. Finally, the OIG recommends that current employees, as well as those newly hired, should certify that they have received, read, and will abide by the organization's code of conduct. These certifications, updated any time the code is revised or amended by the organization, should be retained in the employee's personnel file and made available for review.[18]

The OIG believes that *all* nursing facilities should operate under the guidance of a code of conduct. While the OIG recognizes that some nursing facilities may not have the resources to establish a comprehensive compliance program, we believe that every nursing facility can design a program that addresses the seven elements set out in this guidance, albeit at different levels of sophistication and complexity. In its most fundamental form, a facility's code of conduct is a basic set of standards that articulate the organization's philosophy, summarize basic legal principles, and teach employees how to respond to practices that may violate the code of conduct. These standards should be posted and distributed to every employee. Further, even a small nursing facility should obtain written attestation from its employees to confirm their understanding and commitment to the nursing facility's code of conduct.

2. Specific Risk Areas

As part of their commitment to a compliance program, nursing facilities should prepare a comprehensive set of written policies and procedures that are in place to prevent fraud and abuse in facility operations and to ensure the appropriate care of their residents. These policies and procedures should educate and alert all affected managers and employees of the Federal health care program and private payor requirements, the consequences of noncompliance, and the specific procedures that nursing facility employees should follow to report problems, to ensure compliance, and to rectify any prior noncompliance.

The OIG recognizes that many States require nursing facilities to have a policies and procedures manual and that most facilities have in place procedures to prevent fraud and abuse in their institutions. These providers may not need to develop a new, comprehensive set of policies as part of their compliance program if existing policies effectively encompass the provider's operations and relevant rules. However, the nursing home industry is subject to numerous Federal and State statutes, rules, regulations and manual instructions.[19] Because these program requirements are frequently modified, the OIG recommends that all nursing facilities evaluate their current compliance policies and procedures by conducting a baseline assessment of risk areas, as well as subsequent reevaluations.[20] The OIG also recommends that these internal compliance reviews be undertaken on a regular basis to ensure compliance with current program requirements.

To assist nursing facilities in performing this internal assessment, the OIG has developed a list of potential risk areas affecting nursing facility providers. These risk areas include quality of care and residents' rights, employee screening, vendor relationships, billing and cost reporting, and record keeping and documentation. This list of risk areas is not exhaustive, nor all encompassing. Rather, it should be viewed as a starting point for an internal review of potential vulnerabilities within the nursing facility.[21] The objective of this assessment should be to ensure that the employees, managers and directors are aware of these risk areas and that steps are taken to minimize, to the extent possible, the types of problems identified. While there are many ways to accomplish this objective, comprehensive written policies and procedures that are communicated to all appropriate employees and contractors are the first step in an effective compliance program.

The OIG believes that sound operating compliance policies are essential to all nursing facilities, regardless of size and capability. If a lack of resources to develop such policies is genuinely an issue, the OIG recommends that those nursing facilities focus first on those risk areas most likely to arise in their business operations. At a *minimum,* resources should be directed to analyze the results of annual surveys,[22] and to verify that the facility has effectively addressed any deficiencies cited by the surveyors. An effective and low-cost means to accomplish this is through the use of the facility's Quality Assessment and Assurance Committee. The committee should consist of facility staff members, including the Director of

[16] The OIG strongly encourages the participation and involvement of the nursing facility's owner(s), governing board, CEO, as well as other personnel from various levels of the organizational structure in the development of all aspects of the compliance program, especially the standards of conduct. Management and employee involvement in this process communicates a strong and explicit commitment to all employees of the need to comply with the organization's standards of conduct.

[17] The code also should be distributed, or at least available, to the residents and their families, as well as the physicians and contractors associated with the facility.

[18] Documentation of employee training and other compliance efforts is important in conducting internal assessments of the compliance program, as well as during any third-party evaluation of the facility's efforts to comply with Federal health care program requirements. *See* section II.F.

[19] *See* http://www.hcfa.gov for information on obtaining a set of all Medicare and Medicaid manuals.

[20] In addition, all providers should be aware of the enforcement priorities of Federal and State regulators and law enforcement agencies. OIG periodically issues Special Fraud Alerts and Special Advisory Bulletins that identify activities believed to raise enforcement concerns. These documents and other materials that provide insight into the nursing home enforcement priorities of the OIG are referenced throughout this guidance.

[21] The OIG recommends that, in addition to the list set forth below, the provider review the OIG's Work Plan to identify vulnerabilities and risk areas on which the OIG will focus during the following year. In addition, it is recommended that the nursing facility routinely review the OIG's semiannual reports, which identify program vulnerabilities and risk areas that the OIG has targeted during the preceding six months. All of these documents are available on the OIG's webpage at http://www.hhs.gov/oig.

[22] State and local agegncies enter into agreements with DHHS under which they survey and make recommendations regarding whether providers meet the Medicare participation requirements or other requirements for SNFs and NFs. *See* 42 CFR 488.10, 488.12.

Nursing and the medical director. Inclusion and participation of direct care staff (*e.g.,* nurses and nurses' aides who provide direct resident care) should be encouraged. This committee is best suited to establish measurable, outcome-based criteria that focus on vulnerabilities that adversely affect the care of residents. On a periodic basis, the committee should meet to identify issues affecting the quality of care provided to the residents and to develop and implement appropriate corrective actions. The time commitment required for this collaborative effort will vary according to the magnitude of the facility's quality assessment and assurance issues.

Creating a resource manual from publicly available information may be a cost-effective approach for developing policies and procedures to improve the quality of each resident's life. For example, a simple binder that contains a facility's written policies and procedures, the most recent survey findings and plan of correction, relevant HCFA instructions and bulletins, and summaries of key OIG documents (*e.g.,* Special Fraud Alerts, Advisory Bulletins, inspection and audit reports) can be regularly updated and made accessible to all employees. Particularly in the case of more technical materials, it may be advisable to provide summaries in the handbook and make the source documents available upon request. If individualized copies of this handbook are not made available to all employees, then a reference copy should be available in a readily accessible location, as well as from the designated compliance officer.

a. Quality of Care

The OIG believes that a nursing facility's compliance policies should start with a statement that affirms the facility's commitment to providing the care and services necessary to attain or maintain the resident's ''highest practicable physical, mental and psychosocial well-being.'' [23] To achieve the goal of providing quality care, nursing facilities should continually measure their performance against comprehensive standards that, at a minimum, must include Medicare requirements.[24] In addition to these regulations, a facility should develop its own quality of care protocols and implement mechanisms for evaluating compliance with those protocols. As part of its ongoing commitment to quality care, the facility should implement a system that reviews each resident's outcomes and improves on those outcomes through analysis and modification of the delivery of care. After the care delivery protocols have been modified, the facility should re-analyze the residents' outcomes to assure that the modification had the desired result and has actually improved care. Although resident care protocols are a useful tool for maintaining or improving the quality of care, facilities should ensure that measurable resident outcomes are used to determine the adequacy of the care actually rendered.

As noted above, current and past surveys are a good place to begin to identify specific risk areas and regulatory vulnerabilities at the individual facility. Any deficiencies discovered by an annual State agency survey, Federal validation survey or complaint survey reflect noncompliance with the program requirements for nursing homes and can be the basis for enforcement actions.[25] Those deficiencies identified by the State agency survey instrument must be addressed and, where appropriate, the corrective action should be incorporated into the facility's policies and procedures as well as reflected in its training and educational programs. In addition to responding promptly to deficiencies identified through the survey and certification process, nursing facilities should take proactive measures to identify, anticipate, and respond to quality of care risk areas identified by the nursing home ombudsman or other sources.

As noted throughout this guidance, each provider must assess its vulnerability to particular abusive practices in light of its unique circumstances. However, the OIG, HCFA, the Department of Justice, and State enforcement agencies have substantial experience in identifying quality of care risk areas. Some of the special areas of concern include:

- absence of a comprehensive, accurate assessment of each resident's functional capacity and a comprehensive care plan that includes measurable objectives and timetables to meet the resident's medical, nursing, and mental and psychosocial needs; [26]
- inappropriate or insufficient treatment and services to address residents' clinical conditions, including pressure ulcers, dehydration, malnutrition, incontinence of the bladder, and mental or psychosocial problems; [27]
- failure to accommodate individual resident needs and preferences; [28]
- failure to properly prescribe, administer and monitor prescription drug usage; [29]
- inadequate staffing levels or insufficiently trained or supervised staff to provide medical, nursing, and related services; [30]

[23] 42 CFR 483.25. *See* OIG report OEI–02–98–00060 ''Quality of Care in Nursing Homes: An Overview,'' in which the OIG found that, although the overall number of deficiencies identified through the survey and certification process was decreasing, the number of ''quality of care'' and other serious deficiencies was increasing.

[24] *See* 42 CFR part 483, which establishes requirements for long term care facilities. HCFA's regulations establish requirements that must be met for a nursing facility to qualify to participate in the Medicare and Medicaid programs. State licensure laws may impose additional requirements for the establishment and certification of a nursing facility.

[25] *See* 42 CFR part 488, subparts A, B, C, E, and F. The survey instrument is used to identify deficiencies, such as: failure to notify residents of their rights; improper use of restraints for discipline purposes; lack of a clean and safe environment; failure to provide care for basic living activities, including failing to prevent and/or treat pressure ulcers, urinary incontinence and hydration; and failing to properly feed residents.

[26] As stated above, each resident must receive the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the resident's assessment and plan of care. *See* 42 CFR 483.25. The OIG recognizes that this standard does not always lend itself to easy, objective evaluation. The matter is further complicated by the right of the resident, or his or her legal representative, to decide on a course of treatment that may be contraindicated. The Patient Self-Determination Act (Omnibus Budget Reconciliation Act of 1990, Pub. L. 101–508, sec. 4206 and 4751) requires health care institutions to educate patients about advance directives and to document their decision on life-sustaining treatments.

[27] HCFA has created a repository of best practice guidelines for the care of residents at risk of pressure ulcers, dehydration, malnutrition, and other clinical conditions. *See* http://www.hcfa.gov/medicaid/siq/siqhmpg.htm.

[28] 42 CFR 483.15(e)(1).

[29] The OIG has conducted a series of reviews that focused on prescription drug use in nursing homes. *See* OIG reports OEI–06–96–00080, OEI–06–96–00081, OEI–06–96–00082—''Prescription Drug Use in Nursing Homes—Reports 1, 2 and 3.'' The OIG found that patients experienced adverse reactions to various drugs as a result of inappropriate prescribing and inadequate monitoring of medication usage. The reviews revealed serious concerns, including residents receiving drugs for which their medical records lacked evidence of a prescription and the prescription of drugs judged inappropriate for use by elderly persons. The studies also found that medication records were often incomplete and not readily accessible, making it difficult for a pharmacist to identify or confirm drug regimens or problems.

[30] For example, Federal regulations require that the medical care of each resident be supervised by a physician, who must see the resident at least once every 30 days for the first 90 days after admission and at least once every 60 days thereafter. *See* 42 CFR 483.40(c). The facility also must retain the services of a registered nurse for at least 8 consecutive hours a day, 7 days a week (42 CFR 483.30), as well as a qualified dietitian (42 CFR 483.35). In addition to these basic Federal requirements, the OIG strongly believes that the facility should conform to State-mandated staffing levels where they exist and, in addition, adopt its own minimum ''hours per patient'' (or acuity) staffing standards. A facility should ensure that it

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• failure to provide appropriate therapy services; [31]

• failure to provide appropriate services to assist residents with activities of daily living (*e.g.,* feeding, dressing, bathing, etc.);

• failure to provide an ongoing activities program to meet the individual needs of all residents; and

• failure to report incidents of mistreatment, neglect, or abuse to the administrator of the facility and other officials as required by law.[32]

As noted previously, a nursing facility that has a history of serious deficiencies should use those survey results as a starting point for implementing a comprehensive plan to improve its quality of care. The quality of life for nursing home residents can be improved most directly by effectively addressing these risk areas with written policies and procedures, which are then implemented through effective training programs and supervision.

b. Residents' Rights

The Budget Reconciliation Act (OBRA) of 1987, Public Law 100–203, established a number of requirements to protect and promote the rights of each resident.[33] In addition, many States have adopted specific lists of residents' rights.[34] The nursing facility's policies should address the residents' right to a dignified existence that promotes freedom of choice, self-determination, and reasonable accommodation of individual needs. To protect the rights of each resident, the OIG recommends that a provider address the following risk areas as part of its compliance policies:

• discriminatory admission or improper denial of access to care; [35]

• verbal, mental or physical abuse, corporal punishment and involuntary seclusion; [36]

• inappropriate use of physical or chemical restraints; [37]

• failure to ensure that residents have personal privacy and access to their personal records upon request and that the privacy and confidentiality of those records are protected; [38]

• denial of a resident's right to participate in care and treatment decisions; [39] and

• failure to safeguard residents' financial affairs.[40]

c. Billing and Cost Reporting

Abusive and fraudulent billing practices in the Federal health care programs drain the public fisc of the funds needed to provide program beneficiaries medically necessary items and services. These types of abusive practices also have had an adverse financial impact on private health insurance plans and their subscribers. Over the last twenty years, the OIG has identified patterns of improper and fraudulent activities that cover the spectrum of health care services and have cost taxpayers billions of dollars.[41] These fraudulent billing practices, as well as abuses in other risk areas that are described in this compliance program guidance, have resulted in criminal, civil and administrative enforcement actions. Because the consequences of these enforcement actions can have a profound adverse impact on a provider, the identification of risk areas associated with billing and cost reporting should be a major component of a nursing facility's compliance program.

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has a sufficient number of staff, including registered nurses (RNs), Licensed Practical Nurses (LPNs,) Certified Nurses Assistants (CNAs) and Nursing Assistants (collectively ''Nursing Staff'') and other health care professionals to fully meet the needs of all of its residents. Sufficient staff should be provided to ensure that residents receive nursing and other health care services on a 24-hour basis that allows each resident to attain or maintain the highest practicable physical, mental and psychosocial well-being as determined by individual resident assessments and plans of care. A facility should establish staffing standards on a facility-specific (or, often more appropriately, a unit-specific) basis that reflect the acuity level and needs of the residents. The use of an acuity level/staffing ratio model gives the facility the ability to adjust staffing levels as resident needs fluctuate, as well as a basis for conducting compliance audits. On an ongoing basis, the compliance officer should monitor the facility's compliance with the staffing ratios established by the quality assurance committee, to ensure that the facility maintains staffing levels sufficient to serve resident needs. At the heart of many quality of care deficiencies is a lack of adequate staff needed to provide basic nursing services.

