

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:

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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

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.

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>.

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,

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.

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

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/>

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

³⁵ *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.

³⁶ 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.

³⁷ 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/8states.htm>.

³⁸ 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.

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").

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

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: Copays 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).

³⁸ See, e.g., OIG, OIG Report OIG-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).

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 reviews⁵⁸ 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

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.

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

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.

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

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

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>.

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).

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

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>.

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

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? Is it 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

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.

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.

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 applications⁹⁸ 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 harbor⁹⁹ 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

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.

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.

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 harbor¹⁰² 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 "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)).

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).

¹⁰² 42 CFR 1001.952(d).

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

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.

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

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.

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

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,

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.*

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).

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.

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>.

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/>.

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

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>.

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

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/>

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.

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Daniel R. Levinson,
Inspector General.

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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.

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