[31] *See* OIG report OEI–09–97–00120 ''Medical Necessity of Physical and Occupational Therapy in Skilled Nursing Facilities,'' which found a high rate of medically unnecessary therapies in a number of nursing facilities; such unnecessary services may lead to inappropriate care. *See also* OAS Report A–06–99–00058 ''Infusion Therapy Services Provided in Skilled Nursing Facilities,'' which found similar problems with unnecessary infusion therapy services. With the introduction of the prospective payment system, nursing facilities should ensure that financial pressures do not create incentives to *underutilize* medically necessary therapeutic services.

[32] In addition to providing the facility's management important information about the state of care in the facility, the self-reporting of resident abuse, including injuries of unknown sources, is a condition of participation. *See* 42 CFR 483.13(c)(2). Although State surveyors conduct complaint surveys when they receive a complaint, these surveys can only occur if the surveyors are aware of the problem.

[33] *See generally,* 42 U.S.C. 1395i–3 and 42 CFR part 483.

[34] In OIG report OEI–02–98–00350 ''Long Term Ombudsman Program: Complaint Trends,'' the OIG points out that complaints about resident care and resident rights have been increasing. Resident care concerns included complaints about personal care, such as pressure ulcers and hygiene, lack of rehabilitation, the inappropriate use of restraints, abuse and neglect, problems with admissions and eviction, and the exercise of personal rights. Some ombudsmen observed that the increasing number of complaints could be due to a greater presence of ombudsmen staff in nursing homes. However, a comparison of each State's staffing ratio and visitation rate to their complaint ratio found that States with more staff and more frequent visits did not necessarily have more complaints.

[35] Nursing facilities must offer care to all residents who are eligible in accordance with Federal and State laws governing admissions. *See* 42 CFR 483.12(d). The provider also must maintain identical policies regarding ''transfer, discharge, and provision of services under the State plan'' for all residents, regardless of payment source. *See* 42 CFR 483.12(c). *See also* OIG report OEI–02–99–00401 ''Early Effects of the Prospective Payment System on Access to Skilled Nursing Facilities.'' It also is inappropriate to condition admission on a prospective resident's agreement to hold the facility harmless for injuries or poor care provided to the individual.

[36] *See California Nursing Homes: Care Problems Persist Despite Federal and State Oversight,* GAO/HEHS–98–202 (July 1998). As noted previously, the facility must establish a process by which the facility administrator and other officials in accordance with State law (including the State survey and certification agency) are informed of incidents of abuse and an investigation is conducted within 5 days of the incident. *See* 42 CFR 483.13(c)(4).

[37] *See* OIG report OEI–01–91–00840 ''Minimizing Restraints in Nursing Homes: A Guide to Action.''

[38] It is a violation of the Medicare participation requirements to make unauthorized disclosures from the resident's medical records. *See* 42 CFR 483.10(e). The facility also must establish policies that respect each resident's right to privacy in personal communications, including the right to receive mail that is unopened and to the use of a telephone where calls can be made in privacy. *See* 42 CFR 483.10(i) and (k).

[39] The right of self-determination includes the resident's right to choose a personal physician, to be fully informed of his or her health status, and participate in advance in treatment decisions, including the right to refuse treatment, unless adjudged incompetent or incapacitated. *See* 42 CFR 483.10(d).

[40] This includes preserving the resident's right to manage his or her financial affairs or permit the facility to hold and manage personal funds. The resident must receive a full and complete accounting of personal funds held by the facility. *See* 42 CFR 483.10(c). If misappropriation of a resident's property is uncovered, the facility administrator and other officials, in accordance with State law, must be notified immediately and an investigation conducted. Finally, the provider must take measures to ensure that personal funds have not been used to pay for items or services paid for by Medicare or Medicaid. *Id.*

[41] *See* OIG report A–17–99–00099 ''Improper Fiscal Year 1998 Fee-for-Service Payments,'' in which the OIG estimated that improper Medicare benefit payments made during fiscal year 1998 totaled $12.6 billion in processed fee-for-service payments. SNF payment errors were a result of claims for services lacking medical necessity and represented 7 percent of the total estimated improper payments. The OIG could not and did not quantify what percentage of the improper payments was the result of fraud. Significantly, it was only through a review of medical records that the majority of these billing errors were detected, since when the claims were submitted to the Medicare contractor, they contained no visible errors.

The introduction of a prospective payments system (PPS) for Medicare SNFs, consolidated billing of all services furnished to a resident in a covered Part A stay and the forthcoming implementation of consolidated billing for SNF residents in a Part B stay create additional issues to be addressed when designing billing and cost reporting compliance policies and procedures.[42] In the following discussion of billing risk areas, the OIG has attempted to identify issues that pose concerns under the current systems of reimbursement and the transition period to consolidated billing, as well as anticipate potential compliance issues stemming from these program changes. As is the case with all aspects of compliance, the nursing facility must continually reassess its billing procedures and policies to ensure that unanticipated problems are promptly identified and corrected. Listed below are some of the reimbursement risk areas a nursing facility should consider addressing as part of its written compliance policies and procedures:

- billing for items or services not rendered or provided as claimed;[43]
- submitting claims for equipment, medical supplies and services that are medically unnecessary; [44]
- submitting claims to Medicare Part A for residents who are not eligible for Part A coverage; [45]
- duplicate billing; [46]
- failing to identify and refund credit balances; [47]
- submitting claims for items or services not ordered; [48]
- knowingly billing for inadequate or substandard care; [49]
- providing misleading information about a resident's medical condition on the MDS or otherwise providing inaccurate information used to determine the RUG assigned to the resident;
- upcoding the level of service provided; [50]
- billing for individual items or services when they either are included in the facility's per diem rate or are of the type of item or service that must be billed as a unit and may not be unbundled; [51]
- billing residents for items or services that are included in the per diem rate or otherwise covered by the third-party payor;
- altering documentation or forging a physician signature on documents used to verify that services were ordered and/or provided; [52]

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[42] The Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33), established PPS for SNFs. Under PPS, all costs (routine, ancillary, and capital) related to services furnished to beneficiaries covered under Part A, including certain Part B services, are paid a predetermined per diem amount. This amount is based on the medical condition and needs of the resident, as reflected in the Resource Utilization Group (RUG) code assigned to that resident. The BBA also required consolidated billing for SNFs. Under consolidated billing, all services provided by the SNF, including those furnished under arrangements with an outside supplier, for a resident of a SNF in a covered Part A stay are included in the SNF's Part A bill. If a resident is *not* in a covered Part A stay, under consolidated billing, the SNF still bills for all services furnished to the resident (except for those services specifically excluded from consolidated billing). However, the implementation of consolidated billing with respect to services furnished to residents in a Part B stay has been delayed indefinitely, and various ancillary services continue to be reimbursed separately to outside suppliers until further notice. *See* HCFA Program Memorandum (PM) Transmittal No. AB–98–35 (July 1998); PM Transmittal No. AB–98–45 (August 1998); and PM Transmittal No. AB–99–90 (Dec. 1999).

[43] For example, the OIG has investigated suppliers of ancillary services that improperly bill for an hour of therapy when only a few minutes were provided. Similarly, vendors that knowingly submit a claim for an expensive prosthetic device when the resident only received non-covered adult diapers have been the subject of enforcement actions. When consolidated billing is implemented, vendors will not submit bills directly to Medicare for such services. As the entity submitting the claim, the nursing facility will need to have any certifications or orders necessary to provide the service, as well as any required supporting documentation, to receive payment.

[44] Billing for medically unnecessary services, supplies and equipment involves seeking reimbursement for a service that is not warranted by a resident's 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''). At the same time, nursing facilities are required to provide the services necessary to attain or maintain the highest practicable physical, mental and psychosocial well-being of each resident. *See* 42 U.S.C. 1395i–3(b)(2) and 1396r(b)(2). In order to meet these obligations, nursing homes should formulate policies and procedures that include periodic clinical reviews, both prior and subsequent to billing for services, as a means of verifying that patients receive appropriate services.

In the Special Fraud Alert ''Fraud and Abuse in the Provision of Services in Nursing Facilities'' (June 1996), the OIG identified several types of fraudulent arrangements through which health care providers inappropriately billed Medicare and Medicaid for unnecessary or non-rendered items and services. Under PPS, the provision of unnecessary services may take a different form. As discussed below, manipulation of the Minimum Data Set (MDS) to fit a resident into a higher RUG can result in the provision of medically unnecessary services. In addition, a nursing facility may not enter into arrangements with providers of ancillary services through which the facility overutilizes services reimbursed under Part B in return for an offset in the cost of items or services covered under Part A.

[45] In order for a SNF stay to be covered by Medicare, the beneficiary must have a preceding three-day inpatient hospital stay. Observational stays and emergency room care do not qualify towards the 3-day hospital stay requirement. In addition, Medicare Part A benefits in skilled nursing facilities are limited to beneficiaries who require skilled services rendered by technical or professional personnel in a skilled nursing setting. *See* 42 CFR 409.31. Knowingly misrepresenting the nature or level of services provided to a Medicare beneficiary to circumvent the program's limitation is fraudulent.

[46] Duplicate billing occurs when the nursing facility bills for the same item or service more than once or when a vendor bills the Federal health care program for an item or service also billed by the facility. Although duplicate billing can occur due to simple error, the knowing submission of duplicate claims—which is sometimes evidenced by systematic or repeated double billing—can create liability under criminal, civil, or administrative law. A recent OIG survey of SNF PPS claims found a significant number of erroneous payments made by the Medicare carrier for services for which payments were already included in the SNF's PPS payment. As Medicare continues the implementation of consolidated billing, facilities should modify all agreements with vendors to require that the vendor bill the facility for those services covered under consolidated billing requirements and not submit bills directly to Medicare for such services. Communication mechanisms also should be established to ensure duplicative billings do not occur. For example, a facility may wish to flag a referral to an outpatient provider as a ''PPS resident'' and inform the provider that the nursing home will be responsible for billing Medicare for the ancillary services.

[47] A credit balance is an excess payment made to a health care provider as a result of patient billing or claims processing error. Nursing facilities should institute procedures to provide for the timely identification, accurate reporting and repayment of credit balances. In addition, the provider should promptly repay if a resident is also entitled to a credit. See OIG reports OEI–07–09–00910 ''Medicare Credit Balances in Skilled Nursing Facility Patient Accounts'' and OEI–07–09–00911 ''Medicaid Credit Balances in Skilled Nursing Facility Patient Accounts,'' in which the OIG found that skilled nursing facilities were not accurately or completely adjusting and reporting credit balance amounts due to the Medicare and Medicaid programs. Significantly, the intentional concealment of a known overpayment may expose a provider to criminal sanctions (see 42 U.S.C. 1320a–7b(a)(3)), and civil liability under the False Claims Act.

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

[49] See discussion on quality of care standards in nursing facilities in section II.B.2.a above and the accompanying notes. Although the OIG is not suggesting that each and every survey citation or failure to meet the applicable standard of care is a *per se* violation of the False Claims Act (or a criminal, other civil, or administrative violation), knowingly billing for nonexistent or substandard care, items, or services may give rise to criminal, civil, and/or administrative liability.

[50] Upcoding involves the selection of a billing code that is not the most appropriate descriptor of the service or condition, in order to maximize reimbursement. Under PPS, upcoding may take the form of ''RUG creep.'' RUG creep occurs when a provider falsely or fraudulently completes the MDS, which results in assigning a resident to a higher RUG category.

[51] A related risk area involves bill splitting schemes. This billing abuse usually takes the form of manipulating the billing for procedures to create the appearance that the services were rendered over a period of days when, in fact, all treatment occurred during one visit.

[52] The OIG has investigated a number of cases where signatures were forged, either to fabricate evidence that a physician ordered equipment or services or to create a paper trail in support of items or services that were never provided.

• failing to maintain sufficient documentation to support the diagnosis, justify treatment, document the course of treatment and results, and promote continuity of care; and

• false cost reports.[53]

The OIG recommends that a nursing facility, through its policies and procedures, take all reasonable steps to ensure compliance with the Federal health care programs when submitting information that affects reimbursement decisions. A key component of ensuring accurate information is the proper and ongoing training and evaluation of the staff responsible for coding diagnoses and regular internal audits of coding policies and procedures. With the arrival of consolidated billing and the next edition of the coding manuals, it will be even more critical that knowledgeable individuals are performing these coding tasks.

The risk areas associated with billing and cost reporting have been among the most frequent subjects of investigations and audits by the OIG. In addition to facing criminal sanctions and significant monetary penalties, providers that have failed to adequately ensure the accuracy of their claims and cost report submissions can have their Medicare payments suspended (42 CFR 405.371), be excluded from program participation (42 U.S.C. 1320a–7(b)), or, in lieu of exclusion, be required by the OIG to execute a corporate integrity agreement (CIA). [54]

d. Employee Screening

Nursing facilities are required by Federal, and in some cases State, law to investigate the background of certain employees.[55] Nursing facilities should conduct a reasonable and prudent background investigation and reference check before hiring those employees who have access to patients or their possessions, or who have discretionary authority to make decisions that may involve compliance with the law. The employment application should specifically require the applicant to disclose any criminal conviction, as defined by 42 U.S.C. 1320a–7(i); or exclusion from participation in the Federal health care programs. Because many of the services provided in nursing facilities are furnished under arrangement with non-employee personnel, including registry and personnel agency staff, the nursing facility also should require these individuals to be subject to the same scrutiny by their agency prior to placement in the facility.

This pre-employment screening is critical to ensuring the integrity of the facility's work force and safeguarding the welfare of its residents. Because providers of nursing care have frequent, relatively unsupervised access to vulnerable people and their property, a nursing facility also should seriously consider whether to employ individuals who have been convicted of crimes of neglect, violence, theft or dishonesty, financial misconduct, or other offenses related to the particular job.[56]

Nursing facility policies should prohibit the continued employment of individuals who have been convicted of a criminal offense related to health care or who are debarred, excluded, or otherwise become ineligible for participation in Federal health care programs. [57] In addition, if the facility has notice that an employee or contractor is currently charged with a criminal offense related to the delivery of health care services or is proposed for exclusion during his or her employment or contract, the facility should take all appropriate actions to ensure that the responsibilities of that employee or contractor do not adversely affect the quality of care rendered to any patient or resident, or the accuracy of any claims submitted to any Federal health care program.[58] If resolution of the matter results in conviction, debarment, or exclusion, the nursing facility should terminate its employment or contract arrangement with the individual.

In order to ensure that nursing facilities undertake background checks of all employees to the extent required by law, the OIG recommends that the following measures be incorporated into the compliance program's policies and procedures:

• investigate the background of employees by checking with all applicable licensing and certification authorities to verify that requisite licenses and certifications are in order; [59]

• require all potential employees to certify (*e.g.,* on the employment application) that they have not been convicted of an offense that would preclude employment in a nursing facility and that they are not excluded from participation in the Federal health care programs;

• require temporary employment agencies to ensure that temporary staff assigned to the facility have undergone background checks that verify that they have not been convicted of an offense

[53] Nursing homes are required to submit various reports to Federal and State agencies in connection with facility operations and to receive reimbursement for the care provided to program beneficiaries. Because program payments are in part based on self-reported operating costs, providers must implement procedures to ensure that these reports are prepared as accurately as possible. This should include measures to ensure that adequate documentation exists to support information provided in the report, non-allowable costs are appropriately identified and removed, and related party transactions are treated consistent with program requirements. *See* 42 CFR part 413. If the provider intends to claim costs in non-conformity with program rules, those items should be flagged in a letter accompanying the cost report.

Prior enforcement actions involving nursing home cost reports have focused on nursing facilities that claimed salary expenses for employees who did not exist, inflated the number of residents served, included non-reimbursable costs with nursing home-related expenses, inappropriately shifted costs to cost centers that were below the reimbursement cap, and shifted non-Medicare related costs to Medicare cost centers.

[54] The CIA imposes reporting requirements, independent audits, and other procedures on providers who have demonstrated an inability or unwillingness to independently adopt these measures. It is clearly in a provider's best interest to avoid the implementation of a CIA by instituting its own prevention, detection, and disclosure mechanisms.

[55] 42 CFR 483.13(c)(1).

[56] In OIG report A–12–97–0003 ''Safeguarding Long Term Care Residents,'' it was noted that, although no Federal requirement exists for criminal background checks on nursing home staff, 33 States currently require that such checks occur. However, there appears to be great diversity in the way States identify, investigate, and report suspected abuse of nursing home residents.

[57] The effect of an OIG exclusion from Federal health care programs is that no Federal health care program payment may be made for any items or services: (1) furnished by an excluded individual or entity; or (2) directed or prescribed by an excluded physician. *See* 42 CFR 1001.1901. An excluded individual or entity that submits a claim for reimbursement to a Federal health care program, or causes such a claim to be submitted, may be subject to a civil money penalty of $10,000 for each item or service furnished during the period that the person or entity was excluded. *See* 42 U.S.C. 1320a–7a(a)(1)(D). The individual or entity also may be subject to treble damages for the amount claimed for each item or service. *See* 42 U.S.C. 1320a–7a(a). *See also* OIG Special Advisory Bulletin ''The Effect of Exclusion From Participation in Federal Health Care Programs'' (September 1999).

[58] Likewise, the facility should establish standards prohibiting the execution of contracts with companies that recently have been 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. Prospective employees or contractors that have been officially reinstated into the Medicare and Medicaid programs by the OIG may be considered for employment upon proof of such reinstatement.

[59] Among the sources of information on prospective employees are the State registry of nurses' aides, which provides a list of nurse aides that have successfully completed training and competency evaluations and the National Practitioner Data Bank (NPDB). The NPDB is a database that contains information about physicians subject to 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 database to seek information about their own medical or clinical staff, as well as prospective employees or physician contractors.

that would preclude employment in the facility;

• check the OIG's List of Excluded Individuals/Entities and the GSA's list of debarred contractors to verify that employees are not excluded from participating in the Federal health care programs; [60]

• require current employees to report to the nursing facility if, subsequent to their employment, they are convicted of an offense that would preclude employment in a nursing facility or are excluded from participation in any Federal health care program; and

• periodically check the OIG and GSA web sites to verify the participation/exclusion status of independent contractors and retain on file the results of that query. [61]

Regardless of the size or resources of the nursing facility, employee screening is critical. Nursing facilities, like all corporations, must act through their employees and are held accountable for their actions. One of the best ways to ensure that the organization will act in conformance with the law is to hire employees and contractors who can be trusted to embrace a culture of compliance. While the resources required to check the OIG List of Excluded Individuals/Entities are minimal, the absence of an accessible centralized site for criminal background checks may result in inefficiencies and expense. While large providers may elect to outsource the screening process, this may not be a realistic option for smaller nursing facilities. Nevertheless, the OIG recommends that all nursing facilities implement a policy to undertake background checks of all employees.

e. Kickbacks, Inducements and Self-Referrals

A nursing facility should have policies and procedures to ensure compliance with the anti-kickback statute,[62] the Stark physician self-referral law [63] and other relevant Federal and State laws by providing guidance in situations that could lead to a violation of these laws.[64] In particular, arrangements with hospitals, hospices, physicians and vendors are vulnerable to abuse. For example, in the case of hospitals, physicians and hospital staff exert influence over the patient and can influence the choice of a nursing facility. In addition, in his or her roles as medical director and/or attending physician, a physician frequently can influence the utilization of ancillary services.[65] Moreover, by contrast, a nursing facility operator can influence the selection of which hospices will provide hospice services and which vendors will deliver equipment and services to the facility's residents. In addition to developing policies to address arrangements with other health care providers and suppliers, nursing facilities also should implement measures to avoid offering inappropriate inducements to residents. Possible risk areas that should be addressed in the policies and procedures include:

• routinely waiving coinsurance or deductible amounts without a good faith determination that the resident is in financial need, or absent reasonable efforts to collect the cost-sharing amount; [66]

• agreements between the facility and a hospital, home health agency, or hospice that involve the referral or transfer of any resident to or by the nursing home; [67]

• soliciting, accepting or offering any gift or gratuity of more than nominal value to or from residents, potential referral sources, and other individuals and entities with which the nursing facility has a business relationship; [68]

• conditioning admission or continued stay at a facility on a third-party guarantee of payment, or soliciting payment for services covered by Medicaid, in addition to any amount required to be paid under the State Medicaid plan; [69]

• arrangements between a nursing facility and a hospital under which the facility will only accept a Medicare beneficiary on the condition that the hospital pays the facility an amount over and above what the facility would receive through PPS; [70]

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[60] The OIG ''List of Excluded Individuals/Entities'' provides information to health care providers, patients, and others regarding individuals and entities that are excluded from participation in Medicare, Medicaid, and other Federal health care programs. This report, in both an on-line searchable and downloadable database, can be located on the Internet at http://www.hhs.gov/oig. In addition, the General Services Administration maintains a monthly listing of debarred contractors, ''List of Parties Excluded From Federal Procurement and Nonprocurement Programs,'' at http://epls.arnet.gov.

The OIG sanction information is readily available to users in two formats on over 15,000 individuals and entities currently excluded from program participation through action taken by the OIG. The on-line searchable database allows users to obtain information regarding excluded individuals and entities sorted by: (1) the legal bases for exclusions; (2) the types of individuals and entities excluded by the OIG; and (3) the States where excluded individuals reside or entities do business.

[61] The introduction of PPS and consolidated billing for Medicare Part B services means that vendors and their subcontractors no longer submit bills directly to Medicare for their services. Instead, the nursing facility will be submitting consolidated bills for certain services provided to residents. Because of the new responsibilities that are imposed on nursing facilities under these reimbursement schemes, the facility may be held responsible if it claims reimbursement for items or services provided by a contractor that has been excluded.

[62] The anti-kickback statute provides criminal penalties for individuals and entities that knowingly offer, pay, solicit or receive bribes, kickbacks, or other remuneration in order to induce business reimbursable by Federal health care programs. *See* 42 U.S.C. 1320a–7b(b). Civil penalties and exclusion from participation in the Federal health care programs may also result from a violation of the prohibition. *See* 42 U.S.C. 1320a–7a(a)(5) and 1320a–7(b)(7).

[63] The Stark physician self-referral law prohibits a physician from making a referral to an entity with which the physician or any member of the physician's immediate family has a financial relationship, if the referral is for the furnishing of designated health services. *See* 42 U.S.C. 1395nn.

[64] The OIG has issued several advisory opinions applying the anti-kickback statute to arrangements that affect nursing facilities. The opinions are available on the Internet at http://www.hhs.gov/oig.

[65] Contracts between the facility and any entity in which the facility's medical director has a financial interest may be subject to the Stark law and should be reviewed and approved by legal counsel.

[66] In the OIG Special Fraud Alert ''Routine Waiver of Part B Co-payments/Deductibles'' (May 1991), the OIG describes several reasons why routine waivers of these cost-sharing amounts pose abuse concerns. The Alert sets forth the circumstances under which it may be appropriate to waive these amounts.

[67] In the Special Fraud Alert ''Fraud and Abuse in Nursing Home Arrangements with Hospices'' (March 1998), the OIG sets out the vulnerabilities in nursing home arrangements with hospices. The Alert provides several examples of questionable arrangements between hospices and nursing homes that could inappropriately influence the referral of patients. Examples include the offering of free goods or goods at below fair market value to induce a nursing home to refer patients to the hospice. Other examples demonstrating vulnerability to fraud and abuse include: (1) a hospice paying for room and board in excess of the amounts the nursing home would normally charge or receive from Medicaid; (2) a hospice paying for additional services that should be already included in the room and board payment; and (3) a hospice referring patients to the nursing home in return for the nursing home's referral to the hospice. While the Special Fraud Alert focused on arrangements with hospices, nursing facilities should adopt policies that prohibit similar questionable arrangements with all health care providers.

[68] Providers should establish clear policies governing gift-giving, because such exchanges may be viewed as inducements to influence business decisions. Offering or providing any gift of more than nominal value to any beneficiary may be done with the intent to inappropriately influence health care decisions of the beneficiary or his or her family. Similarly, accepting gifts, hospitality, or entertainment from a source that is in a position to benefit from the referral of business, raises concerns that the gift may influence the employee's independent judgment. If the provider decides to allow employees to accept gifts or other gratuities below a certain nominal value or in an aggregate amount below an established amount per year, the provider should consider requiring employees to report those gifts.

[69] *See* 42 U.S.C. 1320a–7b(d)(2), which prescribes criminal penalties for knowingly and willfully charging for services provided to a Medicaid patient in excess of the rates established by the State. *See also* 42 CFR 483.12(d).

[70] Under PPS, the payment rates represent payment in full, subject to applicable coinsurance.

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• financial arrangements with physicians, including the facility's medical director; [71]

• arrangements with vendors that result in the nursing facility receiving non-covered items (such as disposable adult diapers) at below market prices or no charge, provided the facility orders Medicare-reimbursed products; [72]

• soliciting or receiving items of value in exchange for providing the supplier access to residents' medical records and other information needed to bill Medicare; [73]

• joint ventures with entities supplying goods or services; [74] and

• swapping.[75]

In order to keep current with this area of the law, a nursing facility should obtain copies of all relevant OIG and HCFA regulations, Special Fraud Alerts, and Advisory Opinions that address the application of the anti-kickback and Stark self-referral laws to ensure that the policies reflect current positions and opinions. Most of these documents are readily available on the Internet. Further, nursing facility policies should provide that all nursing facility contracts and arrangements with actual or potential sources of referrals are reviewed by counsel and comply with applicable statutes and requirements.

3. Creation and Retention of Records

When implementing a compliance program, nursing facilities should provide for the development and implementation of a records system that ensures complete and accurate medical record documentation. This system should establish policies and procedures regarding the creation, distribution, retention, and destruction of documents. Policies should provide for the complete, accurate, and timely documentation of all nursing and therapy services, including subcontracted services, as well as MDS information. In designing a records systems, privacy concerns and regulatory requirements also should be taken into consideration.

In addition to maintaining appropriate and thorough medical records on each resident, the OIG recommends that the system should include the following types of documents:

• all records and documentation (*e.g.,* billing and claims documentation) required for participation in Federal, State, and private health care programs, including the resident assessment instrument, the comprehensive plan of care and all corrective actions taken in response to surveys; [76]

• all records, documentation, and audit data that support and explain cost reports and other financial activity, including any internal or external compliance monitoring activities; and

• all records necessary to demonstrate the integrity of the nursing facility compliance process and to confirm the effectiveness of the program.[77]

While conducting its compliance activities, as well as its daily operations, a nursing facility should document its efforts to comply with applicable statutes, regulations, and Federal health care program requirements. For example, where a nursing facility requests advice from a Government agency (including a Medicare fiscal intermediary or carrier) charged with administering a Federal health care program, the nursing facility should document and retain a record of the request and any written or oral response. This step is extremely important if the nursing facility 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 nursing facility and third parties will help the organization document its attempts at compliance. In addition, these records may become relevant in a subsequent investigation to the issue of whether the facility's reliance was ''reasonable'' and whether it exercised due diligence in developing procedures and practices to implement the advice.

In short, all nursing facilities, regardless of size, must retain appropriate documentation. Further, the OIG recommends that the nursing facility:

• secure this information in a safe place;

• maintain hard copies of all electronic or database documentation;

• limit access to such documentation to avoid accidental or intentional fabrication or destruction of records; [78] and

• conform document retention and destruction policies to applicable laws.

As the Government increases its reliance on electronic data interchange to conduct business and gather information more quickly and efficiently, it is important that the nursing facility work toward the goal of developing the capacity to ensure that all informational systems maintained by the facility are in working order, secured, and capable of accessing Federal and State databases.

4. Compliance as an Element of Employee Performance

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

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This includes payment for all costs associated with furnishing covered SNF services to Medicare beneficiaries. It is impermissible for a hospital to pay for SNF services if it were to do so only for those residents who are Medicare beneficiaries discharged from that hospital. However, it would be permissible for a hospital to provide or pay for items or services that are furnished to SNF residents generally, if such payments are made without regard to the payment source for the individual resident. In addition, a hospital and a SNF can enter into a permissible bed reservation agreement. *See Provider Reimbursement Manual,* Part I, section 2105.3.

[71] All physician contracts and agreements should be reviewed to avoid violation of the anti-kickback, self-referral, and other relevant Federal and State laws. The OIG has published safe harbors that define practices not subject to the anti-kickback statute, because such arrangements would be unlikely to result in fraud or abuse. Failure to comply with a safe harbor provision does not make an arrangement per se illegal. Rather, the safe harbors set forth specific conditions that, if fully met, would assure the entities involved of not being prosecuted or sanctioned for the arrangement qualifying for the safe harbor. One such safe harbor applies to personal services contracts. *See* 42 CFR 1001.952(d).

[72] *See* OIG Special Fraud Alert ''Fraud and Abuse in the Provision of Medical Supplies to Nursing Facilities'' (August 1995). As well as violating the anti-kickback statute, both the supplier and the nursing facility may be liable for false claims if the medically unnecessary items are billed to Federal health care programs. *See also* OIG Advisory Opinion 99–2 (February 1999).

[73] In addition to raising concerns related to the anti-kickback statute, the unauthorized disclosure of confidential records violates the resident's rights. *See* 42 CFR 483.10(e).

[74] *See* OIG Special Fraud Alert ''Joint Venture Arrangements'' (August 1989); OIG Special Fraud Alert ''Fraud and Abuse in the Provision of Services in Nursing Facilities'' (May 1996).

[75] ''Swapping'' occurs when a supplier gives a nursing facility discounts on Medicare Part A items and services in return for the referrals of Medicare Part B business. With swapping, there is a risk that suppliers may offer a SNF an excessively low price for items or services reimbursed under PPS in return for the ability to service and bill nursing facility residents with Part B coverage. *See* OIG Advisory Opinion 99–2 (February 1999).

[76] Medical record documentation should support the medical necessity of the services provided as well as the level of service billed.

[77] Among the materials useful in documenting the compliance program are employee certifications relating to training and other compliance initiatives, copies of compliance training materials, and hotline logs and any corresponding reports of investigation, outcomes, and employee disciplinary actions. In addition, the facility should keep all relevant correspondence with carriers, fiscal intermediaries, private health insurers, HCFA, and State survey and certification agencies.

[78] In addition to prohibiting the falsification and backdating of records, the provider should have clear guidelines, consistent with applicable professional and legal standards, that set out those individuals with authority to make entries in the medical record and the circumstances when late entries may be made in a record.

involved in the direct care of residents and in claims development and submission:

• 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 procedures is a condition of employment; and

• disclose to all supervised personnel that the nursing facility will take disciplinary action, up to and including termination, for violation of these policies or requirements.

Managers and supervisors should be disciplined for failing to adequately instruct their subordinates or for failing to detect noncompliance with applicable policies and legal requirements, where reasonable diligence would have led to the discovery of any problems or violations and given the nursing facility the opportunity to correct them earlier. Conversely, those supervisors who have demonstrated leadership in the advancement of the company's code of conduct and compliance objectives should be singled out for recognition.

The OIG believes that all nursing facilities, regardless of resources or size, should ensure that its employees understand the importance of compliance with program requirements and the value the company places on its compliance program. If the small nursing facility does not have a formal employee evaluation system, it should informally convey to employees their compliance responsibilities whenever the opportunity arises. Positive reenforcement is generally more effective than sanctions in conditioning behavior and managers should be given mechanisms to reward employees who promote compliance.

C. Designation of a Compliance Officer and a Compliance Committee

1. Compliance Officer

Every nursing home provider should designate a compliance officer to serve as the focal point for compliance activities.[79] This responsibility may be the individual's sole duty or added to other management responsibilities, depending upon the size and resources of the nursing facility and the complexity of the task. Designating a compliance officer with the appropriate authority is critical to the success of the program, necessitating the appointment of a high-level official with direct access to the nursing facility's president or CEO, governing body, all other senior management, and legal counsel.[80] The officer should have sufficient funding and staff to perform his or her responsibilities fully.

Coordination and communication are the key functions of the compliance officer with regard to planning, implementing, and monitoring the compliance program. Particularly in a small facility, the compliance officer may need to rely on the expertise of several professionals within the facility to carry out all of his or her responsibilities. For example, the compliance officer may need the payment specialist to help with billing issues, the director of nursing to address quality of care issues, etc. At the same time, the compliance officer must retain the integrity and objectivity not to compromise the program in deference to one or more disciplines or departments.

The compliance officer's primary responsibilities should include:

• overseeing and monitoring implementation of the compliance program;

• reporting on a regular basis to the nursing facility's governing body, CEO, and compliance committee (if applicable) on the progress of implementation, and assisting these components in establishing methods to improve the nursing facility's efficiency and quality of services, and to reduce the facility's vulnerability to fraud, abuse, and waste;

• periodically revising the program in light of changes in the organization's needs, and in the law and policies of Government and private payor health plans;

• developing, coordinating, and participating in a multifaceted educational and training program that focuses on the elements of the compliance program, and seeking to ensure that all relevant employees and management understand and comply with pertinent Federal and State standards;

• ensuring that independent contractors and agents who furnish physician, nursing, or other health care services to the residents of the nursing facility are aware of the residents' rights as well as requirements of the nursing facility's compliance program applicable to the services they provide;

• coordinating personnel issues with the nursing facility's Human Resources/Personnel office (or its equivalent) to ensure that (i) the National Practitioner Data Bank[81] has been checked with respect to all medical staff and independent contractors (as appropriate) and (ii) the OIG's List of Excluded Individuals/Entities[82] has been checked with respect to all employees, medical staff, and independent contractors;[83]

• assisting the nursing facility's financial management in coordinating internal compliance review and monitoring activities, including annual or periodic reviews of departments;

• independently investigating and acting on matters related to compliance, including the flexibility to design and coordinate internal investigations (*e.g.*, responding to reports of problems or suspected violations) and any resulting corrective action (*e.g.*, making necessary improvements to nursing facility policies and practices, taking appropriate disciplinary action, etc.) with all nursing facility departments, subcontracted providers, and health care professionals under the nursing facility's control;

• participating with facility's counsel in the appropriate reporting of self-discovered violations of program requirements; and

• continuing the momentum of the compliance program after the initial years of implementation.[84]

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, medical and billing records, and documents concerning the marketing efforts of the nursing facility and its arrangements with other health

[79] For multi-facility organizations, the OIG encourages coordination with each facility owned by the corporation through the use of a headquarter's compliance officer, communicating with parallel positions or compliance liaison in each facility or regional office, as appropriate.

[80] The OIG believes it is not advisable for the compliance function to be subordinate to the nursing facility's general counsel, or comptroller or similar financial officer. Free-standing compliance functions help to ensure independent and objective legal reviews and financial analysis 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 nursing facility make this a feasible option), a system of checks and balances is established to more effectively achieve the goals of the compliance program.

[81] *See* note 59.

[82] *See* note 60.

[83] The compliance officer may also have to ensure that the criminal backgrounds of employees have been checked depending upon State requirements or nursing facility policy.

[84] There are many approaches the compliance officer may enlist to maintain the vitality of the compliance program. Periodic on-site visits of nursing facility operations, bulletins with compliance updates and reminders, distribution of audiotapes or videotapes on different risk areas, lectures at management and employee meetings, and circulation of recent health care articles covering fraud and abuse are some examples of approaches the compliance officer can employ.

care providers, including physicians and independent contractors. This review authority enables the compliance officer to examine 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 or regulatory requirements.

A small nursing facility may not have the resources to hire or appoint a full time compliance officer. Multi-facility providers also may consider appointing one compliance officer at the corporate level and designating compliance liaisons at each facility. In any event, each facility should have a person in its organization (this person may have other functional responsibilities) who can oversee the nursing facility's compliance with applicable statutes, rules, regulations, and policies. The structure and comprehensiveness of the facility's compliance program will help determine the responsibilities of each individual compliance officer.

2. Compliance Committee

The OIG recommends that a compliance committee be established to advise the compliance officer and assist in the implementation of the compliance program.[85] When developing an appropriate team of people to serve as the nursing facility's compliance committee, a facility should consider a variety of skills and personality traits that are expected from those in such positions.[86] Once a nursing facility chooses the people that will accept the responsibilities vested in members of the compliance committee, the nursing facility needs to train these individuals on the policies and procedures of the compliance program, as well as how to discharge their duties.

The committee's functions may include:

- analyzing the legal requirements with which the nursing facility must comply, and specific risk areas;
- assessing existing policies and procedures that address these risk areas for possible incorporation into the compliance program;
- working with appropriate departments to develop standards of conduct and policies and procedures to promote compliance with legal and ethical requirements;
- recommending and monitoring, in conjunction with the relevant departments, the development of internal systems and controls to carry out the organization's policies;
- determining the appropriate strategies and approaches to promote compliance with program requirements 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 deficiencies, and implementing corrective action.

The committee also may undertake other functions as the compliance concept becomes part of the overall nursing facility operating structure and daily routine. The compliance committee is an extension of the compliance officer and provides the organization with increased oversight. The OIG recognizes that some nursing facilities may not have the resources or the need to establish a compliance committee. However, when potential problems are identified, the OIG recommends these nursing facilities create a ''task force'' to address the particular problem. The members of the task force may vary depending upon the issue.

D. Conducting Effective Training and Education

The proper education and training of corporate officers, managers, and health care professionals, and the continual retraining of current personnel at all levels, are critical elements of an effective compliance program. These training programs should include sessions summarizing the organization's compliance program, fraud and abuse laws, and Federal health care program and private payor requirements. More specific training on issues such as claims development and submission processes, residents' rights, and marketing practices should be targeted at those employees and contractors whose job requirements make the information relevant.[87]

The organization must take steps to communicate effectively its standards and procedures to all affected employees, physicians, independent contractors, and other significant agents by requiring participation in such training programs or by other means, such as disseminating publications that explain specific requirements in a practical manner.[88]

Managers of specific departments or groups can assist in identifying areas that require training and in carrying out such training.[89] Training instructors may come from outside or inside the organization, but must be qualified to present the subject matter involved and sufficiently experienced in the issues presented to adequately field questions and coordinate discussions among those being trained.

The nursing facility should train new employees soon after they have started working.[90] Appropriate training for temporary employees should be provided by the facility before they are assigned responsibility for resident care. Training programs and materials should be designed to take into account the skills, experience, and knowledge of the individual trainees. The compliance officer should document any formal training undertaken by the nursing facility as part of the compliance program.

A variety of teaching methods, such as interactive training and, where a nursing facility has a culturally diverse staff, training in different languages, should be implemented so that all affected employees (including temporary employees) understand the institution's standards of conduct and procedures for alerting senior management to problems and concerns.[91]

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[85] The compliance committee benefits from having the perspectives of individuals with varying responsibilities in the organization, such as operations, finance, audit, human resources, and clinical management (*e.g.*, the medical director), as well as employees and managers of key operating units. The compliance officer should be an integral member of the committee as well. All committee members should have the requisite seniority and comprehensive experience within their respective departments to implement any necessary changes to policies and procedures as recommended by the committee.

[86] A health care provider should expect its compliance committee members and compliance officer to demonstrate high integrity, good judgment, assertiveness, and an approachable demeanor, while eliciting the respect and trust of employees of the nursing facility. These interpersonal skills are as important as the professional experience of each member of the compliance committee.

[87] Specific compliance training should complement any ''in-service'' training sessions that a nursing facility may regularly schedule to provide an ongoing program for the training of employees as required by the Medicare program.

[88] Some publications, such as OIG's special Fraud Alerts, audit and inspection reports, and advisory opinions are readily available from the OIG and can provide a basis for educational courses and programs for appropriate nursing facility employees.

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

[90] Certain positions, such as those that involve billing, coding and the submission of reimbursement data, create greater organizational legal exposure, and therefore require specialized training. Those hired to treat residents should undergo specialized training in residents' rights.

[91] Post-training tests can be used to assess the success of training provided and employee

In addition to specific training in the risk areas identified in section II.B.2, primary training for appropriate corporate officers, managers, and facility staff should include such topics as:

- compliance with Medicare participation requirements relevant to their respective duties and responsibilities;
- appropriate and sufficient documentation;
- prohibitions on paying or receiving remuneration to induce referrals;
- proper documentation in clinical or financial records;
- residents' rights; and
- the duty to report misconduct.

The OIG suggests that all relevant personnel participate in the various educational and training programs of the nursing facility.[92] Employees should be required to have a minimum number of educational hours per year, as appropriate, as part of their employment responsibilities.[93] For example, for certain employees involved in the nursing facility admission functions, periodic training in applicable reimbursement coverage and eligibility requirements should be required. In nursing facilities with high employee turnover, periodic training updates are critical.

The OIG recognizes that the format of the training program will vary depending upon the resources of the nursing facility. For example, a nursing facility with limited resources may want to create a videotape for each type of training session so new employees can receive training in a timely manner. If videos are used for compliance training, the OIG suggests that a nursing facility make a knowledgeable individual available to field questions from video trainees.

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

E. Developing Effective Lines of Communication

1. Access to the Compliance Officer

In order for a compliance program to work, employees must be able to ask questions and report problems. The first line supervisors play a key role in responding to employee concerns and it is appropriate that they serve as a first line of communications. In order to encourage communications, confidentiality and non-retaliation policies should be developed and distributed to all employees.[94]

Open lines of communication between the compliance officer and nursing facility employees is equally important to the successful implementation of a compliance program and the reduction of any potential for fraud and abuse. In addition to serving as a contact point for reporting problems, the compliance officer should be viewed as someone to whom personnel can go to get clarification on the facility's policies. Questions and responses should be documented and dated and, if appropriate, shared with other staff so that standards can be updated and improved to reflect any necessary changes or clarifications.[95]

2. Hotlines and Other Forms of Communication

The OIG encourages the use of hotlines,[96] e-mails, newsletters, suggestion boxes, and other forms of information exchange to maintain open lines of communication.[97] If the nursing facility establishes a hotline, the telephone number should be made readily available to all employees, independent contractors, residents, and family members by circulating the number on wallet cards or conspicuously posting the telephone number in common work areas. Nursing facilities also are required to post the names, addresses and telephone numbers of all pertinent State client advocacy groups such as the State survey and certification agency, State licensure office, State ombudsman program, the protection and advocacy network, and the State Medicaid Fraud Control Unit.[98]

Employees should be permitted to report matters on an anonymous basis. Matters reported through the hotline or other communication sources that suggest substantial violations of compliance policies or Federal health care program statutes and regulations should be documented and investigated promptly to determine their veracity. The compliance officer should maintain a log that records such calls, including the nature of any investigation and its results.[99] Such information, redacted of individual identifiers, should be included in reports to the governing body, the CEO, and compliance committee.[100] While the nursing facility should always strive to maintain the confidentiality of an employee's identity, it also should make clear that there may be a point where the individual's identity may become known or may have to be revealed in certain instances. The OIG recognizes that protecting anonymity may be infeasible for small nursing facilities. However, the OIG believes all facility employees, when seeking answers to questions or reporting potential instances of fraud and abuse, should know to whom to turn for attention and

comprehension of the nursing facility's policies and procedures.

[92] In addition, where feasible, the OIG recommends that a nursing facility give vendors and outside contractors the opportunity to participate in the nursing facility's compliance training and educational programs. Such training is particularly important for facilities that rely on agencies to provide temporary direct care staff. The introduction of consolidated billing gives added importance to educating vendors about the facility's compliance policies and procedures.

[93] 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 claims development and billing.

[94] In some 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 the employee brought a questionable, fraudulent, or abusive situation to the attention of senior corporate officials. Whistle blowers must be protected against retaliation, a concept embodied in the provisions of the False Claims Act. *See* 31 U.S.C. 3730(h).

[95] Nursing facilities also may wish to consider rewarding employees for appropriate use of established reporting systems. After all, the employee who identifies and helps stop an abusive practice can benefit the corporation as much as one who identifies cost-savings measures or increases corporate revenues.

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

[97] In addition, an effective employee exit interview program could be designed to solicit information from departing employees regarding potential misconduct and suspected violations of nursing facility policy and procedures.

[98] 42 CFR 483.10(b)(7)(iii). Nursing facilities also should post in a prominent area the HHS–OIG Hotline telephone number, 1–800–447–8477 (1–800–HHS–TIPS).

[99] To efficiently and accurately fulfill such an obligation, the nursing facility 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 results of the internal investigation, and, as appropriate, the corrective action implemented, the disciplinary measures imposed, and any identified overpayments returned.

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

should be able to do so without fear of retribution.

F. Auditing and Monitoring

The OIG believes that an effective program should incorporate thorough monitoring of its implementation and an ongoing evaluation process. The compliance officer should document this ongoing monitoring, including reports of suspected noncompliance, and share these assessments with the nursing facility's senior management and the compliance committee. The extent and frequency of the compliance audits may vary depending on variables such as the nursing facility's available resources, prior history of noncompliance, and the risk factors particular to the facility.[101]

Although many assessment techniques are available, one effective tool is the performance of regular, periodic compliance audits by internal or external evaluators who have expertise in Federal and State health care statutes, regulations, and program requirements, as well as private payor rules. These assessments should focus both on the nursing facility's day-to-day operations, as well as its adherence to the rules governing claims development, billing and cost reports, and relationships with third parties. The reviews also should address the nursing facility's compliance with Medicare requirements and the specific rules and policies that have been the focus of particular attention by the Medicare fiscal intermediaries or carriers, survey agencies, and law enforcement.[102]

Monitoring techniques may include sampling protocols that permit the compliance officer to identify and review variations from an established performance baseline.[103] This performance baseline should include measurable patient outcomes, such as resident weight maintenance and pressure ulcers, established by the facility's Quality Assessment and Assurance Committee. Significant variations from the baseline should trigger an inquiry to determine the cause of the deviation. If the inquiry determines that the deviation occurred for legitimate reasons, the compliance officer and nursing facility management may want to take no action. If it is determined that the deviation was caused by a departure from or misunderstanding of the facility's policies, the nursing facility should take prompt steps to correct the problem. Any overpayments discovered as a result of such deviations should be returned promptly to the affected payor,[104] with appropriate documentation and a sufficiently detailed explanation of the reason for the refund.[105]

In addition to evaluating the facility's conformance with program rules, an effective compliance program also should 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, ongoing educational programs, and internal investigations of alleged non-compliance. This process will assess actual conformance by all departments with the compliance program and may identify areas for improvements in the program, as well as the nursing facility's general operations.

The OIG requires a provider operating under a CIA to conduct an annual assessment of its compliance with the elements of the CIA. A compliance officer may want to review several CIAs in designing the facility's self-audit protocol.[106]

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

- on-site visits to all facilities owned and/or operated by the nursing home owner;
- testing the billing and claims reimbursement staff on its knowledge of applicable program requirements and claims and billing criteria;
- unannounced mock surveys and audits;
- examination of the organization's complaint logs and investigative files;
- legal assessment of all contractual relationships with contractors, consultants and potential referral sources;
- reevaluation of deficiencies cited in past surveys for State requirements and Medicare participation requirements;
- checking personnel records to determine whether individuals who previously have been reprimanded for compliance issues are now conforming to facility policies;
- questionnaires developed to solicit impressions of a broad cross-section of the nursing facility's employees and staff concerning adherence to the code of conduct and policies and procedures, as well as their work loads and ability to address the residents' activities of daily living;
- validation of qualifications of nursing facility physicians and other staff, including verification of applicable State license renewals;
- trend analysis, or longitudinal studies, that uncover deviations in specific areas over a given period; and
- analyzing past survey reports for patterns of deficiencies to determine if the proposed corrective plan of action identified and corrected the underlying problem.

The reviewers should:

- have the qualifications and experience necessary to adequately identify potential issues with the subject matter that is reviewed;
- be objective and independent of line management to the extent reasonably possible;[107]
- have access to existing audit and health care resources, relevant personnel, and all relevant areas of operation;
- present written evaluative reports on compliance activities to the CEO, governing body, and members of the compliance committee on a regular basis, but no less often than annually; and
- specifically identify areas where corrective actions are needed.

The extent and scope of a nursing facility's compliance self-audits will depend on the facility's identified risk areas, past history of deficiencies and

[101] Even when a nursing facility or group of facilities is owned by a larger corporate entity, the regular auditing and monitoring of the compliance activities of an individual facility 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.

[102] See also section II.B.2.

[103] The OIG recommends that when a compliance program is established in a nursing facility, the compliance officer, with the assistance of department managers, should take a ''snapshot'' of their operations from a compliance perspective. This assessment can be undertaken by outside consultants or internal staff, provided they have knowledge of health care program requirements. This ''snapshot'' can serve as a baseline for the compliance officer and other managers to judge the nursing facility's progress in reducing potential areas of vulnerability.

[104] See Provider Reimbursement Manual Part I, section 2836(D)(3), which sets out the MDS correction policy.

[105] In addition, when appropriate, as referenced in section II.H.2, below, reports of fraud or systemic problems also should be made to the appropriate governmental authority.

[106] Examples of CIA audit protocols can be obtained from the OIG by submitting a request pursuant to the Freedom of Information Act. The OIG recently has entered into CIAs with a number of nursing home providers that may be of particular relevance. In addition, the American Institute of Certified Public Accountants (AICPA) has issued a detailed guide for conducting an independent assessment of a health care provider's conformance to a CIA. *See* AICPA Statement of Position 99–1, ''Guidance to Practitioners in Conducting and Reporting on an Agreed-Upon Procedures Engagement to Assist in Evaluating Compliance with a Corporate Integrity Agreement'' (May 1999).

[107] The OIG recognizes that nursing facilities that have limited resources may not be able to use internal reviewers who are not part of line management or hire outside reviewers.

enforcement actions, and resources. If the facility comes under Government scrutiny in the future, the Government will assess whether the facility developed a reasonable audit plan based upon identified risk areas and resources. If the Government determines that the nursing facility failed to develop an adequate audit program, the Government will be less likely to afford the nursing facility favorable treatment under the Federal Sentencing Guidelines.

G. Enforcing Standards Through Well-Publicized Disciplinary Guidelines

1. Disciplinary Policy and Enforcement

An effective compliance program should include disciplinary policies that set out the consequences of violating the nursing facility's standards of conduct, policies, and procedures. Intentional noncompliance should subject transgressors to significant sanctions. Such sanctions could range from oral warnings to suspension, termination, or financial penalties, as appropriate. 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. Each situation must be considered on a case-by-case basis to determine the appropriate response.

The written standards of conduct should elaborate on the procedures for handling disciplinary problems and those who will be responsible for taking appropriate action. Some disciplinary actions can be handled by department or agency managers, while others may have to be resolved by a senior administrator. The nursing facility should advise personnel 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 employees regarding these standards. The consequences of noncompliance should be consistently applied and enforced, in order for the disciplinary policy to have the required deterrent effect. All levels of employees should be potentially subject to the same types of disciplinary action for the commission of similar offenses, because the commitment to compliance applies to all personnel within a nursing facility. This means that corporate officers, managers, and supervisors should be held accountable for failing to comply with, or for the foreseeable failure of their subordinates to adhere to, the applicable standards, laws, and procedures.

H. Responding to Detected Offenses and Developing Corrective Action Initiatives

Violations of a nursing facility's compliance program, failures to comply with applicable Federal or State law, and other types of misconduct threaten a facility's status as a reliable, honest and trustworthy provider of health care. Detected but uncorrected deficiencies can seriously endanger the reputation and legal status of the nursing facility. Consequently, upon receipt of reports or reasonable indications of suspected noncompliance, it is important that the compliance officer or other management officials immediately investigate the allegations to determine whether a material violation of applicable law or the requirements of the compliance program has occurred and, if so, take decisive steps to correct the problem.[108] As appropriate, such steps may include a corrective action plan,[109] the return of any overpayments, a report to the Government,[110] and/or a referral to criminal and/or civil law enforcement authorities.

Where potential fraud is not involved, the OIG recommends that the nursing facility use normal repayment channels to return overpayments as they are discovered. However, even if the nursing facility's billing department is effectively using the overpayment detection and return process, the OIG believes that the facility needs to alert the compliance officer to those overpayments that may reveal trends or patterns indicative of a systemic problem.

Where there are indications of potential fraud, an internal investigation may be warranted and will probably include interviews and a review of relevant documents. Under some circumstances, the facility may need to consider engaging outside counsel, auditors, or health care experts to assist in an investigation. The investigative file should contain documentation of the alleged violation, a description of the investigative process (including the objectivity of the investigators and methodologies utilized), copies of interview notes and key documents, a log of the witnesses interviewed and the documents reviewed, the results of the investigation, *e.g.,* any disciplinary action taken, and the corrective action implemented. While any action taken as the result of an investigation will necessarily vary depending upon the situation, nursing facilities should strive for some consistency by using sound practices and disciplinary protocols.[111] Further, 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 the nursing facility undertakes an investigation of an alleged violation and the compliance officer believes the integrity of the investigation may be at stake because of the presence of employees under investigation, the facility should remove those individuals from their current responsibilities until the investigation is completed (unless there is an ongoing internal or Government-led undercover operation known to the nursing facility). 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 nursing facility determines that disciplinary action is warranted, it should be promptly imposed in accordance with the facility's written standards of disciplinary action.

[108] Instances of noncompliance must be determined on a case-by-case basis. The existence or amount of a *monetary* loss to a health care program is not solely determinative of whether the conduct should be investigated and reported to governmental authorities. In fact, there may be instances where there is no readily identifiable monetary loss, but corrective actions are still necessary to protect the integrity of the applicable program and its beneficiaries, *e.g.,* where failure to comply with the facility's policies and procedures results in inadequate or inappropriate care being furnished to a facility resident.

[109] The nursing facility may seek advice from its in-house counsel or an outside law firm to determine the extent of the facility's liability and to plan the appropriate course of action.

[110] Nursing facilities are required to immediately report all alleged incidents of mistreatment, neglect, abuse (including injuries of unknown source), and misappropriation of resident property to both the facility administrator and other officials in accordance with State law. *See* 42 CFR 483.13(c)(2). This is the appropriate channel for reporting quality of care issues. The OIG also has established a provider self-disclosure protocol that encourages providers voluntarily to report suspected fraud. The concept of voluntary self-disclosure is premised on a recognition that the Government alone cannot protect the integrity of 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.hhs.gov/oig.

[111] The parameters of a claims review subject to an internal investigation will depend on the circumstances surrounding the issues identified. By limiting the scope of an internal audit to current billing, a nursing facility may fail to discover major problems and deficiencies in operations, and may subject itself to liability.

1. Reporting

Where the compliance officer, compliance committee, or a 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, the facility should promptly report the existence of misconduct to the appropriate Federal and State authorities [112] within a reasonable period, but not more than 60 days [113] after determining that there is credible evidence of a violation.[114] Prompt voluntary reporting will demonstrate the nursing facility's good faith and willingness to work with governmental authorities to correct and remedy the problem. In addition, reporting such conduct will be considered a mitigating factor by the OIG in determining administrative sanctions (*e.g.,* penalties, assessments, and exclusion), if the reporting provider becomes the target of an OIG investigation.[115]

When reporting to the Government, a nursing facility should provide all evidence relevant to the alleged violation of applicable Federal or State law(s) and potential cost impact. The compliance officer, under advice of counsel and with guidance from the governmental authorities, could be requested to continue to investigate the reported violation. Once the investigation is completed, the compliance officer should 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 nursing facility should immediately notify appropriate Federal and State authorities.

As previously stated, the nursing facility should take appropriate corrective action, including prompt identification and return of any overpayment to the affected payor. If potential fraud is involved, the nursing facility should return any overpayment during the course of its disclosure to the Government. Otherwise, the nursing facility should use normal repayment channels for reimbursing identified overpayments.[116] A knowing and willful failure to disclose overpayments within a reasonable period of time could be interpreted as an attempt to conceal the overpayment from the Government, thereby establishing an independent basis for a criminal violation with respect to the nursing facility, as well as any individual who may have been involved.[117] For this reason, nursing facility compliance programs should emphasize that overpayments should be promptly disclosed and returned to the entity that made the erroneous payment.

III. Assessing the Effectiveness of a Compliance Program

Considering the financial and human resources needed to establish an effective compliance program, sound business principles dictate that the nursing home's management evaluate the return on that investment. In addition, a compliance program must be ''effective'' for the Government to view its existence as a mitigating factor when assessing culpability. How a nursing facility assesses its compliance program performance is therefore integral to its success. The attributes of each individual element of a compliance program must be evaluated in order to assess the program's ''effectiveness'' as a whole. Examining the comprehensiveness of policies and procedures implemented to satisfy these elements is merely the first step. Evaluating how a compliance program performs during the provider's day-to-day operations becomes the critical indicator.[118]

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

Every nursing facility needs to seriously consider whoever fills the integral roles of compliance officer and compliance committee members, and periodically monitor how the individuals chosen satisfy their responsibilities. Does a compliance officer have sufficient professional experience working with billing, clinical records, documentation, and auditing principles to perform assigned responsibilities fully? Has a compliance officer or compliance committee been unsuccessful in fulfilling their duties because of inadequate funding, staff, and authority necessary to carry out their jobs? Did the addition of the compliance officer function to a key management position with other significant duties compromise the goals of the compliance program (*e.g.,* chief financial officer who discounts certain overpayments identified to improve the company's bottom line profits)? Since a

[112] Appropriate Federal and State authorities include the OIG, the Criminal and Civil Divisions of the Department of Justice, the U.S. Attorney in relevant districts, the Federal Bureau of Investigation, and the other investigative arms for the agencies administering the affected Federal or State health care programs, such as the State Survey Agency, the State Medicaid Fraud Control Unit, the Defense Criminal Investigative Service, the Department of Veterans Affairs, and the Office of Personnel Management (which administers the Federal Employee Health Benefits Program). State law may further specify types of misconduct and to whom a facility must report its findings. See note 110.

[113] In contrast, to qualify for the ''not less than double damages'' provision of the False Claims Act, the provider must provide the report to the Government within 30 days after the date when the provider first obtained the information. See 31 U.S.C. 3729(a).

[114] Some violations may be so serious that they warrant immediate notification to governmental authorities prior to, or simultaneous with, commencing an internal investigation. By way of example, the OIG believes a provider should report misconduct that: (1) is a clear violation of OIG administrative authorities, or civil or criminal fraud laws; (2) has a significant adverse effect on the quality of care provided to residents (in addition to any other legal obligations regarding quality of care); or (3) indicates evidence of a systemic failure to comply with applicable laws or an existing corporate integrity agreement, regardless of the financial impact on Federal health care programs.

[115] 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).

[116] A nursing facility should consult with its Medicare fiscal intermediary (FI) and the appropriate sections of the Provider Reimbursement Manual for additional guidance regarding refunds under Medicare Part A. *See* note 104. The FI may require certain information (*e.g.,* alleged violation or issue causing overpayment, description of the internal investigative process with methodologies used to determine any overpayments, and corrective actions taken, etc.) to be submitted with the return of any overpayments, and that such repayment information be submitted to a specific department or individual. When appropriate, interest may be assessed on the overpayment. *See* 42 CFR 405.378.

[117] *See* 42 U.S.C. 1320a–7b(a)(3) and 18 U.S.C. 669.

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

As evidenced throughout this guidance, the proper education and training of corporate officers, managers, health care professionals, and other applicable employees of a provider, and the continual retraining of current personnel at all levels, are significant elements of an effective compliance program. Accordingly, such efforts should be routinely evaluated. How frequently are employees trained? Are employees tested after training? Do the training sessions and materials adequately summarize the important aspects of the organization's compliance program? Are training instructors qualified to present the subject matter and field questions? When thorough compliance training is periodically conducted, employees receive the reinforcement they need to ensure an effective compliance program.

An open line of communication between the compliance officer and a provider's employees is equally important to the success of a compliance program. In today's intensive regulatory environment, the OIG believes that a provider cannot possibly have an effective compliance program if it does not receive feedback from its employees regarding compliance matters. For instance, if a compliance officer does not receive appropriate inquiries from employees: Do policies and procedures adequately guide employees to whom and when they should be communicating compliance matters? Are employees confident that they can report compliance matters to management without fear of retaliation? Are employees reporting issues through the proper channels? Do employees have the proper motives for reporting compliance matters? Regardless of the means that a provider uses, whether it is telephone hotline, email, or suggestion boxes, employees should seek clarification from compliance staff in the event of any confusion or question dealing with compliance policies, practices, or procedures.

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

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

It is essential that the compliance officer or other management officials immediately investigate reports or reasonable indications of suspected noncompliance. If a material violation of applicable law or compliance program requirements has occurred, a provider must take decisive steps to correct the problem. Nursing facilities that do not thoroughly investigate misconduct leave themselves open to undiscovered problems. When a provider learns of certain issues, it should evaluate how it assesses its legal exposure. What is the correlation between the deficiency identified and the corrective action necessary to remedy? Are isolated overpayment matters properly resolved through normal repayment channels? Is credible evidence of misconduct that may violate criminal, civil or administrative law promptly reported to the appropriate Federal and State authorities? If the process of responding to detected offenses is circumvented, such conduct would indicate an ineffective compliance program.

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

IV. Conclusion

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

The OIG recognizes that the health care industry in this country, which reaches millions of beneficiaries and expends about a trillion dollars annually, is constantly evolving. The time is right for nursing facilities to implement a strong voluntary health care compliance program. Compliance is a dynamic process that helps to ensure that nursing facilities and other health care providers are better able to fulfill their commitment to ethical behavior, as well as meet the changes and challenges being placed upon them by Congress and private insurers. Ultimately, it is the OIG's hope that a voluntarily created compliance program will enable nursing facilities to meet their goals, improve the quality of resident care, and substantially reduce fraud, waste, and abuse, as well as the cost of health care to Federal, State, and private health insurers.

Dated: March 9, 2000.

June Gibbs Brown,

Inspector General.

[FR Doc. 00–6423 Filed 3–15–00; 8:45 am]

BILLING CODE 4150–04–P

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 H—Clinical Groups.

Date: March 23–24, 2000.

Time: 6:30 PM to 1 PM.

Agenda: To review and evaluate grant applications.

Place: Chevy Chase Holiday Inn, 5520 Wisconsin Avenue, Chevy Chase, MD 20815.

Contact Person: Deborah R. Jaffe, Scientific Review Administrator, Grants Review Branch, Division of Extramural Activities, National Cancer Institute, National Institutes of Health, Bethesda, MD 20892.

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

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

Dated: March 7, 2000.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 00–6476 Filed 3–15–00; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Complementary and Alternative Medicine; Notice of Closed Meeting

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

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

Name of Committee: National Center for Complementary & Alternative Medicine Special Emphasis Panel.

Date: March 21, 2000.

Time: 3:30 p.m. to 5 p.m.

Agenda: To review and evaluate contract proposals.

Place: 9000 Rockville Pike, Bldg. 31, Room 5B50, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Sheryl K. Brining, National Center for Complementary and Alternative Medicine, National Institutes of Health, 31 Center Drive, Room 5B50, Bethesda, MD 20892–2182, (301) 496–7498, sb44k@nih.gov.

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

Dated: March 9, 2000.

Ann Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 00–6473 Filed 3–15–00; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Deafness and Other Communication Disorders; 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 Institute on Deafness and Other Communications Disorders Special Emphasis Panel.

Date: April 5, 2000.

Time: 1 pm to 3:30 pm.

Agenda: To review and evaluate grant applications.

Place: Executive Plaza South, Room 400C, 6120 Executive Blvd., Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Stanley C. Oaks, Jr., Scientific Review Branch, Division of Extramural Research, Executive Plaza South, Room 400C, 6120 Executive Blvd. Bethesda, MD 20892–7180, 301–496–8683.

(Catalogue of Federal Domestic Assistance Program Nos. 93.173, Biological Research Related to Deafness and Communicative Disorders, National Institutes of Health, HHS)

Dated: March 9, 2000.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 00–6474 Filed 3–15–00; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; 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 Institute of Environmental Health Sciences Special Emphasis Panel R13 Conference Grants

Date: April 5, 2000.

Time: 1 PM to 2 PM.

Fraud Alerts

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OFFICE OF INSPECTOR GENERAL

SPECIAL FRAUD ALERT

FRAUD AND ABUSE IN NURSING HOME ARRANGEMENTS WITH HOSPICES

March 1998

The Office of Inspector General was established at the Department of Health and Human Services by Congress in 1976 to identify and eliminate fraud, abuse and waste in the Department's programs and to promote efficiency and economy in departmental operations. The OIG carries out this mission through a nationwide program of audits, investigations, and inspections.

To reduce fraud and abuse in the Federal health care programs, including Medicare and Medicaid, the OIG actively investigates fraudulent schemes to obtain money from these programs and, when appropriate, issues Special Fraud Alerts that identify segments of the health care industry that are particularly vulnerable to abuse. This Special Fraud Alert focuses on the interrelationship between the hospice and nursing home industries and describes some potentially illegal practices the OIG has identified in arrangements between these providers.

What Is Hospice Care And Who Is Eligible To Receive It

Medicare's hospice benefit provides palliative care to individuals who are terminally ill. Palliative care focuses on pain control, symptom management, and counseling for both the patient and family. Medicare hospice payments increased from about $958 million for Fiscal Year 1993 to over $1.8 billion for Fiscal Year 1995. Although the hospice benefit is still a relatively small portion of total Medicare Part A expenditures (about 1.5 percent), it has grown considerably over the past several years.

In order to elect the hospice benefit, a Medicare beneficiary must be entitled to Medicare Part A services and certified as terminally ill, which is defined as a

medical prognosis of a life expectancy of 6 months or less if the illness runs its normal course. A beneficiary who elects to enroll in a hospice program waives his or her rights to all curative care related to his or her terminal illness. Medicare will continue to pay for services furnished by the patient's non-hospice attending physician and for the treatment of conditions unrelated to the terminal illness.

The hospice must have a written plan of care which covers physician and nursing services; physical, occupational, and speech therapy; medical social services; home health aides and homemakers; short-term inpatient care; counseling; respite care; and medical supplies, including drugs and biologicals. Certain of the hospice services ("core services") must be provided directly to the beneficiary by employees of the hospice, while other non-core hospice services may be provided in accordance with contracts with other providers. However, the hospice must retain professional management for all contracted services.

Reimbursement For Hospice Care Provided In Nursing Homes

Medicare does not have a separate payment rate for routine hospice services provided in a nursing home. Because hospice services are typically provided to patients in their homes, the routine home care hospice rate does not include any payment for room or board. For services provided to patients in nursing homes, hospices receive the Medicare routine home care rate, which is a fixed amount per day for the services provided by the hospice, regardless of the volume or intensity of the services provided. Accordingly, where the hospice patient resides in a nursing home, the patient remains responsible for payment of the nursing home's room and board charges.

If, however, a patient receiving Medicare hospice benefits in a nursing home is also eligible for Medicaid, Medicaid will pay the hospice at least 95 percent of the State's daily nursing home rate, and the hospice is then responsible for paying the nursing home for the beneficiary's room and board. The specific services included in the daily rate payment are determined by a State's Medicaid program and may vary from State to State.

In addition to the room and board payment, a hospice may contract with the nursing home for the nursing home to provide non-core hospice services (i.e., those services which the hospice is not required by law to provide itself) to its hospice patients.

Vulnerabilities In Nursing Home Arrangements With Hospices

Hospice services may be appropriate and beneficial to terminally ill nursing home residents who wish to receive palliative care. However, arrangements between nursing homes and hospices are vulnerable to fraud and abuse because nursing home operators have control over the specific hospice or hospices they will permit to provide hospice services to their residents. An exclusive or semi-exclusive arrangement with a nursing home to provide hospice services to its residents may have substantial monetary value to a hospice. In these circumstances, some nursing home operators and/or hospices may request or offer illegal remuneration to influence a nursing home's decision to do business with a particular hospice.

Hospice patients residing in nursing homes may be particularly desirable from a hospice's financial standpoint. First, a nursing home's population represents a sizeable pool of potential hospice patients. Second, nursing home hospice patients may generate higher gross revenues per patient than patients residing in their own homes because nursing home residents receiving hospice care have, on average, longer lengths of stay than hospice patients in their homes. Also, there may be some overlap in the services that the nursing homes and hospices provide, thereby providing one or the other the opportunity to reduce services and costs. A recent OIG report found that residents of certain nursing homes receive fewer services from their hospice than patients in their own homes. Since hospices receive a fixed daily payment regardless of the number of services provided or the location of the patient, fewer services may result in higher profits per patient.

However, a hospice's access to nursing home patients depends on the nursing home operator. Nursing home operators may restrict residents to one or two hospice providers. While an exclusive or semi-exclusive arrangement can promote efficiency and safety by permitting the nursing home operator to coordinate care, screen hospice caregivers, and maintain control of the premises, it also enhances the value of the nursing home operator's decision. In these circumstances, some nursing home operators or hospices may request or offer illegal inducements to influence the selection of a hospice.

Paying Or Receiving Kickbacks In Order To Induce Medicare Or Medicaid Referrals

Because kickbacks can distort medical decision making, result in overutilization, and have an adverse effect on the quality of care patients receive, they are prohibited under the Federal health care programs, including Medicare and Medicaid. Under the anti-kickback statute, it is illegal to knowingly and willfully solicit, receive, offer, or pay anything of value to induce referrals of items or services payable by a Federal health care program.

The OIG has observed instances of potential kickbacks between hospices and nursing homes to influence the referral of patients. In general, payments by a hospice to a nursing home for "room and board" provided to a Medicaid hospice patient should not

exceed what the nursing home otherwise would have received if the patient had not been enrolled in hospice. Any additional payment must represent the fair market value of additional services actually provided to that patient that are not included in the Medicaid daily rate.

Specific practices which are suspected kickbacks include:

- A hospice offering free goods or goods at below fair market value to induce a nursing home to refer patients to the hospice.

- A hospice paying "room and board" payments to the nursing home in amounts in excess of what the nursing home would have received directly from Medicaid had the patient not been enrolled in hospice.

- A hospice paying amounts to the nursing home for "additional" services that Medicaid considers to be included in its room and board payment to the hospice.

- A hospice paying above fair market value for "additional" non-core services which Medicaid does not consider to be included in its room and board payment to the nursing home.

- A hospice referring its patients to a nursing home to induce the nursing home to refer its patients to the hospice.

- A hospice providing free (or below fair market value) care to nursing home patients, for whom the nursing home is receiving Medicare payment under the skilled nursing facility benefit, with the expectation that after the patient exhausts the skilled nursing facility benefit, the patient will receive hospice services from that hospice.

- A hospice providing staff at its expense to the nursing home to perform duties that otherwise would be performed by the nursing home.

Parties that violate the anti-kickback statute may be criminally prosecuted or subject to civil monetary penalties, and also may be subject to exclusion from the Federal health care programs.

What To Do If You Suspect Fraud Involving Arrangements Between Nursing Homes and Hospices

If you have information about nursing homes and hospices engaging in any of the activities described above, contact any of the regional offices of the Office of

Investigations of the Office of Inspector General, U.S. Department of Health and Human Services, at the following locations:

Field Offices	States Served	Telephone
Boston	MA, VT ,NH, ME, RI, CT	617-565-2660
New York	NY, NJ, PR, VI	212-264-1691
Philadelphia	PA, MD, DE, WV, VA, DC	215-596-6796 - before 5/11/98 215-861-4586 - after 5/11/98
Atlanta	GA, KY, NC, SC, FL, TN, AL, MS	404-562-7603
Chicago	IL, MN, WI, MI, IN, OH, IA, MO	312-353-2740
Dallas	TX, NM, OK, AR, LA, CO, UT, WY, MT, ND, SD, NE, KS	214-767-8406
Los Angeles	AZ, NV, So. CA	714-246-8302
San Francisco	No. CA, AK, HI OR, ID, WA	415-437-7960

OFFICE OF
INSPECTOR
GENERAL

Fraud and Abuse in the Provision of Services in Nursing Facilities

May 1996

The Office of Inspector General (OIG) was established at the Department of Health and Human Services by Congress in 1976 to identify and eliminate fraud, waste and abuse in Health and Human Services programs and to promote efficiency and economy in departmental operations. The OIG carries out this mission through a nationwide program of audits, investigations and inspections.

To help reduce fraud and abuse in the Medicare and Medicaid programs, the OIG actively investigates schemes to fraudulently obtain money from these programs and, when appropriate, issues Special Fraud Alerts which identify segments of the health care industry that are particularly vulnerable to abuse. This Special Fraud Alert focuses on the provision of medical and other health care services to residents of nursing facilities and identifies some of the illegal practices that the OIG has uncovered.

How Nursing Facility Benefits Are Reimbursed

There were 17,000 nursing facilities in the United States, as of June 1995. An OIG study reported that in 1992, Medicare payments to nursing facilities included Part B payments of $2.7 billion and Part A payments of $3.1 billion for covered stays in nursing facilities. When the Federal share of the $24 billion spent by Medicaid is factored in, the Federal cost of nursing care reached a total of, approximately $20 billion.

Many nursing facilities receive reimbursement from both Medicare and Medicaid for care and services provided to eligible residents. Under Medicare Part A, skilled nursing facility services are paid on the basis of cost for covered stays of a limited length. Nursing facility residents may be concurrently eligible for benefits under Medicare Part B. For Medicaid-eligible residents, extended nursing facility stays may be reimbursed by state-administered programs financed in part by Medicaid.

Nursing facilities and their residents have become common targets for fraudulent schemes. Nursing facilities represent convenient resident "pools" and make it lucrative for unscrupulous persons to carry out fraudulent schemes. The OIG has become aware of a number of fraudulent arrangements by which health care providers, including medical professionals, inappropriately bill Medicare and Medicaid for the provision of unnecessary services and services which were not provided at all. Sometimes, nursing facility management and staff also are involved in these schemes.

False or Fraudulent Claims Relating to the Provision of Health Care Services

The government may prosecute persons who submit or cause the submission of false or fraudulent claims to the Medicare or Medicaid program. Examples of false or fraudulent claims include claims for items that were never provided or were not provided as claimed, and claims for services which a person knows are not medically necessary.

Submitting or causing false claims to be submitted to Medicare or Medicaid may subject the individual or entity to criminal prosecution, civil penalties including treble damages, and exclusion from participation in the Medicare and Medicaid programs. The OIG has uncovered the following types of fraudulent transactions related to the provision of health care services to residents of nursing facilities reimbursed by Medicare and Medicaid:

Claims for Services Not Rendered or Not Provided as Claimed

Common schemes entail falsifying bills and medical records to misrepresent the services, or extent of services, provided at nursing facilities. Some examples follow:

- One physician improperly billed $350,000 over a 2-year period for comprehensive physical examinations of residents without ever seeing a single resident. The physician went so far as to falsify medical records to indicate that nonexistent services were rendered.
- A psychotherapist working in nursing facilities manipulated Medicare billing codes to charge for 3 hours of therapy for each resident when, in fact, he spent only a few minutes with each resident. In a nursing facility, 3 hours of psychotherapy is highly unusual and often clinically inappropriate.
- An investigation of a speech specialist uncovered documentation showing that he overstated the time spent on each session claimed. Claims analysis showed that the speech specialist actually claimed to spend 20 hours with residents every day, far more time than possible. Further investigation revealed that some residents had never met the specialist, and some were dead at the time when the specialist claimed to have provided speech services to them.
- A company providing mobile X-ray services made visits to nursing facilities, and billed for taking two X-rays when only one was actually taken. The case also presented serious concerns about quality of care when the investigation revealed that company personnel were not certified to take X-rays.

Claims Falsified to Circumvent Coverage Limitations on Medical Specialties

Practitioners of medical specialties have been found to misrepresent the nature of services provided to Medicare and Medicaid beneficiaries because the Federally funded programs have stringent coverage limitations for some specialties, including podiatry, audiology and optometry. For instance:

- The OIG has learned about podiatrists whose entire practices consist of visits to nursing facilities. Non-covered routine care is provided, e.g., toenail clipping, but Medicare is billed for covered services which were not provided or needed. In one case, an investigator discovered suspicious billing for foot care when it was reported that a podiatrist was performing an excessive number of toenail removals, a service that is covered but not frequently or routinely needed. This podiatrist billed Medicare as much as $100,000 in 1 year for toenail removals. Investigators discovered one resident for whom bills were submitted claiming a total of 11 toenail removals.
- An optometrist claimed reimbursement for covered eye care consultations when he, in fact, performed routine exams and other non-covered services. His billing history indicated that he claimed to have performed as many as 25 consultations in one day at a nursing home. This is an unreasonably high number, given the nature of a Medicare-covered consultation.
- An audiologist made arrangements with a nursing facility and affiliated physicians to get orders for hearing exams that were not medically necessary. The audiologist used this access to residents exclusively to market hearing aids. In this case, the facility and physicians, in addition to the audiologist, could be held liable for false or fraudulent claims if they acted with knowledge of the claims for unnecessary services.

What To Look For in the Provision of Services to Nursing Facilities

The following situations ***may*** suggest fraudulent or abusive activities:

- "Gang visits" by one or more medical professionals where large numbers of residents are seen in a single day. The practitioner may be providing medically unnecessary services, or the level of service provided may not be of a sufficient duration or scope consistent with the service billed to Medicare or Medicaid.
- Frequent and recurring "routine visits" by the same medical professional. Seeing residents too often may indicate that the provider is billing for services that are not medically necessary.
- Unusually active presence in nursing facilities by health care practitioners who are given or request unlimited access to resident medical records. These individuals may be collecting information used in the submission of false claims.
- Questionable documentation for medical necessity of professional services. Practitioners who are billing inappropriately may also enter, or fail to enter, important information on medical charts.

What To Do If You Have Information About Fraud and Abuse Against the Medicare and Medicaid Programs

If you have information about the types of activities described above, contact any of the field offices of the Office of Investigations of the Office of Inspector General, U.S. Department of Health and Human Services, at the following locations:

Field Offices	States Served	Telephone
Boston	MA, VT, NH, ME RI, CT	617-565-2660
New York	NY, NJ, PR, VI	212-264-1691
Philadelphia	PA, MD, DE, WV VA	215-596-6796
Atlanta	GA, KY, NC, SC FL, TN, AL MS (No. District)	404-331-2131
Chicago	IL, MN, WI, MI IN, OH, IA, MO	312-353-2740
Dallas	TX, NM, OK, AR LA, MS (So. District) CO, UT, WI, MT, ND, SD, NE, KS	214-767-8406
Los Angeles	AZ, NV (Clark Co.) So. CA	714-246-8302
San Francisco	No. CA, NV, AK, HI, OR, ID, WA	415-437-7960
Washington, D.C.	DC and Metropolitan areas of VA & MD	202-619-1900

To report Suspected Fraud, Call or Write:

1-800-HHS-TIPS
Department of Health and Human Services
Office of Inspector General
P.O. Box 23489
L'Enfant Plaza Station
Washington, D.C. 20026-3489

[Federal Register: August 10, 1995 (Volume 60, Number 154)]
[Notices]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Office of Inspector General

Publication of OIG Special Fraud Alerts: Home Health Fraud, and Fraud and Abuse in the Provision of Medical Supplies to Nursing Facilities

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

ACTION: Notice.

SUMMARY: This Federal Register notice sets forth two recently issued OIG Special Fraud Alerts concerning fraud and abuse practices in the home health industry and in the provision of medical supplies to nursing facilities. For the most part, the OIG Special Fraud Alerts address national trends in health care fraud, including potential violations of the Medicare anti-kickback statute. These two Special Fraud Alerts, issued directly to the health care provider community and now being reprinted in this issue of the Federal Register, specifically address fraud and abuse in the provision of (1) home health services and (2) medical supplies to nursing facilities, including the submission of false claims and anti-kickback violations.

FOR FURTHER INFORMATION CONTACT: Joel J. Schaer, Office of Management and Policy, (202) 619-0089.

SUPPLEMENTARY INFORMATION:

I. Background

The Office of Inspector General (OIG) issues Special Fraud Alerts based on information it obtains concerning particular fraudulent and abusive practices within the health care industry. These Special Fraud Alerts provide the OIG with a means of notifying the industry that we have become aware of certain abusive practices which we plan to pursue and prosecute, or bring civil and administrative action, as appropriate. The alerts also serve as a powerful tool to encourage industry compliance by giving providers an opportunity to examine their own practices.

The Special Fraud Alerts are intended for extensive distribution directly to the health care provider community, as well as those charged with administering the Medicare and Medicaid programs. On December 19, 1994, the OIG published in the Federal Register the texts of 5 previously-issued Special Fraud Alerts, and announced the

intention to publish in the same manner subsequent issuances as a regular part of distribution of these Special Fraud Alerts (59 FR 65372).

The first of these new Special Fraud Alert serves to point out the prevalence of certain types of home health care fraud, including (1) cost report frauds; (2) billing for excessive services or services not rendered; (3) use of unlicensed or untrained staff; (4) falsified plans of care; (5) forged physician signatures on plans of care; and (6) kickbacks that the OIG has uncovered.

The second new Special Fraud Alert, focusing on the provision of medical supplies to nursing facilities, identifies some of the illegal practices that the OIG has recently uncovered. These include (1) the submitting of claims to Part B of Medicare for medical supplies and equipment that are not medically necessary; (2) submitting claims for items that are not provided as claimed; (3) double billings; and (4) paying or receiving kickbacks in exchange for Medicare or Medicaid referrals.

These two issuances are the first in a series of new Special Fraud Alerts being developed by the OIG over the next year to heighten both the public's and industry's awareness of fraudulent health care practices. A reprint of both of these Special Fraud Alerts follows.

II. Special Fraud Alert: Home Health Fraud

(June 1995)

The Office of Inspector General was established at the Department of Health and Human Services by Congress in 1976 to identify and eliminate fraud, abuse and waste in Health and Human Services programs and to promote efficiency and economy in departmental operations. The OIG carries out this mission through a nationwide program of audits, investigations and inspections.

To help reduce fraud and abuse in the Medicare and Medicaid programs, the OIG actively investigates schemes to fraudulently obtain money from these programs and, when appropriate, issues Special Fraud Alerts which identify segments of the health care industry that are particularly vulnerable to abuse. This Special Fraud Alert focuses on the home health industry and identifies some of the illegal practices the OIG has uncovered.

What Is Home Health Care And Who Is Eligible To Receive It?

Medicare's home health benefit allows people with restricted mobility to remain non-institutionalized and receive needed care at home. Home health services and supplies are typically provided by nurses and aides under a physician-certified plan of care.

Medicare will pay for home health services if a beneficiary's physician certifies that he or she:

- is homebound--i.e., confined to the home except for infrequent or short absences or trips for medical care, and
- requires one or more of the following qualifying services: physical therapy, speech-language pathology, or intermittent skilled nursing.

If a homebound patient requires a qualifying service, Medicare also covers services of medical social workers and certain personal care such as bathing, feeding, and assistance with medications. However, a beneficiary who needs only this type of personal or custodial care does not qualify for the home health benefit.

Fraud and Abuse in the Home Health Industry

Home care is consuming a rapidly increasing portion of the federal health budget. This year, Medicare payments for home health will reach close to $16 billion, up from $3.3 billion in 1990--nearly a five fold increase. Home health care is particularly vulnerable to fraud and abuse because:

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- Medicare covers an unlimited number of visits per patient;
- Beneficiaries pay no co-payments except on medical equipment;
- Patients don't receive explanations of benefits (EOBs) for bills submitted for home health services; and
- There is limited direct medical supervision of home health services provided by non-medical personnel.

The OIG has learned of several types of fraudulent conduct, outlined below, which have or could result in improper Medicare reimbursement for home health services.

False or Fraudulent Claims Relating to the Provision of Home Health Services

The government may prosecute persons who submit or cause false or fraudulent claims for payment to be submitted to the Medicare or Medicaid programs. Examples of false or fraudulent claims include claims for services that were never provided, duplicate claims submitted for the same service, and claims for services to ineligible patients. A claim for a service that a health care provider knows was not medically necessary may also be a fraudulent claim.

Submitting or causing false claims to be submitted to Medicare or Medicaid may subject a person to criminal prosecution, civil penalties including treble damages, and exclusion from participation in the Medicare and Medicaid programs. OIG has uncovered the following types of fraudulent claims related to the provision of home health services.

Claims For Home Health Visits That Were Never Made And For Visits to Ineligible Beneficiaries

OIG has uncovered instances where home health agencies are submitting false claims for home health visits. These include:

- Claims for visits not made.
- Claims for visits to beneficiaries not homebound.
- Claims for visits to beneficiaries not requiring a qualifying service.
- Claims for visits not authorized by a physician.

One home health agency billed Medicare for 123 home health visits to a patient who never received a single visit, and submitted claims for beneficiaries who were in an acute care hospital during the period the agency claimed to have provided home visits. Another agency provided a home health aide to a beneficiary so mobile that he volunteered at a local hospital several times a week.

A third agency claimed nearly $26 million during one year in visits that were not made, visits to patients that were not homebound, and visits not authorized by a physician. OIG interviews indicated that beneficiary signatures were forged on visit logs and physician

signatures were forged on plans of care. This agency had subcontracted with other entities to provide home health care to its patients, and claimed that the subcontractors falsely documented that visits were made and services were provided.

Medicare permits a home health agency to contract with other organizations, including agencies not certified by Medicare, to provide care to its patients. However, the agency remains liable for all billed services provided by its subcontractors. The use of subcontracted care imposes a duty on home health agencies to monitor the care provided by the subcontractor.

Home health agencies, as well as the physicians who order home health services, are responsible for ensuring the medical necessity of claims submitted to Medicare. A physician who orders unnecessary home health care services may be liable for causing false claims to be submitted by the home health agency, even though the physician does not submit the claim. Furthermore, if agency personnel believe that services ordered by a physician are excessive or otherwise inappropriate, the agency cannot avoid liability for filing improper claims simply because a physician has ordered the services.

Fraud in Annual Cost Report Claims

In addition to submitting claims for specific services, home health agencies submit annual cost reports to Medicare for reimbursement of administrative, overhead and other general costs. For these costs to be allowable, Medicare regulations require that they be (1) reasonable, (2) necessary for the maintenance of the health care entity, and (3) related to patient care. However, the OIG has audited cost reports which include costs for entertainment, travel, lobbying, gifts, and other expenses unrelated to patient care such as luxury automobiles and cruises. One home health agency claimed several million dollars in unallowable costs during one cost reporting year. These included utility and maid service payments for the owner's condominium, golf pro shop expenses, lease payments on a luxury car for the owner's son at college, and payment of cable television fees for the owner's mother.

Medicare also requires home health agencies to disclose in their cost reports the identity of related parties with whom they conduct business, in order to adjust costs that are likely to be inflated by health care providers who self-deal (i.e., purchase goods or services from related companies). A related party issue exists when there is common control or common interest between the provider and the organization with whom it is doing business. OIG has investigated home health agencies which failed to disclose ownership or other relationships with entities with whom they contracted for accounting services, management/consulting services, and medical supplies. These agencies billed Medicare unallowable amounts for marked-up supplies and services.

Paying Or Receiving Kickbacks In Exchange For Medicare or Medicaid Referrals

Kickbacks in exchange for the referral of reimbursable home health services is another type of fraud that OIG has observed. The Medicare program guarantees freedom of choice to its beneficiaries in the selection of health care providers. Because kickbacks violate that principle and also increase the cost of care, they are prohibited under the Medicare and Medicaid programs. Under the anti-kickback statute, it

is illegal to knowingly and willfully solicit, receive, offer or pay anything of value to induce, or in return for, referring, recommending or arranging for the furnishing of any item or service payable by Medicare or Medicaid.

OIG is aware of home health providers offering kickbacks to physicians, beneficiaries, hospitals, and rest homes in return for referrals. Kickbacks have taken the following forms:

Payment of a fee to a physician for each plan of care certified by the physician on behalf of the home health agency.

Disguising referral fees as salaries by paying referring physicians for services not rendered, or in excess of fair market value for services rendered.

Offering free services to beneficiaries, including transportation and meals, if they agree to switch home health providers.

Providing hospitals with discharge planners, home care coordinators, or home care liaisons in order to induce referrals.

Providing free services, such as 24 hour nursing coverage, to retirement homes or adult congregate living facilities in return for home health referrals.

Subcontracting with retirement homes or adult congregate living facilities for the provision of home

[[Page 40849]]
health services, to induce the facility to make referrals to the agency.

Parties that violate the anti-kickback statute may be criminally prosecuted, and also may be subject to exclusion from the Medicare and Medicaid programs.

Marketing Uncovered Or Unneeded Home Care Services to Beneficiaries

OIG has learned of high pressure sales tactics employed by some agencies in the home health community to maximize their patient population and their profits. These agencies target healthy beneficiaries on the street or in their homes and offer non-covered services, such as grocery shopping or housekeeping, in exchange for Medicare identification numbers. Physicians have also reported that some agencies attempt to pressure them to order unnecessary personal care services by informing them that their patients are requesting these services and will find another physician if their demands are not met.

These abusive marketing practices can result in false claims liability on the part of agencies and/or physicians, and may also constitute illegal kickbacks.

III.

(August 1995)

The Office of Inspector General was established at the Department of Health and Human Services by Congress in 1976 to identify and eliminate fraud, abuse and waste in Health and Human Services programs and to promote efficiency and economy in departmental operations. The OIG carries out this mission through a nationwide program of audits, investigations and inspections.

To help reduce fraud and abuse in the Medicare and Medicaid programs, the OIG actively investigates schemes to fraudulently obtain

money from these programs and, when appropriate, issues Special Fraud Alerts which identify segments of the health care industry that are particularly vulnerable to abuse. This Special Fraud Alert focuses on the provision of medical supplies to nursing facilities and identifies some of the illegal practices that the OIG has uncovered.

How Nursing Facility Benefits are Reimbursed

Many nursing facilities receive reimbursement from Medicare and Medicaid for care and services provided to eligible residents. Under Medicare Part A, skilled nursing facility services are paid on the basis of cost, and compensate the provider for covered nursing stays of a limited length. For Medicaid-eligible residents, extended nursing facility stays may be reimbursed by state-administered programs financed in part by Medicaid. Nursing facility residents may be concurrently eligible for benefits under Medicare Part B. These benefits may include payment for medically necessary equipment, prosthetic devices and supplies.

Nursing facilities and their residents have become common targets for fraudulent schemes involving medical supplies. The OIG has become aware of a number of fraudulent arrangements by which medical suppliers profit from inappropriate business dealings, in the name of unwitting nursing facility residents.

Sometimes, nursing facility management and staff also are involved in these schemes.

False or Fraudulent Claims Relating to the Provision of Medical Supplies

The government may prosecute persons who submit or cause the submission of false or fraudulent claims to the Medicare or Medicaid program. Examples of false or fraudulent claims include claims for items that were never provided or were not provided as claimed, duplicate claims submitted for the same item, and claims for items that the supplier knows are not medically necessary.

Submitting or causing false claims to be submitted to Medicare or Medicaid may subject the individual or entity to criminal prosecution, civil penalties including treble damages, and exclusion from participation in the Medicare and Medicaid programs. The OIG has uncovered the following types of fraudulent transactions related to the provision of medical supplies to nursing facilities.

Claims for Medical Supplies and Equipment That Are Not Medically Necessary

Many of the supplies and equipment used in the care of nursing facility residents are provided by the nursing facility and should be reflected in the facility's Medicare cost report. The OIG has uncovered numerous instances in which suppliers provide the nursing facility with general medical supplies such as tape, adhesive remover, skin creams and syringes, but rather than bill the facility, the supplier submits claims to Medicare Part B. The claims misrepresent that the items are medically necessary for individual beneficiaries and therefore reimbursable under Part B.

For example, one supplier billed Part B for an ``oral/nasal hygiene program'' which consisted of supplies, such as saline solution, latex gloves and cotton swabs, marketed as prepackaged kits. Upon

investigation, the OIG determined that these items, which were shipped to the facility in bulk quantities, were neither medically necessary, nor used for the care of the residents identified on the claims. In such a case, the supplier may be liable under criminal, civil and administrative laws for submitting fraudulent claims. The nursing facility may also be liable if the OIG determines that the nursing facility knew or should have known that the claims were false and participated in the offense.

Claims for Items That Are Not Provided as Claimed or Double Billed

Many inappropriate transactions involve marketing of incontinence supplies. In one case, a supplier was found to have delivered adult diapers, which are not covered by Medicare Part B, and improperly billed these items as expensive prosthetic devices called ``female external urinary collection devices.'' In another case, a supplier delivered only incontinence care products, such as lubricants and cleansers. These items are covered only as accessories to medically necessary prosthetic devices such as female external urinary collection devices. Medicare received bills for each accessory, even though the primary item was not provided.

In some cases, multiple payments are made for particular items shipped to nursing facilities. For instance, a nursing facility ordered and accepted delivery of certain medical supplies for the facility's general use. The nursing facility appropriately claimed the supplies as expenses related to patient care on its Medicare cost report. However, the supplier also submitted separate claims to Medicare Part B on behalf of each resident in the facility. In order to receive Part B reimbursement, the supplier misrepresented its entitlement to payment, as well as the eligibility and coverage of individual beneficiaries. Other payment sources, such as Medicaid or private payers, may also have been billed by the supplier. The supplier may be liable under criminal, civil and administrative provisions if the supplier claimed falsely that the beneficiary met the required eligibility and coverage criteria. The nursing facility may also be liable for falsifying its Part A cost report if it knew or should have known of the duplicate billing and participated in the offense.

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Paying or Receiving Kickbacks in Exchange for Medicare or Medicaid Referrals

It is illegal under the anti-kickback statute to knowingly and willfully solicit, receive, offer or pay remuneration in cash or in kind to induce or in return for referring, recommending or arranging for the furnishing of any item or service payable by Medicare or Medicaid.

Violation of the anti-kickback statute may carry criminal penalties, program exclusion, or both. Immunity may be available where otherwise illegal conduct meets the criteria specified in ``safe harbor'' regulations published by the Secretary of the Department of Health and Human Services. These regulations may be found in 42 CFR part 1001.

A supplier gives a nursing facility non-covered medical products at no charge, provided the facility assists in the ordering of

Medicare-reimbursed products. For instance, incontinence care kits may consist of reimbursable supplies as well as non-reimbursable items, such as disposable underpads or adult diapers. The OIG has identified instances where suppliers have billed the program for providing nursing facilities with thousands of medical supplies contained within incontinence kits which were not medically necessary for the care of the patients. The nursing facilities accepted delivery of the kits, removed the diapers and other items useful in general patient care, and discarded the remainder of the kits. At the same time, the supplier received Medicare reimbursement for shipment of products which were not medically necessary and often not used.

Both the supplier and the nursing facility may be liable for false claims as in the previous examples. However, both parties may also be liable under the anti-kickback statute, if one purpose of providing the free diaper was to induce the nursing facility to arrange for the procurement of items paid for by Medicare or Medicaid.

Other Examples of Fraudulent Practices

The OIG has received many complaints from nursing facility administrators and staff about suppliers that deliver unordered goods which are billed to Medicare. Analysts and investigators also have found that many nursing facilities do not always report such abuses, perhaps because the nursing facilities may gain a benefit from the use of these ``free'' supplies. In other cases, nursing facilities actively solicit unauthorized deliveries or other items of value, such as cash and in-kind rewards. In exchange, the nursing facility offers the equipment supplier access to patients' medical records and other information needed to bill Medicare.

Note: Under 42 CFR 483.10(e), it is a violation of a resident's rights, and therefore of the facility's conditions of participation, to make unauthorized disclosures from the resident's medical records.

The OIG has investigated suppliers who supply nursing facilities with low-cost items, but submit Part B claims for high-priced items. For instance, one supplier provided simple restraining devices, but claimed that custom-made orthotic body jackets were provided to specified Part B beneficiaries.

The OIG also has investigated a case in which a supplier gathered information on the death of nursing facility residents. Immediately thereafter, the supplier back-dated orders of medical supplies in quantities consistent with Medicare's 30-day limitation on after-death shipments.

What To Look For in Nursing Facility Supply Transactions

Suppliers engaged in the fraudulent schemes described above attempt to avoid detection in a variety of ways. Nursing facility administrators and staff aware of supplier fraud may be bribed through the payment of kickbacks and other illegal remuneration. Also, beneficiaries may be kept unaware of fraudulent billings if a supplier routinely ``waives,'' or fails to collect, co-payments from the residents for Part B items. The following factors may also indicate improper supply transactions:

Excessive volumes of medical supplies delivered to, or

solicited by, nursing facilities and kept as inventory for lengthy periods.

Items provided directly to nursing facility residents that are unordered, unnecessary or unused.

Unusually active presence in nursing facilities of medical supply sales representatives who are given, or request, unlimited access to patient medical records.

Questionable documentation for medical necessity of supplies.

IV. Contacting the OIG About Fraud and Abuse

The following common language is set forth in both OIG Special Fraud Alerts:

What To do If You Have Information About Fraud and Abuse Against the Medicare and Medicaid Programs

If you have information about the types of activities described above, contact any of the regional offices of the Office of Investigations of the Office of Inspector General, U.S. Department of Health and Human Services, at the following locations:

Regions	States served	Telephone
Boston.....	MA, VT, NH, ME, RI, CT....	617-565-2660
New York.....	NY, NJ, PR, VI.....	212-264-1691
Philadelphia.....	PA, MD, DE, WV, VA.....	215-596-6796
Atlanta.....	GA, KY, NC, SC, FL, TN, AL, MS (No. District).	404-331-2131
Chicago.....	IL, MN, WI, MI, IN, OH, IA, MO.	312-353-2740
Dallas.....	TX, NM, OK, AR, LA, MS (So. District).	214-767-8406
Denver.....	CO, UT, WY, MT, ND, SD, NE, KS.	303-844-5621
Los Angeles.....	AZ, NV (Clark Co.), So. CA	714-836-2372
San Francisco.....	No. CA, NV, AZ, HI, OR, ID, WA.	415-556-8880
Washington, D.C.....	DC and Metropolitan areas of VA & MD.	202-619-1900

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To Report Suspected Fraud, Call or Write: 1-800-HHS-TIPS, Department of Health and Human Services, Office of Inspector General, P.O. Box 23489, L'Enfant Plaza Station, Washington, D.C. 20026-3489.

Dated: August 4, 1995.
June Gibbs Brown,
Inspector General.
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